NOTICES OF PROPOSED RULEMAKING
Initiated After January 1, 1995

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first filing a Notice of Proposed Rulemaking, containing the preamble and the full text of the rules, with the Secretary of State's Office. The Secretary of State shall publish the notice along with the Preamble and the full text in the next available issue of the *Arizona Administrative Register.*

Under the Administrative Procedure Act (A.R.S. § 41-1001 *et seq.*), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for adoption, amendment, or repeal of any rule. A.R.S. §§ 41-1013 and 41-1022.

NOTICE OF PROPOSED RULEMAKING

TITLE 9. HEALTH SERVICES

CHAPTER 14. DEPARTMENT OF HEALTH SERVICES LABORATORIES

PREAMBLE

1. Sections Affected — Rulemaking Action

R9-14-403	Amend
R9-14-404	Amend
Exhibit X	New Exhibit
Exhibit Y	New Exhibit
Exhibit Z	New Exhibit

2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

   Authorizing statute: A.R.S. §§ 36-136(F) and 41-1003

   Implementing statute: A.R.S. §§ 28-691.01, 28-695, and 29-696

3. The name and address of agency personnel with whom persons may communicate regarding the rulemaking:

   Name: Wynand H. Nimmo

   Address: Department of Health Services
   3443 North Central Avenue, Suite 810
   Phoenix, Arizona 85012

   Telephone: (602)255-3454

   Fax: (602)255-3462

4. An explanation of the rule, including the agency's reasons for initiating the rule:

   The RBT IV breath-testing device along with the related operator procedure and quality assurance forms (Exhibits X, Y, and Z) were approved by the Director on March 9, 1994, in accordance with R9-14-403(K). R9-14-403(K) authorizes the Director to approve breath-testing devices and their operational forms prior to their inclusion in the rule. The purpose of R9-14-403(K) is to allow the use of breath-testing devices with new technology and financial savings to law enforcement agencies who otherwise might not be able to use a breath-testing device for DUI apprehension until an amended rule was promulgated. The proposed rules add the RBT IV to the quantitative breath-testing devices listed in R9-14-403(G). R9-14-404 refers to the new Exhibits (X,Y, and Z) for the RBT IV and defines the specific procedures for their use. The new Exhibit forms (X,Y, and Z) are included in the rule packet. The Director's approval of the RBT IV will expire March 10, 1996, unless R9-14-403(G) is amended to include the RBT IV in accordance with R9-14-403(K).

5. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

   None applicable.

6. The preliminary summary of the economic, small business, and consumer impact:

   Law enforcement agencies in Arizona started using the RBT IV for DUI apprehension in late 1994 after the Director's approval pursuant to R9-14-403(K). Therefore, economic and consumer impact has already been incurred. Agencies have purchased the RBT IV, instruction courses for the RBT IV are operational, and officers have been trained to operate, maintain, and instruct others in the use of the RBT IV. Consumers have benefited due to the lower equipment cost and the mobility of the RBT IV which allows for immediate testing and faster DUI apprehension. DUI convictions are also enhanced when the time between apprehension and breath testing is reduced. There are no small businesses impacted by the rule.

   The proposed rule will allow a program already in place to continue. The impact to each agency that does not already have an RBT IV, but which intends to purchase them in the future, can be significant, the cost being $1000 per machine plus the expense of officer training. However, this is significantly less than the $5000 per machine for comparable equipment. DUI arrests and convictions would increase for these agencies. If the proposed rule is not promulgated, agencies would incur the increased cost of having to obtain a different breath-testing device for their DUI program.

7. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Wynand H. Nimmo
Address: Department of Health Services
3443 North Central Avenue, Suite 810
Phoenix, Arizona 85012
Telephone: (602) 255-3454
Fax: (602) 255-3462

8. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Date: November 27, 1995
Time: 10 a.m.
Location: Department of Health Services
1740 West Adams, Conference Room A
4th Floor
Phoenix, Arizona 85007
Nature: Public hearing

The Department will accept oral and written comments from now until the close of public record, November 27, 1995, at 5 p.m.

9. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

None.

10. Incorporations by reference and their location in the rules:

None

11. The full text of the rules follows:

TITLE 9. HEALTH SERVICES

CHAPTER 14. DEPARTMENT OF HEALTH SERVICES LABORATORIES

ARTICLE 4. DETERMINATION OF ALCOHOL CONCENTRATION

Section
R9-14-403. Breath Testing and Collection Devices
R9-14-404. Testing Procedures
Exhibit X Operational Checklist - Standard Operational Procedure - Intoximeter RBT IV - Duplicate Test
Exhibit Y Standard Quality Assurance Procedures - Intoximeter RBT IV - Standard Calibration Check Procedure
Exhibit Z Standard Quality Assurance Procedures - Intoximeter RBT IV

ARTICLE 4. DETERMINATION OF ALCOHOL CONCENTRATION

R9-14-403. Breath Testing and Collection Devices

A. Devices used to determine alcohol concentration from breath, or to collect a sample from breath for subsequent determination by an analyst, may be approved for use, by the Director, after the Department successfully tests a typical model of the device for compliance with the standards in subsections (B) and (C).

B. Devices utilized to determine alcohol concentration from a sample of breath shall meet the following standards of performance:

1. Breath specimens tested shall be alveolar in composition.
2. breath-testing devices shall be capable of analysis of a solution of known alcohol concentration with an accuracy limit of a systematic error of no more than ±0.005 grams per 210 liters of breath or ±5%, whichever is greater, and a precision limit of an average standard deviation of no more than .0042 grams per 210 liters of breath. The accuracy and precision of the devices being evaluated shall be determined on the basis of 10 consecutive measurements at 4 alcohol vapor concentrations which are between 0.05 and 0.25 grams per 210 liters of breath.
3. The device shall be capable of testing a breath sample which results in alcohol concentrations of less than .01 grams per 210 liters of breath when alcohol-free subjects are tested.

C. Devices utilized to collect a sample from breath for subsequent determination of alcohol concentration by an analyst shall meet the following standards of performance:

1. The device shall be capable of reproducing the known alcohol concentration of a reference sample with an accuracy limit of a systematic error of no more than ±.005 grams per 210 liters of breath or ±5%, whichever is greater, and a precision limit of an average standard deviation of no more than .0042 grams per 210 liters of breath. The accuracy and precision of the devices being evaluated shall be determined on the basis of 10 consecutive measurements at 4 alcohol vapor concentrations which are between 0.050 and 0.250 grams per 210 liters of breath.
2. The device shall be capable of collecting a sample from breath which results in an alcohol concentration of less than 0.01 grams per 210 liters of breath when alcohol-free subjects are tested.

D. Collection devices approved by the Director may be used in conjunction with any compatible approved breath-testing device.

E. The Department, upon specific findings that a device, method, or procedure is not accurate, is unreliable, or is not

an acceptable analysis or test for determining alcohol concentration or of collecting samples or that its use has been discontinued in the state, shall disapprove further use of the device, method, or procedure.

F. The methods approved by the Director for use by breath-testing devices to determine alcohol concentration are infrared absorbance, spectrophotometry, gas chromatography, and specific fuel cell detectors.

G. The following quantitative breath testing and collection devices are approved by the Director:

Model	Manufacturer
Breathalyzer 900/900A	Smith and Wesson Co.
Alco-Sensor III	Intoximeters, Inc.
Intoxilyzer Models 4011A Modified and 4011AS Modified with or without Beam Attenuator	CMI, Inc./Federal Signal
Intoxilyzer Models 4011A Modified and 4011AS Modified with Sample Preservation Modification with or without Beam Attenuator	CMI, Inc./Federal Signal
Intoxilyzer Model 5000	CMI, Inc./Federal Signal
Intoxilyzer Model 5000 with or without Vapor Recirculation and with or without Keyboard	CMI, Inc.
Intoximeter Model 3000	Intoximeters, Inc.
Mark IV GCI	Intoximeters, Inc.
GCI Field Collection Unit	Intoximeters, Inc.
PST-10 Silica Gel Tube (also known as SM-10 Silica Gel Tube)	Luckey Laboratories,Inc./ U.S. Alcohol Testing of America, Inc.
RBT IV (Alco Sensor IV with a RBT IV printer microprocessor)	Intoximeters, Inc.
Toxtrap Silica Gel Tube	Toxtrap, Inc./ Federal Signal

H. Products included on the National Highway Traffic Safety Administration's Conforming Products List of Evidential Breath Measurement Devices set forth in 57FR8376, March 9, 1992, and no further amendments, incorporated by reference and on file with the Office of the Secretary of State, are approved by the Director as preliminary breath testers to determine alcohol concentration.

I. Except when a device is used as a PBT, an operator's permit and approved operational procedure is required for the operation of quantitative breath-testing devices listed in subsection (G).

J. Quantitative breath-testing devices listed in subsection (G) may be used to administer preliminary breath tests.

K. In addition to the quantitative breath testing and collection devices approved in subsection (G), the Director shall approve, in writing, a device and the related quality assurance and operator procedure forms after the device is successfully tested for compliance with the standards in subsections (B) and (C) for use prior to and pending such device being added to subsection (G). The approval shall expire two years after its effective date unless subsection (G) is amended to include the approved device.

R9-14-404. Testing Procedures

A. Law enforcement agencies or individuals acting independently of such agencies who conduct alcohol concentration determinations by means of breath-testing devices shall implement a quality assurance program conducted by a quality assurance specialist. This quality assurance program shall include:

1. Criteria for insuring the proper operation of devices by testing device controls and indicators to ensure that they are functioning as required by the Department quality assurance procedure for the devices. The examinations shall be performed and recorded within 90 days of each other following the appropriate Department quality assurance procedure set forth in Exhibits F, H, J, M, Q, QQ, T, ~~and~~ V, and Z or as approved by the Director in accordance with R9-14-403(K).
2. Calibration checks of breath-testing devices which shall be performed and recorded in accordance with the requirements of the appropriate Department quality assurance procedure set forth in Exhibits F, J, L, P, PP, S, ~~and~~ V, and Y or as approved by the Director in accordance with R9-14-403(K).
3. Calibration checks of breath-testing devices which shall be performed within 31 days of each other. These checks shall indicate that the device is capable of determining the value of a known alcohol reference standard with an acceptable accuracy limit of ± 0.01 grams per 210 liters of breath or $\pm 10\%$, whichever is greater. A device performing outside this accuracy limit shall be removed from service until repair or maintenance is performed and the device operates within the accuracy limits.
4. Evaluation of collection devices used to provide preserved breath alcohol samples. Collection device samples shall be collected within 90 days of each other and analyzed within 60 days of collection to ensure they are reasonably reliable.
5. Standards for preparation of calibration solutions which shall be prepared using one or more of the following techniques. In addition, calibration solutions made by techniques (a) or (b) below shall be verified by titration or gas chromatography:
   a. Volumetric dilution of an absolute ethyl alcohol sample,
   b. Gravimetric dilution of an absolute ethyl alcohol sample,
   c. Volumetric dilution of a known ethyl alcohol sample,
   d. Gravimetric dilution of a known ethyl alcohol sample, or
   e. Commercially-produced ethyl alcohol standard.
6. Records of quality assurance testing, calibration checks, device adjustments, and any maintenance for each device in use.

B. Operator permit holders shall utilize the operator procedure approved by the Department for the device being operated on performing tests and collecting samples for the determination of alcohol concentration, as contained in Exhibits E, EE, G, I, II, K, KK, N, NN, O, OO, OOO, R, RR, U, UU, W, WW, ~~and~~ WWW and X or as approved by the Director in accordance with R9-14-403(K).

C. Duplicate quantitative breath tests shall be administered at intervals of not less than 5 minutes nor more than 10 minutes. The results of both tests shall be within .020 alcohol concentration of each other. If the second test is not within .020 alcohol concentration of the first test, additional tests shall be administered until the results of two consecutive tests are within .020 alcohol concentration.

EXHIBIT X

OPERATIONAL CHECKLIST

DEPARTMENT OF HEALTH SERVICES

STANDARD OPERATIONAL PROCEDURE
INTOXIMETER RBT IV

DUPLICATE TEST

AGENCY_____
NAME OF SUBJECT_____DATE_____
RBT IV SERIAL NO._____ALCO-SENSOR IV SERIAL NO._____
OPERATOR_____LOCATION OF TEST_____
TEST RESULTS
0._____AC TIME
0._____
0._____ _____
Immediately preceding the administration of the tests the subject underwent a 15-minute deprivation period from_____to_____ by_____

( ) 1. Turn on RBT IV.
( ) 2. Push Start button.
( ) 3. Insert mouthpiece.
( ) 4. Device temperature registers between 10°C and 40°C.
( ) 5. Blank completed.
( ) 6. Press Set button.
( ) 7. Have subject blow as long as possible, sample captured.
( ) 8. Press Set button.
( ) 9. Press red eject button to remove mouthpiece.
( ) 10. Remove test record when printout is complete.
( ) 11. Repeat steps 2 through 10 until a duplicate test is complete.
( ) 12. Turn off RBT IV.

Note: Duplicate tests shall be between 5 and 10 minutes apart. Two consecutive tests shall agree within 0.020 alcohol concentration.

EXHIBIT Y

THIS REPORT PREPARED PURSUANT TO DUTY IMPOSED BY R9-14-404(A)

DEPARTMENT OF HEALTH SERVICES

STANDARD QUALITY ASSURANCE PROCEDURES
INTOXIMETER RBT IV

STANDARD CALIBRATION CHECK PROCEDURE

Agency _____Date _____
RBT IV SERIAL NO._____ALCO-SENSOR IV SERIAL NO._____
QA Specialist _____LOCATION_____
(Print Name)

( ) 1. Have a standard alcohol source of known value ready. This may be a simulator(at 34°C±0.2°C) or a dry gas alcohol standard. Standard value:0._____AC.
( ) 2. Turn on RBT IV. Press START. Insert mouthpiece.
( ) 3. Device temperature registers between 10°C and 40°C.
( ) 4. Blank completed. Press SET button.
( ) 5. When RBT IV instructs user to "PROCEED WITH TEST", push STD OPTION button until the RBT IV displays "RUN STANDARD".
( ) 6. Attach alcohol source to mouthpiece.
( ) 7. Introduce standard into the Alco-Sensor IV for at least 4 seconds; at 3 seconds, and while there is still gas flowing, press MANUAL button on the Alco-Sensor IV to take the sample.
( ) 8. Disconnect alcohol source from mouthpiece.
( ) 9. Press SET button.
( ) 10. Test results 0._____ AC
( ) 11. Press red eject button to remove mouthpiece.
( ) 12. Remove test record when printout is complete.
( ) 13. Turn off RBT IV.

SIGNATURE _____

EXHIBIT Z

THIS REPORT PREPARED PURSUANT TO DUTY IMPOSED BY R9-14-404(A)

DEPARTMENT OF HEALTH SERVICES

STANDARD QUALITY ASSURANCE PROCEDURES
INTOXIMETER RBT IV

Agency _____ Date _____
RBT IV SERIAL NO._____ ALCO-SENSOR IV SERIAL NO._____
QA Specialist _____ LOCATION_____
(Print Name)

_____Date and time correct.
_____Alcohol-free subject test result 0._____ AC.
_____Proper sample recognition system.
_____"Test Refused" prints.
_____Controls, displays and printer worked correctly during the above quality assurance procedures.

CALIBRATION OF INTOXIMETER RBT IV

( ) 1. Have a standard alcohol source of known value ready. This may be a simulator (at 34°C±0.2°C) or a dry gas alcohol standard. Standard value: 0._____AC.
( ) 2. Remove the Alco-Sensor IV battery cover.
( ) 3. Turn on RBT IV. Press START. Insert mouthpiece.
( ) 4. Device temperature registers between 23°C and 27°C.
( ) 5. After the blank is taken and while .000 is displayed, depress button 3 until a number is displayed. SET is displayed when button 3 is released.
( ) 6. Press the SET button. Raise or lower the number now displayed (using buttons 1 or 2) to match the value of the standard being used. Press button 3 when correct. CAL will be displayed and the RBT IV will display PROCEED WITH TEST.
( ) 7. Attach the alcohol standard to the mouthpiece and introduce gas into the Alco-Sensor IV. At 5 seconds and while gas is still flowing, press the MANUAL button.
( ) 8. Press the SET button. Eject the mouthpiece. Remove the test record when printout is complete.
( ) 9. Run a calibration check on the Standard Calibration Check Procedure.

COMMENTS _____
_____
SIGNATURE _____