



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Office of the Secretary

State Capitol Complex, Building 3, Room 206
Charleston, West Virginia 25305
Telephone: (304) 558-0684 Fax: (304) 558-1130

Bob Wise
Governor

Paul L. Nusbaum
Secretary

April 22, 2004

Ms. Judy Cooper
Administrative Law Division
Office of the Secretary of State
Building 1, Room 157 K
Charleston, West Virginia 25305-0770

2004 APR 23 A 11: 25
FILED
STATE OF WEST VIRGINIA
SECRETARY OF STATE

Dear Judy:

Re: Methods and Standards for Chemical Tests for Intoxication

I'm enclosing with this letter the Notice of Agency Approval of a Proposed Rule and Filing with the Legislative Rule-Making Review Committee for the above referenced rule. I have reviewed the manual which Debra Graham provided, and I think we have this in order. The only problem I would see is that our folks seem to have combined the summary of the rule with the statement of circumstance.

If this is a problem, give me a call.

As I understand it, you accept the rule, stamp it, and then send a copy back to me.

If you will send me back the stamped copy, I'll process it with Legislative Rule-Making Review. As you know, since Martha left I am feeling my way through this, so give me a call if I've done anything incorrectly.

Sincerely,

John D. Law
Assistant Secretary

JDL:frk

Enclosure

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.

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.

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.

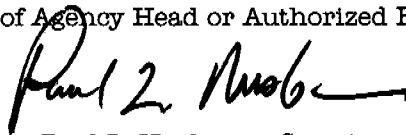
No impact

C. Economic Impact on Citizens/Public at Large.

No impact

Date:

Signature of Agency Head or Authorized Representative:

A handwritten signature in black ink, appearing to read "Paul L. Nusbaum", with a long horizontal flourish extending to the right.

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

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: April 16, 2003

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

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

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

1. Authorizing statute(s) citation §16-1-4 and §§17C-5-4, 17C-5-5, 17C-5-6 and 17C-5-8

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

January 28th, 2004

b. What other notice, including advertising, did you give of the hearing?

c. Date of Public Hearing(s) *or* Public Comment Period ended:

March 10, 2004

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached _____

No comments received X

- e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

April 16, 2004

- f. **Name, title, address and phone/fax/e-mail numbers** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Ann Spaner, Director, Public Health Regulations, Bureau for Public Health, Room 702, 350 Capitol St., Charleston, WV 25301-3712; AND ALSO, Ellie Marshall, Administrative Assistant, BPH Office of Laboratory Services, 167 11th Ave., So. Charleston, WV 25303-1137

- g. **IF DIFFERENT FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

2nd Lt. Douglas Parsons, State Police, 725 Jefferson Road, So. Charleston, WV 25309-1698

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

- a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

n/a

b. Date of hearing or comment period:

Comment period ran from Jan. 28, 2004 to March 10, 2004

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

n/a

d. Attach findings and determinations and reasons:

Attached n/a

FILED

2004 APR 23 A 11:25

OFFICE WEST VIRGINIA
SECRETARY OF STATE

**TITLE 64
LEGISLATIVE RULE
DIVISION OF HEALTH
BUREAU FOR PUBLIC HEALTH**

**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.~~

3.2. "Alcohol" means ethyl alcohol and may include methyl alcohol and isopropyl alcohol.

~~3.2.~~ 3.3. "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.

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

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

3.6. "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 "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.

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

~~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.~~

3.9. "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.

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

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.

~~3.9.~~ 3.19. "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 shall 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:

(1) 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 ~~4.3~~ 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</u>	<u>.002</u>
	5	

Average deviation = $\frac{.010}{5} = .002$ and $.002$ is less than $.005$; therefore the breath test instrument passes the accuracy inspection test.