

**WEST VIRGINIA
SECRETARY OF STATE
JOE MANCHIN, III
ADMINISTRATIVE LAW DIVISION**
Form #7

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2004 JAN 28 P 4:42

OFFICE WEST VIRGINIA
SECRETARY OF STATE

Effective Date

NOTICE OF AN EMERGENCY RULE

AGENCY: DHHR - Bureau for Public Health TITLE NUMBER: 64

CITE AUTHORITY: §16-1-4 and §§17C-5-4, 17C-5-5, 17C-5-6 and 17C-5-8.

EMERGENCY AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 10

TITLE OF RULE BEING AMENDED: Methods and Standards for Chemical Tests for Intoxication

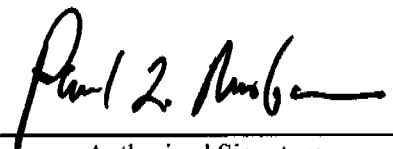
IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE RULE IS BEING FILED AS AN EMERGENCY RULE TO BECOME EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 42ND DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY ARE AS FOLLOWS:

Use additional sheets if necessary


Authorized Signature



EMERGENCY RULE QUESTIONNAIRE

DATE: February 2, 2004

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) Department of Health and Human Resources,
Bureau for Public Health

2004 FEB - 2 P 4: 17
OFFICE NEST VIRGINIA
SECRETARY OF STATE

FILED

EMERGENCY RULE TITLE: Methods and Standards for Chemical Tests for Intoxication

1. Date of filing January 27, 2004

2. Statutory authority for promulgating emergency rule:
§16-1-4 and §§17C-5-4, 17C-5-5, 17C-5-6 and 17C-5-8

3. Date of filing of proposed legislative rule: January 27, 2004

4. Does the emergency rule adopt new language or does it amend or appeal a current legislative rule? It amends a current legislative rule.

5. Has the same or similar emergency rule previously been filed and expired?
No

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the immediate preservation of public peace, health, safety or welfare.

The current rule refers to the standards, methods and technology of breath testing equipment when it was last amended in 1990. Due to advances in technology and the manufacturers decision to discontinue the production and support of the current devices, funding has been obtained to purchase new ones. The new devices use standards which are not addressed in the existing rule. The emergency arises because the training and use of the new devices is scheduled to begin in March 2004. Going through regular rulemaking would delay use of the new devices until 2005 or 2006.

- 7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

~~Although it has not yet passed, the law reducing the blood alcohol level to .08 is anticipated to be passed. The emergency rule will make the standards used by the breath testing devices consistent with the new legislation.~~

- 8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

~~See answer to question 6. Without this change, the implementation of the new devices would have to be delayed for at least one year. The lack of replacement parts for the old devices and the lack of availability of those devices would be a significant strain on the resources for breath testing of impaired individuals.~~

STATEMENT OF NEED FOR EMERGENCY RULE

Pursuant to West Virginia Code § 29A-3-15(f), the Department of Health and Human Resources finds that an emergency exists requiring the promulgation of an emergency rule. A statement of the facts and circumstances constituting this emergency follows.

WV Code §§ 17C-5-5 and 17C-5-8 provide that the Bureau for Public Health (formerly Division of Health) is the state agency charged with the responsibility of promulgating the methods and standards for conducting chemical tests for intoxication. These methods and standards are contained in Rule 64 C.S.R. 10.

The current device used by law-enforcement agencies in this state to do breath analysis for alcohol content is the Intoxilyzer 5000 CD/FG5. This device has been utilized for approximately nine years. Due to the age of the Intoxilyzer 5000 CD/FG5 and the decision of the manufacturer to cease production of replacement parts, The West Virginia State Police, with the cooperation of the Commission for Drunk Driving Prevention, recently obtained funding and selected the Intoximeter EC/IR II to replace the aging Intoxilyzer 5000 CD/FG5. It is the intention of the Bureau of Health and the West Virginia State Police to begin installation and training on the Intoximeter EC/IR II in March, 2004.

As with most new electronic devices, The Intoximeter EC/IR II includes advances in technology which require the modification of 64 C.S.R. 10. The Intoximeter EC/IR II utilizes a pre-manufactured compressed gas reference standard to perform pre and post test calibration and accuracy checks on the device rather than an aqueous ethanol solution. These reference standards ensure that the device is correctly calibrated and accurate just prior to and after a subject's breath test. The current rule does not provide for the use of a compressed gas reference standard. This emergency rule permits the use of either standard so that both the Intoxilyzer 5000 CD/FG5 and the Intoximeter EC/IR II can be utilized while the transition is taking place. Since the Intoxilyzer 5000 CD/FG5 and the Intoximeter EC/IR II have built in accuracy checks each time a subject is tested, the manufacturers do not require nor recommend a six month accuracy inspection tests. The rule has thus been modified to eliminate the unnecessary six month inspection requirement. In addition, it is anticipated that the legislation lowering the presumption of intoxication from .1 to .08 grams of alcohol per 210 liters of breath will pass this legislative session. This rule change adjusts the target calibration check from .1 to .08 so that the rule will be consistent with the new law. Lastly this rule change provides for minor housekeeping changes that are necessary since the last enactment of 64 C.S.R. 10 on April 6, 1990.

Summary of Proposed Rule

It has been fourteen years since the last update to 64 C.S.R. 10. This emergency rule, as proposed, serves to update the methods and standards for chemical testing to allow for the advances in technology in the devices used for the testing of breath for alcohol content which is required in order to replace the aging equipment currently used by law enforcement.

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Methods and Standard for Chemical Tests for Intoxication

Type of Rule: **Legislative** **Interpretive** **Procedural**

Agency: Department of Health and Human Resources

Address: Building 3, Capitol Complex
Charleston, W. Va. 25305

1. Effect of the Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$ 0	\$ 0	\$ 0	\$ 0	\$ 0
Personal Services	0	0	0	0	0
Current Expense	0	0	0	0	0
Repairs & Alterations	0	0	0	0	0
Equipment	0	0	0	0	0
Other	0	0	0	0	0
Revenue	0	0	0	0	0

2. Explanation of above estimates.

There should be no additional costs incurred. This rule only modifies the existing methods and standards and does not require any additional manpower or expenses.

3. Objectives of this rule:

To modify the methods and standards for chemical tests to accommodate changes in technology.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

No Impact

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

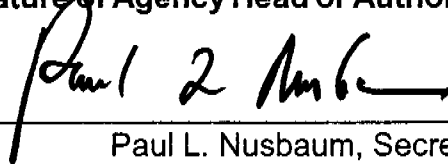
No Impact

C. Economic Impact on Citizens/Public at Large.

No Impact

Date: January 23, 2004

Signature of Agency Head or Authorized Representative:



Paul L. Nusbaum, Secretary
Department of Health and Human Resources

FILED

TITLE 64
LEGISLATIVE RULE
DIVISION OF HEALTH
BUREAU FOR PUBLIC HEALTH

2004 JAN 28 P 4:42

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

SERIES 10
METHODS AND STANDARDS FOR CHEMICAL
TESTS FOR INTOXICATION

§64-10-1. General.

1.1. Scope. -- This legislative rule establishes the methods and standards relating to implied consent for chemical test for intoxication pursuant to appropriate articles of Chapter 17C of the West Virginia Code.

1.2. Authority. -- W. Va. Code ~~§§16-1-7, 17C-5-2, et seq.~~ §16-1-4 and §§17C-5-4, 17C-5-5, 17C-5-6 and 17C-5-8.

1.3. Filing Date. -- ~~April 6, 1990.~~

1.4. Effective Date. -- ~~April 6, 1990.~~

~~1.5. Repeal of Former Rule. -- This rule supersedes and repeals Methods and Standards for Chemical Test for Intoxication, West Virginia Department of Bureau for Public Health Legislative Rules, 64 CSR 10, 1987 1990.~~

§64-10-2. Application and Enforcement.

~~2.1. Application. This legislative rule shall apply to law enforcement officers as follows: a member of the State department of public safety; any sheriff or deputy sheriff of any county; any member of a police department in any municipality as defined in Chapter 8, Article 1, Section 2 of the West Virginia Code; and any conservation officer of the department of natural resources; and to those persons suspected to be driving a motor vehicle while intoxicated. The provisions of this rule are applicable to all law enforcement agencies and personnel engaging in breath, blood, urine, alcohol and/or drug analysis in this state; and to those persons suspected of driving under the influence of alcohol and/or drugs.~~

~~2.2. Enforcement. The enforcement of this legislative rule is vested with the director.~~

§64-10-3. Definitions.

~~3.1. "Agency" means a law enforcement agency in the state engaging in breath, blood, and/or urine alcohol testing.~~

~~3.1. "Accuracy Inspection Test" a test conducted by a certified breath test operator to determine the performance of each breath testing instrument in accordance with the procedures set forth in Section 7.2 of this rule.~~

~~3.3. "Alcohol" means ethyl alcohol and may include methyl alcohol and isopropyl alcohol.~~

~~3.2.~~ 3.4. "Alcohol breath analysis" means ~~Chemical~~ chemical testing of a sample of a person's expired breath, using a breath test instrument designed for this purpose, in order to determine the concentration of ethyl alcohol in the person's blood.

3.5. "Bureau" means the West Virginia Bureau for Public Health.

3.6. "Calibrating unit" means a device designed to produce a predictable alcohol concentration reading on a breath alcohol test instrument.

3.7. "Certified instrument operator" means a person who has successfully completed a specialized training program and has been certified by the Bureau to perform breath alcohol testing using instruments approved for that purpose.

~~3.7.~~ 3.8 "Chemical Test or Testing" means an analysis performed on a biological material, including, but not limited to breath, blood, or urine, to determine the identity or concentration, or both, of particular constituents such as alcohol or controlled substances. Test procedures may rely on one or more physical or chemical properties of the constituents and utilize instrumental or chemical analysis techniques to accomplish the determination.

3.9. "Commissioner" means the commissioner of the West Virginia Bureau for Public Health or his or her lawful designee.

3.10. "Evidential test sequence" means one adequate reference standard analysis, one adequate breath sample analysis, and a second adequate reference standard analysis.

~~3.4. "Department" the West Virginia department of health.~~

~~3.5. "Director" the director of the West Virginia department of health or his or her lawful designee.~~

3.11. "Instrument" means an item or combination of items of equipment designed to make a measurement of alcohol concentration.

3.12. "Instrument blank analysis" means a test of an ambient air sample to insure that the instrument produces a zero result.

3.13. "Lot" means an entire quantity batch of a reference standard.

3.14. "Qualitative breath alcohol analysis" means a test of a person's breath, the results of which indicate the presence or absence of alcohol.

3.15. "Quantitative breath alcohol analysis" means a chemical test of a person's breath that yields a specific result in grams of alcohol per 210 liters of breath.

3.16. "Reference standard" means an aqueous ethanol solution compounded for use in a calibrating unit which, when equilibrated with air yields a predictable alcohol concentration or a sealed pressurized sample of gas that contains a predictable alcohol concentration that can be used to inspect or verify the accuracy of breath test instruments.

~~3.7.~~ 3.17. "Simulator Solution" – means an aqueous standard ethanol solution which, when equilibrated with air in a breath simulator instrument produces an air-alcohol mixture of 0.10 grams W/V that can be used to inspect or verify the accuracy of breath test instruments.

~~3.8~~ 3.18. "Simulator Test" means testing of a sample of simulator solution vapor, using a breath test instrument in order to ~~determine~~ verify the accuracy of the breath test instrument.

3.19 "Dry gas standard" means a sealed pressurized sample of gas that contains a predictable alcohol concentration that can be used to verify the accuracy of breath test instruments.

~~3.9.~~ 3.20. "W/V" means weight divided by volume.

§64-10-4. Preliminary Breath Analysis; Designation of Testing Instrument or Device; Compliance with Methods and Standards Required.

4.1. Each law enforcement agency utilizing a preliminary breath testing instrument or device shall designate such testing instrument or device for the purpose of administering a preliminary breath analysis pursuant to Chapter 17C, Article 5, Section 5 of the West Virginia Code. Such designation of the testing instrument or device shall be filed with the ~~department~~ Bureau on a form provided by the ~~department~~ Bureau.

4.2. Each law enforcement agency shall comply with the methods and the standards established by this rule.

4.3. The ~~department~~ Bureau shall maintain a registry of approved testing instruments or devices.

4.4. All instruments or devices utilized for the purpose of preliminary breath tests shall be approved in writing by the ~~director~~ Commissioner.

4.5. Approvals and designations of preliminary breath testing instruments or devices in effect at the time this rule becomes effective shall continue in effect.

§64-10-5. Breath Analysis; Preliminary Breath Test; Standards and Methods.

5.1. The use of the approved instrument or device shall adhere to the manufacturer's specifications for operation and shall include any maintenance specified by the manufacturer.

5.2. The following general methods shall apply in extracting breath for preliminary breath analysis:

(a) The preliminary breath test shall be administered ~~as soon as possible~~ after the law enforcement officer ~~or police officer~~ has a reasonable belief that the person has been driving while under the influence of alcohol. A fifteen-minute alcohol and smoke free period should be observed before conducting the test.

(b) Where the testing instrument or device requires contact with the mouth of the tested individual, the law enforcement officer ~~or police officer~~ conducting the preliminary breath test shall utilize an individual disposable mouthpiece for each person tested.

(c) The preliminary breath test may be administered by a law enforcement officer ~~or police officer~~ trained and certified as a secondary breath test operator with additional training, theory and practical exercise as recommended by the manufacturer.

5.3. The results of a preliminary breath analysis shall be used solely for the purpose of guiding the officer in deciding whether an arrest should be made.

§64-10-6. Designation of Secondary Test; Compliance with Methods and Standards Required; Certification of Law Enforcement Officers Required.

6.1. Each law enforcement agency shall designate a type of test, either breath, blood or urine for the purpose of administering a secondary test incidental to lawful arrest for the offense of driving a motor vehicle in this state while under the influence of alcohol. Such designation of the test shall be filed with the ~~department~~ Bureau on a form provided by the ~~department~~ Bureau.

6.2. Each law enforcement agency shall comply with the methods and the standards established by this rule.

6.3. The ~~department~~ Bureau shall maintain a registry of approved tests inclusive of methods and standards for proper conduct of the tests.

6.4. Secondary test designations in effect at the time this rule becomes effective shall continue in effect.

6.5. Each law enforcement officer administering a secondary breath analysis shall be trained and certified in the procedures of operation for such testing instrument.

6.6. The ~~department~~ Bureau shall certify each operator properly trained in the procedures of operation and shall issue a certificate to each individual so trained.

6.7. As a minimum training requirement each law enforcement officer shall have completed the Basic Training Program for Breath Examiner Specialist Course as prescribed by the United States Department of Transportation or an equivalent course prior to certification. Such course shall consist of classroom and laboratory training including review sessions and examinations.

6.8. Each law enforcement officer desiring certification to administer the secondary breath analysis shall apply to the ~~department~~ Bureau on a form provided by the ~~department~~ Bureau.

6.9. Certifications of law enforcement officers in effect at the time this rule becomes effective shall continue in effect.

§64-10-7. Breath Analysis; Secondary Breath Test; Standards; Accuracy Inspection Tests; Methods.

7.1. Instrument Standards - Instruments for breath alcohol analysis shall meet the following standards:

(a) The designated instrument and any related accessories shall be capable of the collection and the analysis of breath specimens, which approach alveolar composition.

(b) The designated instrument shall be capable of analyzing a blank sample and of analyzing a suitable ~~simulator solution~~ reference standard, ~~such as air equilibrated with a reference solution of known alcohol content at a known temperature.~~

(c) The designated instrument shall be capable of the analysis of a ~~simulator solution~~ reference

standard within accuracy and precision limits of plus or minus 0.01 grams percent W/V or higher.

(d) The designated instrument shall be capable, in a controlled experiment, of breath alcohol analysis which results in a determination of a person's blood alcohol concentration which has a correlation with his actual blood alcohol concentration as measured on a blood sample taken at approximately the same time as the breath sample.

(e) The instrument shall be capable of breath alcohol analysis which results in a concentration less than 0.01 grams of alcohol per 210 liters of breath ~~one hundred milliliters of blood~~ when alcohol-free persons are tested.

~~(f) The designated instrument shall have its accuracy checked in accordance with subsection 7.2 of this rule. Each law enforcement agency shall maintain a record of such accuracy checks including the type of test employed and the date of such accuracy checks. A certified copy of the record of the accuracy inspection test shall be admissible as evidence in any criminal or administrative proceeding as though: 1) the original record had been offered; 2) the custodian had been present to testify to the record keeping process; and, 3) the individual conducting the test had been present to certify the test result.~~

(f) ~~(g)~~ Any model of instrument utilized for the purpose of secondary breath analysis shall be approved in writing by the department Bureau. Such instrument shall meet or exceed the standards contained herein.

~~7.2. Accuracy Inspection Test~~

~~7.2.1. Frequency—An accuracy inspection test shall be conducted on every test instrument by a certified breath test operator at least once every six months, provided, however, that all instruments in use at the time this rule becomes effective shall be tested within forty-five days from June 12, 1987.~~

~~7.2.2. Procedures~~

~~7.2.2.1. An average deviation test to determine the accuracy of the instrument shall be conducted in the following manner:~~

~~(a) A total of five tests shall be conducted.~~

~~(b) A simulator calibrating unit containing simulator solution a reference standard shall be used.~~

~~(c) The results of all five tests shall be retained be recorded in a master log, which shall be kept for each certified instrument.~~

~~(d) Test results shall be recorded to the third decimal place, if the third decimal place is available.~~

~~7.2.2.2. The breath testing instrument does not pass the accuracy inspection test and shall be removed from service if:~~

~~(a) One or more of the five tests yields a result less than 0.090 0.01 per cent W/V or greater than 0.110 0.01 per cent W/V of the target value; when a calibrating unit containing a aqueous ethanol reference solution is used. One or more of the five tests yields a result less than .005 or more than .005 of the~~

~~target value when a sealed pressurized sample of gas containing a predictable alcohol concentration is used.~~

(b) ~~The average deviation derived by adding the absolute values of the differences between the results of the five tests and the target value a constant value of .10 percent W/V and dividing the total of these absolute values by five exceeds 0.005 per cent W/V.~~

(c) ~~Example of accuracy inspection test: (See Table 64-10A at the end of this rule.)~~

~~7.2.2.3. A breath testing instrument which has been removed from service for failure to pass an accuracy inspection test shall be adjusted or repaired and pass undergo an accuracy inspection test prior to being placed back into service.~~

~~7.2.2.4. The certified breath test operator shall perform the procedures set forth in Subsection 7.2.2.1 in accordance with accepted standard procedures for operation specified by the manufacturer of the device.~~

7.3. 7.2. Methods - The following general methods shall apply in extracting breath for secondary breath analysis:

(a) The individual being tested shall be under constant observation for a period of twenty minutes before the test is administered to insure that the individual has nothing in his or her mouth at the time of the test and that he or she has had no food or drink or foreign matter in his or her mouth during the observation period.

(b) The individual administering the test shall perform the evidential test sequence ~~a simulator test~~ to ~~insure~~ ensure that the instrument is in proper working condition at the time the subject's test is being conducted.

(c) The test shall be administered by a certified instrument operator and in accordance with this rule.

(d) The ~~law enforcement officer~~ certified instrument operator conducting the secondary breath test shall utilize an individual disposable mouthpiece for each person tested.

§64-10-8. Blood Analysis; Standards and Methods.

8.1. Methods of analyzing blood specimens for ethyl alcohol shall meet the following standards:

(a) The method utilized shall be capable of separating and quantitating ethyl alcohol from the blood specimen.

(b) The method utilized shall be capable of the analysis of a reference sample of known alcohol concentration within accuracy and precision limits of plus or minus 0.01 grams per cent W/V of the true value. These limits shall be applied to alcohol concentrations which are 0.01 grams per cent W/V or higher.

(c) The method utilized shall be capable of blood alcohol analysis which results in a concentration less than 0.01 grams of alcohol per one hundred milliliters of blood when alcohol free persons are tested.

(d) The gas-chromatographic method meets the above standards for testing.

8.2. The methods of collecting blood for alcohol analysis shall be as follows:

(a) The blood shall be drawn only by a licensed doctor of medicine or osteopathy or by a registered professional nurse or by a trained medical technician ~~at the place of their employment or any~~ medical professional trained in phlebotomy.

(b) Sterile hypodermic needles and syringes shall be used. Sterile disposable units are recommended.

(c) The skin shall not be disinfected with ethyl alcohol. The use of non-alcoholic antiseptics, those which do not contain ethyl alcohol, including 1-1000 aqueous solution of mercuric chloride, aqueous benzalkonium chloride (zephiran), aqueous merthiolate, or other suitable aqueous disinfectants is acceptable.

(d) The quantity of alcohol found in serum shall be divided by a factor of 1.16 to determine the quantity of alcohol in the blood.

~~(d)~~ (e) The container (tube or vial) must be clean and dry, and have an inert, airtight stopper.

§64-10-9. Urine Analysis; Methods and Standards.

9.1. The methods of analyzing urine specimens for ethyl alcohol shall meet the following standards:

(a) The method utilized shall be capable of separating and quantitating ethyl alcohol from the urine specimen.

(b) The method utilized shall be capable of the analysis of a reference sample of known alcohol concentration within accuracy limits of plus or minus 0.01 grams per cent W/V of the true value. These limits shall be applied to alcohol concentrations which are 0.01 grams per cent W/V or higher.

(c) The method utilized shall be capable of urine alcohol analysis, which results in a concentration less than 0.01 grams of alcohol per one hundred milliliters of alcohol when alcohol free persons are tested.

(d) The gas-chromatographic method meets the above standards for testing.

(e) The quantity of alcohol found in the urine shall be divided by the factor of ~~1.3~~ 1.5 to determine the quantity of alcohol in the blood.

9.2. The methods of collecting urine for alcohol analysis shall be as follows:

(a) The individual shall empty his or her urinary bladder and discard the first specimen.

(b) Following a twenty-minute observation period as described in 9.2(c), the individual shall void a sample of his or her urine into a clean dry container with an inert cap. The container shall be capable of holding at least ten milliliters of urine.

(c) The individual being tested shall be under constant observation for a period of twenty minutes before the specimen for alcohol analysis is taken to insure that the individual has nothing in his or her mouth at the time that the specimen is taken and that he or she has no food or drink or other foreign matter in his or her mouth during the observation period.

§64-10-10. Severability.

The provisions of this rule are declared to be severable. If any provision of this rule shall be held invalid, the remaining provisions shall remain in effect.

Table 64-10A.

EXAMPLE OF ACCURACY INSPECTION TEST

<u>Simulator</u> <u>Solution</u>	<u>Reading</u>	<u>Difference</u> <u>(Absolute Value)</u>
.100	.099	.001
.100	.104	.004
.100	.098	.002
.100	.101	.001
.100	.102	.002
<u>.010 = .002</u>		
<u>5</u>		

Average deviation = .002 and .002 is less than .005; therefore the breath test instrument passes the accuracy inspection test.