RESULTS OF AN INVESTIGATION OF THE PERFORMANCE OF THE SMITH AND WESSON BREATHALYZER MODEL 1000 BREATH ALCOHOL TESTER

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FORWARD

The two staff reports entitled "Results of an Investigation of the Performance of the Smith and Wesson Breathalyzer Model 1000 Breath Alcohol Tester," February 1980, and "The State of Compliance of the Smith and Wesson Breathalyzer Model 1000 A Follow-Up Report," September 1983 were prepared by Dr. A. L. Flores of the Transportation Systems Center (TSC) for the National Highway Traffic Safety Administration (NHTSA).

The February 1980 report details an investigation that was conducted as a result of reports from several police agencies (Maryland State Police, North Carolina Highway Patrol, and Washington D.C. Metropolitan Police) which cited problems with the use of the Model 1000 in the field. The study concluded that the Model 1000 appeared to have a quality control problem. It should be noted that the report did not find a precision/accuracy problem, but rather a problem involving quality control in the manufacture of the instruments and a less than adequate system for maintenance of the instruments in the field. The report recommended:

> "Users of the Breathalyzer Model 1000 should reexamine their program to ensure a strong organization for maintenance. The data of this report shows that when the instrument is performing properly it is an effective evidential breath tester. Frequent tests for accuracy should be performed; maintenance personnel should be trained to a high state of expertise so that trouble-shooting and repair can be performed at or near the user level. Maintenance at the user level is especially important for the Breathalyzer 1000 due to its complexity and the long downtimes accompanying return to the factory for repair. Field maintenance personnel should not be spread out over so many instruments that maintenance efficiency is reduced."

Because the quality control problem with the Model 1000 could be overcome by a comprehensive maintenance program, NHTSA decided not to remove the Breathalyzer 1000 from the Qualified Products List (QPL). The agency made the decision to assist the States using the Breathalyzer 1000 in ensuring that the instruments were being properly maintained. By using this

approach States which had taken steps to ensure the instrument's accuracy would not have their chemical test programs compromised. In May 1982, NHTSA initiated a follow-up investigation of the Model 1000. In January 1983, the manufacturer ceased production of this model. The follow-up report was completed in September 1983 and affirmed the findings of the 1980 investigation. Since the unit was no longer in production, delisting it would have no effect on the quality control of the instrument's manufacturing process. The remaining issue was one of program maintenance of the instrument by the user States.

The results of both of these studies were discussed in detail with the States using these instruments at Regional Chemical Test Directors meetings held in 1980 and 1984. These instruments continue to be used without difficulty by the States of Ohio, Arkansas, and the District of Columbia, due to the implementation of comprehensive chemical test programs.

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1.0 INTRODUCTION

The performance of breath alcohol test equipment used by police is a major concern of the alcohol countermeasures effort of the National Highway Traffic Safety Administration (NHTSA). A Qualified Products List (QPL) has been established to ensure the effectiveness of Federal funds used to purchase such equipment. Equipment which meets published minimum performance standards (Standard for Devices to Measure Breath Alcohol, Federal Register, Vol. 38, No. 212, November 5, 1973) is placed on the QPL. Equipment on the QPL, after being purchased by police, may be found not to meet the minimum standards or may be found to exhibit an excessive malfunction rate. Such equipment may be removed from the QPL by NHTSA.

Following reports of failures to comply with minimum standards and of high malfunction rates, and at the request of NHTSA, the Transportation System Center (TSC) initiated an investigation of the Smith and Wesson Electronics Breathalyzer model 1000. When this instrument was initially tested by TSC in 1974, it was found to meet the requirements of the standards and was placed on the QPL.

Findings are reported below.

2.0 INSTRUMENT DESCRIPTION

The Breathalyzer model 1000 is an acid dichromate based colorimeter. A fixed volume of the human subject's breath is collected at constant temperature and delivered into an ampoule containing the dichromate solution. Any alcohol present reacts with the dichromate quantitatively, reducing the intensity of the yellow color of the solution. The reduction of color intensity is thus a linear function of the amount of alcohol delivered into the ampoule.

The instrument is an automated version of the Breathalyzer models 900 and 900A. The design of the Breathalyzer models 900 and 900A can be divided into three major functional sub-assemblies:

1) Breath collection sub-assembly
2) Alcohol measurement sub-assembly
3) Read-out sub-assembly

The breath collection sub-assembly is a valve/cylinder/piston system by which the last 52 cubic centimeters of breath delivered by the subject are retained at constant temperature for measurement. Manipulation of the valve delivers the breath sample under weight of the piston to the dichromate solution ampoule of the alcohol measurement sub-assembly. After the alcohol -dichromate reaction is completed a light bulb mounted on a fine threaded screw carriage and located between the above ampoule and a second reference dichromate ampoule is

switched on. A light filter photo-detector assembly is located behind each ampoule. The two photo-detectors are incorporated into an electrical bridge circuit. Light passing through each ampoule and filter falls on the photodetectors. Loss of dichromate by reaction with alcohol results in a decrease in intensity of the yellow color of the test ampoule which causes unequal amounts of light to pass through the ampoules. Thus, currents produced by the photodetectors are not equal and the resulting electrical imbalance in the bridge circuit is indicated on a meter. Manual nulling of the circuit imbalance by shifting the position of the light bulb activates the readout sub-assembly. The light carriage is linked to a shaft connected to a pointer which indicates blood alcohol concentration on a scale on the face of the instrument. The instrument design is straightforward and uses relatively few parts. Over the years the instrument has enjoyed a high degree of acceptance by the police due, in part, to its accuracy and reliability.

The three major functions (collection, measurement, and read-out) are automated in the Breathalyzer model 1000 by use of electrical relays, solenoid valves, drive motor, pump, timers, sequencers, counters, etc. A printed circuit board controls the breath test process which in models 900/900A are controlled manually. Servo-driver printed circuit boards activate the above electro-mechanical sub-assemblies. Light carriage travel is converted to a digital signal by a chopper calibration wheel.

Two miniature light bulbs are mounted on one side of the chopper wheel; a photodetector is mounted on the other side. Photodetector output is digitally displayed in terms of blood alcohol concentration. A printed read-out is also provided simultaneously. The operator is required only to initiate the test cycle and indicate to the person being tested when he should blow into the sample tube. Thus, although the possibility of tampering with the test result is removed, the Breathalyzer 1000 is a far more complicated instrument, in terms of parts used, than predecessor models.

This complexity appears to be one reason for performance malfunction failures, as will be discussed below.

3.0 COMPLIANCE INVESTIGATION

In order to obtain a broad basis for evaluation of problems reported for this breath tester, information on its performance from a number of different sources was desired. To this end, the following was done:

- o Performance and malfunction data for the instrument were obtained from several police agencies.
- o Laboratory tests were performed at TSC on new, unused units obtained from several sources including the manufacturer.
- o A quality control inspection of the Breathalyzer model 1000 factory was performed.
- o On-site tests of units in use by police were performed in six states.

3.1 PERFORMANCE AND MALFUNCTION DATA

88 Breathalyzers model 1000 were tested by the state of Maryland in 1978 for precision and accuracy according to the DOT standard. These tests were performed as part of a pre-procurement acceptance test; the units tested were new, obtained directly from the factory. Test results are given in Appendix A. 22 of the instruments failed to meet the requirements of the test. 7 of these 22 instruments had also malfunctioned. 11 other instruments met the requirements but were unacceptable due to malfunction. Thus, a total of 33 of the 88 instruments were unacceptable. 18 of the above 22 instruments were re-tested and 11 of these were again found unsatisfactory, 4 due to the occurrance of malfunctions alone.

During 1977-1978, 23 Breathalyzers model 1000 were in use in the District of Columbia. 95 malfunctions were recorded there over a 21 month period. During the same period, in Schuylkill County, Pennsylvania, where 9 units were in use, 19 malfunctions were recorded. In North Carolina, the State Police had purchased 56 Breathalyzers model 1000 but the high initial malfunction rate encountered had caused the police to discontinue their use. These findings on Breathalyzer model 1000 malfunctions are further discussed in Appendix A.

3.2 LABORATORY TESTS

Seven new Breathalyzer model 1000 instruments, still in factory shipment cartons were obtained from various sources for testing at TSC. Two were obtained from the Metropolitan Police Department of the District of Columbia, one was obtained from the Colorado Department of Health, two were obtained from the Department of Protection, Allegheny County, Pennsylvania, and two were obtained from Smith and Wessen Electronics.

These instruments were tested according to the DOT Standard. Four of the seven units failed to perform within the tolerence required by the Standard. Failures were found in both accuracy and precision requirements for the various tests performed. Tables 1,2,3 and 4 present test data obtained on the units from Allegheny County and from Smith and Wesson Electronics. The test data for the units from the District of Columbia and Colorado are given in Appendix A.

3.3 QUALITY CONTROL INSPECTION

An inspection of the Breathalyzer model 1000 factory in Pittsburgh, Pennsylvania was performed on April 16, 1979. A member of the inspection team was Fredrick M. Seekell, TSC staff, an expert in the principles of product quality control. As a result of this inspection, several areas in apparent need of further consideration by the manufacturer were identified:

- o A mechanism for ensuring product identity and status in the manufacturing process.
- o Methods for detection of drift in standard jigs, fixtures, and test kits used.
- o Methods for ensuring the constancy of different portions of the manufacturing process.
- o A mechanism by which failure information from units in use by police is fed back into the manufacturing process.

The report of Mr. Seekell, which discusses the above in more detail, is contained in Appendix B.

3.4 FIELD TESTS

To obtain direct information on performance of the Breathalyzer model 1000 in the field along with condition of use and maintenance, on-site visits were made to a number of police agencies. First, a listing of the distribution of units in the various states was obtained from the manufacturer. Arrangements were made through the appropriate state offices for visits to selected areas of the state where a

number of these instruments were in use. Areas selected were:

- o Cleveland, Ohio area: 4 units tested
- o Peoria, Illinois area: 4 units tested
- o Pittsburgh, Pennsylvania area: 6 units tested
- o Blytheville, Arkansas area: 5 units tested
- o Charleston, West Virginia area: 5 units tested
- o Raleigh, North Carolinia area: 6 units tested*

In addition to performing precision/accuracy tests on the Breathalyzer model 1000 at each site, information on the experience of the police relative to reliability and maintenance of the instrument was also obtained. Forms used to record the data and other information obtained are contained in Appendix C.

Site visits were made by Officer Floyd Wing and Sergeant Joseph Jacobs of the District of Columbia Metropolitan Police Department, both experts in Breathalyzer model 1000 maintenance. A report of their finding is contained in Appendix D.

The field tests were performed to determine whether or not the precision/accuracy and malfunction problems discussed earlier exist in the field to a significant extent. Practical considerations required that the number of tests made to determine precision/accuracy as specified in the Standard be reduced from 10 at each BAC concentration to 5 at each concentration. Except for instruments with borderline performance, this modified procedure is equivalent to that specified in the Standard. Instruments with good performance will pass either

*These units used by city police, not State Police.

test procedure. Instruments with poor performance will fail either test procedure.

Field test results are given in Table 5. A summary of the results is given below. Since "borderline" instruments may or may not have passed if 10 tests were made instead of 5, the number of failed instruments are listed by the criteria given in the Standard (criteria a) and also by a relaxed criteria (criteria b). Thus, the number of "borderline" instruments which fail by criteria a but pass by criteria b were found to be 3. 16 of the 30 instruments failed by both criteria.

		No. Failed*	
	No. Tested	Criteria a	Criteria b
Ohio	4	1	1
Illinois	4	2	2
Pennsylvania	6	3	2
Arkansas	5	3	3
West Virginia	5	4	3
North Carolina	6	6	5
	30	19	16

	Criteria a	Criteria b
systematic error at .05 BAC	±10%	±12%
systematic error at .10 and .15 BAC	± 5%	± 6%
average standard deviation	≤.004 BAC	≤.005 BAC

In addition, discussions with the users indicated that:

o Condition of new or repaired instruments received from the factory indicate the existance of a serious quality control problem there.

o Instrument downtime is a serious problem; turn-around time for instruments returned to the factory for repair is much too long (4 to 6 month delays) and repairs are too often not satisfactory.

o Expertise of in-house maintenance personnel should be at a high level due to the complexity of the instrument.

o Preventive maintenance or performance tests are not performed at frequent enough intervals in some of the States visited.

o The photometer system and the servo system are a frequent source of problems.

There did not appear to be a strong correlation between failures and States thought to have a strong or weak maintenance programs.

4.0 CONCLUSIONS AND RECOMMENDATIONS

This investigation of the Smith and Wesson Electronics Breathalyzer model 1000 was initiated as a result of reports from several police sources regarding problems in the use of this instrument. Failure of the instrument to meet precision/accuracy requirements and malfunction failures were reported.

Data was obtained from the state of Maryland and from laboratory tests conducted at TSC on a number of new instruments obtained from several sources. Failures to meet precision/accuracy requirements were seen for 4 of the 7 instruments tested at TSC and for 22 of 88 instruments tested by the State of Maryland.

Malfunction reports were obtained from Maryland, the District of Columbia, Pennsylvania, and North Carolina. These reports showed malfunction rates high enough to impair the effectiveness of the use of this instrument.

A quality control inspection was made of the Breathalyzer model 1000 factory; methods for improving quality control of the manufacturing process were identified.

On-site tests were made of 30 instruments at police agencies in six states. 16 of these instruments were found not to meet precision/accuracy requirements and four malfunctions were encountered.

The design of the 900 series Breathalyzer, on which the model 1000 is based, was straight-forward and utilized

relatively few parts. On the other hand the model 1000 uses many more parts and is a far more complex instrument. The complexity of the instrument appears to present a problem in maintaining effective quality control of the manufacturing process.

The above findings demonstrate that a substantial fraction of Breathalyzer model 1000 instruments fail to be in compliance with the Standard for evidential breath testers. This being the case, the following recommendations are made:

a. Users of the Breathalyzer model 1000 should re-examine their program to ensure a strong organization for maintenance. The data of this report shows that when the instrument is performing properly it is an effective evidential breath tester. Frequent tests for accuracy should be performed; maintenance personnel should be trained to a high state of expertise so that trouble-shooting and repair can be performed at or near the user level. Maintenance at the user level is especially important for the Breathalyzer model 1000 due to its complexity and the long downtimes accompanying return to the factory for repair. Field maintenance personnel should not be spread out over so many instruments that maintenance efficiency is reduced.

b. Present quality control procedures in the manufacturing process should be significantly improved. Redesign to simplify the instrument and thereby reduce quality control problems may be warranted. Any redesign should be indicated by change in model designation. Redesign implies submission to DOT for qualification testing if Qualified Product status is desired.

c. The observed rate of precision/accuracy failures and the observed malfunction rate shows that the present overall performance of this instrument does not warrent its inclusion on the Qualified Products List.

TABLE 1. TEST DATA: SMITH AND WESSON BREATHALYZER MODEL 1000 SN 2860 (ALLEGHENY COUNTY)

TEST	1	2	3	4	5	6	7	8	9	10	M	SD	SE	MEETS REQUIREMENTS
(162) Precision/Accuracy														
at 0.05 BAC	.052	.051	.053	.050	.051	.053	.048	.050	.050	.048	.0506	.00178	1.2	
at 0.10 BAC	.098	.098	.102	.098	.102	.103	.101	.099	.104	.098	.1003	.00236	0.3	YES
at 0.15 BAC	.152	.150	.147	.148	.148	.149	.148	.146	.152	.147	.1487	.00206	0.9	
(3) Alcohol Free Subjects	.000	.000	.000	.000	.000	.000	.000	.000	.001	.000	.0001			YES
(5) Power Line Voltage														
at 108 VAC	.099	.102	.100	.102	.102	.100	.102	.102	.102	.101	.1012	.00114	1.2	
at 123 VAC	.102	.101	.100	.100	.099	.100	.101	.100	.099	.102	.1004	.00107	0.4	YES
(6) Ambient Temperature														
at 20°C	.095	.097	.095	.097	.093	.092	.097	.095	.099	.096	.0951	.00173	-4.9	
at 30°C	.103	.103	.103	.101	.100	.101	.102	.101	.103	.102	.1019	.00110	1.9	YES
(7) Post Vibration	.100	.099	.100	.096	.096	.099	.098	.097	.100	.097	.0982	.00162	-1.8	YES
Electrical Safety														YES

M = Mean
SD = Standard Deviation
SE = Systematic Error, %

TABLE 2. TEST DATA SMITH AND WESSON BREATHALYZER MODEL MODEL 1000 SN 2879 (ALLEGHENY COUNTY)

TEST	1	2	3	4	5	6	7	8	9	10	M	SD	SE	MEETS REQUIREMENTS
(1&2) Precision/Accuracy														
at 0.05 BAC	.051	.047	.047	.051	.045	.053	.047	.048	.047	.046	.0482	.00257	-3.6	
at 0.10 BAC	.095	.094	.096	.094	.101	.097	.096	.095	.106	.092	.0966	.00406	-3.4	
at 0.15 BAC	.148	.143	.144	.133	.143	.141	.141	.142	.141	.138	.1414	.00392	-5.7	NO
(3) Alcohol Free Subjects	.000	.000	.000	.000	.005	.000	.001	.000	.005	.000	.0011			YES
(5) Power Line Voltage														
at 108 VAC	.102	.095	.094	.098	.097	.097	.098	.093	.094	.103	.0971	.00335	-2.9	
at 123 VAC	.104	.096	.097	.096	.097	.096	.097	.097	.095	.100	.0975	.00264	-2.5	YES
(6) Ambient Temperature														
at 20°C	.092	.092	.090	.095	.093	.091	.097	.093	.092	.094	.0929	.00202	-7.1	
at 30°C	.099	.097	.098	.098	.096	.097	.098	.097	.095	.097	.0972	.00114	-2.8	NO
(7) Post Vibration	NOT TESTED													
Electrical Safety														YES

M = Mean
SD = Standard Deviation
SE = Systematic Error, %

TABLE 3. TEST DATA SMITH AND WESSON BREATHALYZER MODEL 1000 SN2792 (SMITH AND WESSON)

TEST	1	2	3	4	5	6	7	8	9	10	M	SD	SE	MEETS REQUIREMENTS
(162) Precision/Accuracy														
at 0.05 BAC	.049	.051	.051	.048	.050	.050	.049	.050	.049	.049	.049	.001265	-1.2	
at 0.10 BAC	.103	.102	.099	.099	.106	.095	.101	.096	.097	.098	.100	.003406	-0.0	YES
at 0.15 BAC	.152	.151	.153	.155	.146	.147	.147	.146	.148	.153	.150	.003360	-0.0	
(3) Alcohol Free Subject	.000	.000	.000	.000	.002	.000	.000	.000	.000	.000	.0002			YES
(5) Power Line Voltage														
at 108 VAC	.101	.100	.100	.099	.102	.102	.100	.099	.098	.098	.100	.001449	0.0	
at 123 VAC	.101	.101	.100	.098	.100	.101	.100	.101	.100	.101	.100	.0009485	0.0	YES
(6) Ambient Temperature														
at 20°C	.100	.098	.098	.096	.101	.100	.099	.097	.098	.098	.099	.001509	-1.0	
at 30°C	.098	.099	.099	.101	.099	.105	.104	.103	.102	.103	.101	.002452	+1.0	YES
(7) Post Vibration	.100	.098	.098	.096	.101	.100	.099	.097	.098	.098	.099	.001509	-1.0	YES
Electrical Safety														YES

M = Mean
SD = Standard Deviation
SD = Systematic Error, %

TABLE 4. TEST DATA SMITH AND WESSON BREATHALYZER MODEL 1000 SN 2784 (SMITH AND WESSON)

TEST	1	2	3	4	5	6	7	8	9	10	M	SD	SE	MEETS REQUIREMENTS
(1&2) Precision/Accuracy														
at 0.05 BAC	.049	.049	.050	.049	.050	.051	.050	.050	.048	.048	.049	.001	-2.0	
at 0.10 BAC	.101	.100	.102	.101	.097	.099	.099	.104	.101	.101	.101	.002	+1.0	YES
at 0.15 BAC	.153	.150	.153	.151	.151	.148	.151	.150	.151	.151	.151	.001	+0.6	
(3) Alcohol Free Subjects	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000	.000			YES
(5) Power Line Voltage														
at 108 VAC	.099	.098	.099	.098	.098	.099	.100	.101	.101	.101	.099	.001	-1.0	
at 123 VAC	.101	.101	.100	.099	.100	.100	.100	.099	.101	.101	.100	.001	0.0	YES
(6) Ambient Temperature														
at 20°C	.100	.100	.096	.098	.098	.097	.098	.098	.098	.098	.098	.001	-2.0	
at 30°C	.102	.100	.101	.102	.103	.101	.097	.097	.097	.098	.100	.002	0.0	YES
(7) Post Vibration	.099	.098	.100	.100	.099	.100	.100	.097	.098	.099	.099	.001	.1.0	YES
Electrical Safety														YES

M = Mean
SD = Standard Deviation
SE = Systematic Error, %

TABLE 5. FIELD PERFORMANCE - BREATHALYZER 1000

SERIAL NUMBER LOCATION	ACCURACY/PRECISION AT BAC (MEAN/STD DEVIATION) .050	.100	.150	MALFUNCTION
2798 W.VA.	.0440* (.003464	.0916* .008735	.1428 .002049)*	
2796 W.VA.	.0495 .002121	.0946 .001817	.1460 .006595	Printer
0520097 W.VA.	.0437* .001500	.0938* .002168	.1370* .002449	
2791 W.VA.	.0470 .001414	.0942* .001304	.1428 .0008366	
062040 W.VA.	-	-	-	Breath Chamber
1204903 PA.	.0477 (.005033	.0985 .003697	.1450 .004733)*	
0482567 PA.	.0490 .002646	.0995 .001871	.1488 .004494	
0482569 PA.	.0306* (.02797	.0853* .03786	.1520 .005888)*	
0840222 PA.	-	-	-	Breath Chamber
1072421 PA.	.0493 .0005774	.0970 .002646	.1450 .002646	
0740737 PA.	.0487 .001528	.0947 .0005776	.1500 .0000	
0640709 ARK.	-	-	-	Photo Ass'y
2826 ARK.	.0466 .002408	.0978 .004472	.1480 .001000	
0451085 ARK.	.0052 .004324	.1076* .003209	.1586* .004722	
0962202 ARK.	.0464 .002074	.0970 .001000	.1470 .003674	

TABLE 5.. FIELD PERFORMANCE - BREATHALYZER 1000 (Cont.)

SERIAL NUMBER / LOCATION	ACCURACY/PRECISION AT BAC (MEAN/STD DEVIATION) .050	.100	.150	MALFUNCTION
0740752 ARK	.0530 (.008746	.1085* .01890	.1492 .003834)*	
0562127 OHIO	.0510 .003240	.0966 .004980	.1476 .002702	
0662144 OHIO	.0575* .008544	.1003 .001155	.1513 .0005774	
0862171 OHIO	.0473 .003403	.0990 .002000	.1500 .001732	
0562128 OHIO	.0526 .004561	.1000 .003674	.1553 .002217	
0620294 IL.	.0505 (.001290	.0988 .001304	.1023* .08864)*	
0540614 IL.	.0470 .001225	.0960 .001871	.1440 .008689	
0620326 IL.	.0518 .002217	.1066* .004278	.1550 .001000	
0640673 IL.	.0479 .0009574	.0992 .003114	.1506 .003209	
0962189 NC	.0466 .002191	.0912* .001304	.139* .00394	
1062217 NC	.04580 .001789	.0946 .002074	.1408* .001643	
1162236 NC	.04700 .001581	.09160* .003782	.1438 .003033	
1252008 NC	.05180 (.004817	.0966 .004037	.1480 .006782)*	
0162028 NC	.04220* (.004382	.0814* .001949	.1304* .007503)*	
962190 NC	.04560 .001516	.09520 .0019230	.1396* .003209	

* = out of tolerance required by DOT/NHTSA Standard

Accuracy: ± 10% @ .050 BAC
± 5% @ .100 and .150 BAC

Precision: Avg. Std Deviation ≤ .004 BAC

APPENDIX A

PRELIMINARY REPORT

STANDARDS COMPLIANCE INVESTIGATION

SMITH & WESSON BREATHALYZER MODEL 1000

FEBRUARY 1979

TRANSPORTATION SYSTEMS CENTER

STANDARDS COMPLIANCE INVESTIGATION

SMITH AND WESSON BREATHALYZER MODEL 1000

February 15, 1979

1.0 INTRODUCTION

The Department of Transportation Standard for Devices to Measure Breath Alcohol Federal Register, Vol. 38, No. 212, November 5, 1973, establishes qualification test procedures for development of a Qualified Products List for evidential breath testers. The primary objective of the Qualified Products List is to ensure that Federal funds provided to the States under Section 402 of the Highway Safety Act of 1966 are expended only for effective breath test equipment. The Standard requires investigation of instruments placed on the List which subsequently fail user acceptance tests, which otherwise fail to meet requirements of the standard, or which exhibit excessive breakdown rates. If this investigation indicates that the devices actually sold on the market are not meeting the Standard, then the manufacturer will be notified that the instrument may be dropped from the Qualified Products List. In this event the manufacturer shall have 30 days to reply.

Based on the DOT Transportation Systems Center investigation and the data presented in reply by the manufacturer, the NHTSA will make a determination as to whether the instrument should remain on the Qualified Products List.

The Smith and Wesson Electronics Company Breathalyzer model 1000 was tested in 1974 and was placed on the List. Excessive breakdown frequency and precision/accuracy problems have been reported by users in several states. Based on these reports, the NHTSA initiated a

standards compliance investigation. The standards compliance data consisted of:

- o State Precision/Accuracy Data
- o Instrument Malfunction Reports
- o TSC Qualification Test Data

State precision/accuracy data were obtained from Maryland; malfunction reports were obtained from Maryland, District of Columbia, Pennsylvania, and North Carolina. TSC performed qualification tests on instruments furnished by the District of Columbia Metropolitan Police Department and the Colorado Department of Health.

2.0 STANDARDS COMPLIANCE DATA

2.1 State Precision/Accuracy Data

88 Breathalyzer 1000 instruments were tested by Dr. Yale Kaplan, Toxicologist, Department of Post Mortem Examiners, Office of the Chief Medical Examiner, State of Maryland. 22 of the instruments failed to meet the requirements of the above DOT Standard for precision and accuracy. Test criteria are; systematic error within ± 10% at 0.050 BAC, ±5% at 0.100 BAC and 0.150 BAC; average standard deviation not greater than 0.004 BAC. 7 of these 22 instruments had also malfunctioned. 11 other instruments met the requirements but were unacceptable due to malfunction, which was often failure of the printer to operate. Thus, a total of 33 of the 88 instruments were unacceptable. 18 of the above 22 instruments were re-tested and 11 of these were again found unsatisfactory, 4 due to the occurance of malfunctions alone. There were 10 systematic error failures and 19 standard deviation failures. The instrument was not approved by Maryland. Test data are appended.

2.2 Instrument Malfunction Reports

2.2.1 State of Maryland

In the above precision/accuracy testing of 88 instruments, 27 malfunctions occurred. These malfunctions are listed in Table 1.

2.2.2 District of Columbia

The Metropolitan Police Department used 23 Breathalyzer 1000 instruments from February, 1977 through November, 1978. Reports of 95 malfunctions were furnished by Robert Goldstein, Traffic Enforcement Branch, Metropolitan Police Department. These malfunctions are listed in Table 2.

2.2.3 Pennsylvania

Louis R. Rader, DUI Coordinator, DUI Countermeasures Program, Schuylkill County, Pennsylvania, used 8 Breathalyzer 1000 instruments from March, 1977 through December, 1978. 19 malfunctions were encountered. These are listed in Table 3.

2.2.4 North Carolina

The North Carolina Department of Crime Control and Public Safety, Division of State Highway Patrol, purchased 56 Breathalyzer 1000 instruments. These instruments are not being used due to the number of malfunctions encountered. Two instruments were returned to the factory on July 19, 1978 for complete reconditioning and were subsequently placed in service during the summer of 1978. Despite factory reconditioning the units continued to malfunction. W. K. Chapman, Lieutenant, Zone Operations, furnished the following information concerning the nature of malfunctions:

- Control locking in purge mode.
- High readout in blank mode will not reset properly.
- False reading using simulator solution.
- Positive readout without sample.

2.3 TSC Standards Qualification Test Data

2.3.1 Test Procedure

All tests were carried out at TSC in the Fall of 1978 in accordance with the Standard for Devices to Measure Breath Alcohol, Federal Register, Vol. 38, No. 212, November 5, 1973. The ambient conditions maintained for the tests were: 22-25° C, 30-60% relative humidity, 29-30.3 inches mercury, and operating voltage 117 ± volts AC. These conditions were maintained except as otherwise required by the specific tests.

The specific tests carried out are listed below.

TEST NO. 1 - PRECISION TESTS USING KNOWN ETHANOL VAPOR CONCENTRATION

This test was carried out in accordance with Section 5.1 of the Standard.

TEST NO. 2 - ACCURACY TEST USING KNOWN ETHANOL VAPOR CONCENTRATION

This test was carried out in accordance with Section 5.2 of the Standard. The test data obtained in Test No. 1 are used for this test.

TEST NO. 3 - BLANK TEST USING ALCOHOL-FREE TEST SUBJECTS

This test was carried out in accordance with Section 5.3 of the Standard.

TEST NO. 4 - BREATH SAMPLING TEST (SECTION 5.4 OF THE STANDARD)

The National Highway Traffic Safety Administration has determined that this test requires modification. Results of this test are not reported.

TEST NO. 5 - POWER LINE VOLTAGE TEST

This test was carried out in accordance with Section 5.5 of the Standard.

TEST NO. 6 - AMBIENT TEMPERATURE TEST

This test was carried out in accordance with Section 5.6 of the Standard.

TEST NO. 7 - VIBRATION TEST FOR MOBILE EBT

This test was carried out in accordance with Section 5.7 of the Standard. A Unholtz-Dickie Model TK-100-20 shake table was used for this test.

ELECTRICAL SAFETY INSPECTION

Each instrument tested was inspected for electrical safety in accordance with Section 4.8 of the Standard.

2.3.2 Design Changes

In addition to the above tests, the instruments were compared with a Breathalyzer 1000 purchased by TSC in 1974 when the instrument was first introduced into the market. A number of design changes not reported to TSC were evident between the "old" and "new" units (see appendix) although the units share the same model number.

2.3.3 Test Results

Test results are presented in Tables 4, 5, and 6. The data shown in Table 6 were obtained from a unit with modified photometer apertures and extended photometer lamp "on" time as compared to the instruments used to obtain the data in Tables 4 and 5. The performance of the instrument of Table 6 meets all of the requirements of the Standard except for systematic error results at 0.10BAC and 0.15BAC. The instruments of Table 4 and Table 5 failed a number of tests because of excessive standard deviation and systematic error.

3.0 COMMENTS ON PRECISION/ACCURACY FAILURES AND MALFUNCTIONS

3.1 Precision/Accuracy Failures

The data from the State of Maryland show that the majority of statistical failures were due to standard deviation being out of tolerance. This result is seen in the TSC data except for the data in Table 6 which is for an instrument with a modified photometry system. The preponderance of standard deviation failures suggest possible problems with the breath sampling system of the instrument. The minimum volume of the breath that is "wasted" is only about 1/2 liter. The high flow resistance encountered in delivering breath samples results in deleterious effects which when combined with the low minimum waste volume may cause significant scatter in the data obtained and, hence, standard deviation failures. Also, the modifications of the photometry system of the instrument of Table 6 is seen to decrease the number of failures.

3.2 Malfunction Failures

The high frequency of malfunction seen in Tables 1, 2, and 3 and in North Carolina indicate a serious quality control problem at the factory. It is apparent that a thorough review of quality control procedures at the factory is required.

4.0 SUMMARY

The State of Maryland has performed precision/accuracy tests on 88 Breathalyzer 1000 instruments. 33 of these 88 instruments were unsatisfactory. High malfunction rates were encountered by the Metropolitan Police Department, Washington, D.C., the D.U.I. Countermeasures Program of Schuylbill County, Pennsylvania, and the

State Highway Patrol of North Carolina.

Three Breathalyzer model 1000 breath testers were obtained from the field. These instruments were evaluated according to the Standard for Devices to Measure Breath Alcohol. These instruments were compared with a Breathalyzer model 1000 purchased by TSC in 1974 when the instrument was first introduced to the market. A number of differences were noted between the "old" unit and the "new" (see appendix) although both the "old" and "new" units share the same model number.

TABLE 1. MALFUNCTIONS: MARYLAND

Item	Number of Malfunctions
Printer	16
Control Board	8
Ampoule Cover	1
Display	1
Acid Damage	1

TABLE 2. MALFUNCTIONS: DISTRICT OF COLUMBIA

Item	Repair	Replace
Control Board	1	12
Servo Board		17
Heater		1
Breath Cylinder Board	2	4
Pressure Plate Assy		1
Photo Assy Board	1	5
Photo Bulb		4
Breath Tubing		17
Magnet Assy	3	
Printer	2	5
Photo Cell		2
Calibration Wheel		10
Numitron Tube		2
Solenoid Valve		2
Check Valve		1
Fan		1
Servo Motor		1
Reed Switch		1
Transistor		2
Soldered Wires	4	
Return to Factory (3)		

TABLE 3. MALFUNCTIONS: Schuylkill County

Item	Repair	Replace
Control Board		1
Breath Cylinder Board	1	3
Photo Assy Board		3
Photo Bulb		1
Magnet Assy	1	
Printer		2
Calibration Wheel		1
Breath Chamber	3	
Fan Motor		1
Servo Motor		1
Thermister		1
Malfunction not specified (1)		
In Shop (1)		

TABLE 4. Smith and Wesson Breathalyzer model 1000 S/N 0782625.
Furnished by Metropolitan Police Department, District of Columbia.

Test (1&2) Precision/Accuracy	Test Data 1	2	3	4	5	6	7	8	9	10	M	S.D.	S.E.	Meets Requirements
at 0.05 BAC	.062	.057	.053	.059	.059	.054	.051	.052	.057	.051	.056	.0038	+12.0	
at 0.10 BAC	.100	.098	.096	.098	.100	.099	.101	.101	.101	.102	.100	.0017	0.0	No
at 0.15 BAC	.163	.156	.149	.151	.151	.148	.154	.155	.148	.156	.153	.0047	+2.0	
(3) Alcohol Free Subjects	.001	.000	.004	.000	.000	.000	.000	.000	.000	.000	.000			Yes
(5) Power Line Voltage														
at 108 VAC	.106	.100	.094	.098	.097	.107	.103	.099	.098	.099	.100	.0041	0.0	No
at 123 VAC	.101	.101	.099	.094	.108	.107	.106	.102	.098	.107	.102	.0046	+2.0	
(6) Ambient Temperature														
at 20°C	.099	.096	.094	.092	.087	.082	.096	.094	.107	.087	.093	.0070	-7	No
at 30°C	.097	.108	.107	.107	.100	.104	.105	.100	.099	.094	.102	.0048	+2	
(7) Post Vibration	.125	.105	.094	.102	.089	.104	.104	.099	.101	.097	.102	.0095	+2	No
Electrical Safety														Yes

M = Mean
S.D. = Standard Deviation
S.E. = Systematic Error (%)

TABLE 5. Smith and Wesson Breathalyzer model 1000 S/N 0782622.
Furnished by Metropolitan Police Department, District of Columbia.

Test	Test Data													Meet
(1&2)Precision/Accuracy	1	2	3	4	5	6	7	8	9	10	M	S.D.	S.E.	Requirement
at 0.05 BAC	.070	.049	.052	.055	.051	.052	.052	.049	.050	.053	.053	.0061	+6.0	
at 0.10 BAC	.107	.104	.101	.105	.104	.102	.107	.103	.103	.103	.104	.0019	+4.0	No
at 0.15 BAC	.166	.157	.147	.157	.152	.155	.155	.155	.151	.155	.155	.0049	+3.0	
(3) Alcohol Free Subjects	.001	.000	.001	.000	.000	.000	.000	.000	.000	.000	.000			Yes
(5) Power Line Voltage														
at 108 VAC	.099	.100	.098	.099	.102	.098	.101	.091	.099	.096	.098	.0031	-2.0	Yes
at 123 VAC	.101	.099	.099	.100	.096	.098	.098	.095	.103	.102	.099	.0025	-1.0	
(6) Ambient Temperature														
at 20°C	.097	.094	.084	.092	.087	.079	.097	.094	.107	.091	.092	.0078	-8	No
at 30°C	.112	.111	.106	.104	.101	.100	.099	.101	.099	.096	.103	.0053	+3	
(7) Post Vibration	.133	.105	.105	.100	.106	.104	.103	.100	.104	.099	.106	.0098	+6	No
Electrical Safety														Yes

M = Mean
S.D. = Standard Deviation
S.E. = Systematic Error (%)

TABLE 6. Smith and Wesson Breathalyzer model 1000 S/N 02751.
Furnished by Colorado Department of Health.

Test	Test Data													Meets
(1&2)Precision/Accuracy	1	2	3	4	5	6	7	8	9	10	M	S.D.	S.E.	Requirements
at 0.05 BAC	.054	.047	.054	.043	.051	.044	.044	.042	.042	.043	.046	.00484	-8	
at 0.10 BAC	.090	.090	.094	.093	.094	.093	.094	.096	.097	.097	.094	.00249	-6	No
at 0.15 BAC	.138	.139	.137	.136	.139	.137	.137	.138	.139	.138	.138	.00103	-8	
(3) Alcohol Free Subjects	.001	.000	.000	.001	.000	.000	.000	.000	.000	.000	.000			Yes
(5) Power Line Voltage														
at 108 VAC	.097	.096	.096	.095	.101	.096	.098	.097	.096	.096	.097	.00159	-3	Yes
at 123 VAC	.097	.095	.093	.097	.095	.094	.098	.096	.095	.096	.096	.00151	-4	
(6) Ambient Temperature														
at 20°C	.093	.093	.106	.095	.093	.094	.095	.095	.094	.096	.095	.00386	-5	Yes
at 30°C	.099	.098	.097	.096	.098	.098	.097	.096	.095	.094	.097	.00155	-3	
(7) Post Vibration	.099	.095	.096	.095	.098	.096	.095	.094	.097	.096	.096	.00152	-4	Yes
Electrical Safety														Yes

M = Mean
S.D. = Standard Deviation
S.E. = Systematic Error (%)

APPENDIX A

MARYLAND PRECISION/ACCURACY DATA

SERIAL #	MEAN VALUES 0.050%	0.100%	0.150%	STANDARD DEVIATION 0.050%	0.100%	0.150%	AVG SD	EXCESSIVE DEV.* at 0.100%	MECHANICAL PROBLEMS	INSTRUMENT ACCEPTABLE(A)/ UNACCEPTAI
)972374	0.049%	0.100%	0.149%	0.0031	0.0035	0.0025	0.0030			A
)972375	0.051%	0.099%	0.151%	0.0025	0.0022	0.0023	0.0023			A
)972376	0.051%	0.097%	0.149%	0.0033	0.0037	0.0061	0.0043			A
)972381	0.049%	0.098%	0.143%	0.0011	0.0020	0.0027	0.0019			A
)972382	0.051%	0.099%	0.150%	0.0030	0.0030	0.0015	0.0025			A
)972383	0.050%	0.098%	0.150%	0.0022	0.0020	0.0029	0.0023			A
)9723844	0.049%	0.098%	0.148%	0.0017	0.0021	0.0049	0.0029			A
)972386	0.050%	0.099%	0.147%	0.0021	0.0008	0.0032	0.0020			A
)972387	0.048%	0.091%	0.145%	0.0069	0.0090	0.0024	0.0061	4		U
)972388	0.050%	0.097%	0.158%	0.0017	0.0026	0.0332	0.0125		printer, mode sequence	U
)972389	0.051%	0.102%	0.157%	0.0024	0.0033	0.0045	0.0034		printer	U
)972390	0.049%	0.100%	0.151%	0.0037	0.0047	0.0085	0.0056			U
)972391	0.048%	0.103%	0.146%	0.0013	0.0183	0.0162	0.0119			U
)972392	0.053%	0.106%	0.160%	0.0037	0.0044	0.0037	0.0039	3	printer	U
)972393	0.051%	0.103%	0.153%	0.0024	0.0026	0.0026	0.0025		printer	U
)972394	0.050%	0.101%	0.150%	0.0014	0.0013	0.0024	0.0017		printer, mode sequence	U
)972398	0.050%	0.099%	0.147%	0.0023	0.0027	0.0033	0.0027			A
)972399	0.051%	0.103%	0.158%	0.0018	0.0019	0.0015	0.0017			A
)972400	0.051%	0.100%	0.150%	0.0019	0.0032	0.0028	0.0026			A

*Excessive deviation at 0.100% - the number of tests performed which results were out the range of -0.010%, +0.009% on a 0.100% simulator

SERIAL #	MEAN VALUES 0.050%	0.100%	0.150%	STANDARD DEVIATION 0.050%	0.100%	0.150%	AVG SD	EXCESSIVE DEV. at 0.100%*	MECHANICAL PROBLEMS	INSTRUMENT ACCEPTAI UNACCI
0972401	0.050%	0.097%	0.147%	0.0037	0.0015	0.0029	0.0027			A
0972402	0.048%	0.098%	0.148%	0.0020	0.0019	0.0044	0.0029			A
0972404	0.049%	0.099%	0.150%	0.0018	0.0036	0.0028	0.0027			A
0972405	0.051%	0.098%	0.150%	0.0031	0.0051	0.0080	0.0054			U
0972407	0.049%	0.097%	0.153%	0.0037	0.0041	0.0059	0.0045			A
0972408	0.048%	0.099%	0.150%	0.0018	0.0029	0.0054	0.0033			A
0972409	0.052%	0.103%	0.152%	0.0021	0.0036	0.0025	0.0027			A
0972410	0.051%	0.098%	0.153%	0.0042	0.0048	0.0046	0.0045			A
0972411	0.050%	0.104%	0.153%	0.0018	0.0059	0.0055	0.0044	2	mode sequence	U
0972412	0.052%	0.104%	0.158%	0.0024	0.0036	0.0063	0.0041	1		A
0972413	0.048%	0.096%	0.142%	0.0015	0.0024	0.0025	0.0021		printer	U
0972414	0.054%	0.097%	0.148%	0.0052	0.0040	0.0047	0.0046			U
0972417	0.050%	0.100%	0.154%	0.0017	0.0037	0.0021	0.0025			A
0972418	0.050%	0.100%	0.153%	0.0026	0.0023	0.0018	0.0022			A
1072426	0.056%	0.106%	0.155%	0.0030	0.0036	0.0048	0.0038	2		U
1072427	0.051%	0.105%	0.153%	0.0028	0.0028	0.0056	0.0037	1		A
1072428	0.049%	0.101%	0.155%	0.0023	0.0013	0.0039	0.0025			A

*Excessive deviation at 0.100% - the number of tests performed which results were out of the range of -0.010%, +0.009% on a 0.100% simulator

	0.050%	0.100%	0.150%	0.050%	0.100%	0.150%	SD.	DEV. at 0.100%*	DEV. at 0.150%**	PROBLEMS	ACCEPTABLE(A)/ UNACCEPTABLE(U
0162026	0.054%	0.109%	0.164%	0.0048	0.0069	0.0085	0.0065	4	9		U
0972373	0.049%	0.101%	0.152%	0.0013	0.0023	0.0024	0.0020		1		A
0972378	0.050%	0.106%	0.158%	0.0022	0.0044	0.0081	0.0049	2	6		U
0972377	0.050%	0.102%	0.148%	0.0029	0.0023	0.0021	0.0024				A
0972379	0.051%	0.107%	0.157%	0.0024	0.0020	0.0026	0.0023	2	6	printer	U
0972385	0.051%	0.103%	0.153%	0.0025	0.0034	0.0045	0.0034	1	2		A
0972380	0.049%	0.102%	0.148%	0.0028	0.0056	0.0056	0.0046	1	4		U
0972395	0.051%	0.106%	0.155%	0.0040	0.0074	0.0035	0.0049	3	4	printer	U
0972396	0.051%	0.101%	0.156%	0.0032	0.0033	0.0067	0.0044		5		A
0972397	0.051%	0.101%	0.153%	0.0019	0.0013	0.0026	0.0019		1		A
0972456	0.051%	0.104%	0.151%	0.0016	0.0026	0.0056	0.0032		5	printer	U
1072433	0.051%	0.103%	0.161%	0.0020	0.0026	0.0064	0.0036		8		U
1072434	0.050%	0.100%	0.147%	0.0015	0.0021	0.0029	0.0021		2		A
1072435										mode sequence	U
1272441	0.048%	0.099%	0.150%	0.0023	0.0045	0.0040	0.0036	1	1		A
1272442	0.050%	0.102%	0.151%	0.0025	0.0020	0.0028	0.0024				A
1272443	0.048%	0.098%	0.150%	0.0031	0.0026	0.0032	0.0029		1		A
1272444	0.049%	0.100%	0.156%	0.0032	0.0017	0.0046	0.0031		5	ampoule cover does not fit properly	U
1272445	0.054%	0.099%	0.150%	0.0055	0.0017	0.0023	0.0031				A

*EXCESS. DEV. at 0.100% - the number of tests perfotmed which results were out of the range of -0.010%, +0.009% on a 0.100% simulator.

**EXCESS. DEV. at 0.150% - the number of tests performed which results were out of the range of -0.005%, +0.005% on a 0.150% simulator.

	0.050%	0.100%	0.150%	0.050%	0.100%	0.150%	SD	DEV. at 0.100%*	DEV. at 0.150% **	PROBLEMS	ACCEPTABLE(A) UNACCEPTABLE(
1272446	0.051%	0.100%	0.146%	0.0020	0.0039	0.0041	0.0033	1	6		A
1272447	0.051%	0.100%	0.149%	0.0020	0.0017	0.0032	0.0023				A
1272448	0.050%	0.098%	0.145%	0.0028	0.0028	0.0025	0.0027		5		A
1272449	0.049%	0.099%	0.152%	0.0019	0.0027	0.0045	0.0030		3		A
1272450	0.050%	0.105%	0.155%	0.0027	0.0045	0.0015	0.0029		4		A
1272451	0.049%	0.102%	0.157%	0.0030	0.0027	0.0058	0.0038		5		A
1272452	0.049%	0.103%	0.153%	0.0033	0.0037	0.0034	0.0034	1	2		A
1272453	0.051%	0.101%	0.147%	0.0034	0.0039	0.0056	0.0043		5		A
1272454	0.049%	0.101%	0.151%	0.0017	0.0013	0.0039	0.0023		2		A
1272455	0.049%	0.101%	0.149%	0.0014	0.0028	0.0015	0.0019				A
1272457	0.048%	0.098%	0.147%	0.0017	0.0017	0.0027	0.0020				A
1272458										mode sequence	U
1272459	0.053%	0.100%	0.157%	0.0036	0.0042	0.0047	0.0041		7		A
1272460	0.052%	0.099%	0.154%	0.0024	0.0041	0.0045	0.0036		3		A
1272461	0.051%	0.101%	0.154%	0.0040	0.0076	0.0072	0.0062	2	4		U
1272462	0.051%	0.097%	0.149%	0.0028	0.0017	0.0051	0.0032		3	shows three digits	U
1272463	0.053%	0.104%	0.153%	0.0020	0.0054	0.0015	0.0029	1	1		A
1272464	0.051%	0.103%	0.152%	0.0020	0.0057	0.0052	0.0043	1	1		A

*EXCESS. DEV. at 0.100% - the number of tests performed which results were out of the range of -0.010%, +0.009% on a 0.100% simulator..

**EXCESS. DEV. at 0.150% - the number of tests performed which results were out of the range of -0.005%, +0.005% on a 0.150% simulator.

	0.050%	0.100%	0.150%	0.050%	0.100%	0.150%	SD	EXCESS DEV. at 0.100%*	EXCESS DEV. at 0.150%**		ACCEPTABLE/ UNACCEPTABLE
*0972413										mode sequence	U
*0972414	0.051%	0.101%	0.151%	0.0021	0.0028	0.0023	0.0024		1		A
*0972456	0.049%	0.100%	0.150%	0.0020	0.0021	0.0030	0.0023				A
*1072426	0.048%	0.100%	0.156%	0.0027	0.0040	0.0062	0.0043		5		A
*1072433	0.053%	0.108%	0.158%	0.0027	0.0028	0.0072	0.0042	4	5	printer	U
*1272444	0.052%	0.103%	0.153%	0.0027	0.0038	0.0046	0.0037	1	3		A
*1272458	0.051%	0.101%	0.155%	0.0029	0.0035	0.0047	0.0037		4		A
*1272461	0.050%	0.105%	0.151%	0.0038	0.0086	0.0061	0.0061	3	3		U
*1272462	0.050%	0.099%	0.149%	0.0034	0.0039	0.0048	0.0040		3		A
*1272468	0.052%	0.101%	0.156%	0.0029	0.0027	0.0044	0.0033		5	printer	U
*1272469	0.053%	0.103%	0.157%	0.0041	0.0033	0.0041	0.0038	1	6	printer	U
*1272472	0.051%	0.100%	0.152%	0.0039	0.0033	0.0045	0.0039		2		A
1272484	0.051%	0.099%	0.147%	0.0029	0.0027	0.0088	0.0048		3	printer	U
1272485	0.049%	0.100%	0.151%	0.0030	0.0017	0.0039	0.0028		2	printer	U
1272486	0.050%	0.101%	0.155%	0.0030	0.0040	0.0071	0.0047	1	4		U
*1272477										mode sequence	U
0972412	0.051%	0.100%	0.157%	0.0017	0.0022	0.0044	0.0027		7		A
1072435	0.050%	0.100%	0.156%	0.0014	0.0022	0.0071	0.0035		6		A

*EXCESS DEV. at 0.100% - the number of tests performed which results were out of the range of -0.010%, +0.009% on a 0.100% simulator.

**EXCESS DEV. at 0.150% - the number of tests performed which results were out of the range of -0.005%, +0.005% on a 0.150% simulator.

* not MSP property

SERIAL #	MEAN VALUES			STANDARD DEVIATION			SYS SD	EXCESS DEV. at 0.100%*	EXCESS DEV. at 0.150%**	PROBLEMS	ACCEPTABLE(A) UNACCEPTABLE
	0.050%	0.100%	0.150%	0.050%	0.100%	0.150%					
+ 0462122	0.048%	0.096%	0.146%	0.0049	0.0050	0.0074	0.0057		4		U
+ 0672339	0.047%	0.093%	0.142%	0.0033	0.0019	0.0035	0.0029		8		U
+ 0962193	0.050%	0.101%	0.152%	0.0015	0.0016	0.0031	0.0020				A
*0972378	0.049%	0.104%	0.151%	0.0018	0.0026	0.0022	0.0022		1		A
*0972379	0.051%	0.102%	0.158%	0.0029	0.0030	0.0045	0.0034		7		A
*0972380	0.047%	0.097%	0.149%	0.0129	0.0044	0.0044	0.0072		1		U
*0972387	0.050%	0.101%	0.153%	0.0027	0.0044	0.0041	0.0037	1	2	mode sequence	U
*0972388	0.047%	0.099%	0.146%	0.0020	0.0062	0.0053	0.0045	1	4		A
*0972389	0.049%	0.096%	0.153%	0.0043	0.0036	0.0075	0.0051		4		U
*0972390	0.050%	0.100%	0.150%	0.0033	0.0026	0.0038	0.0032		1		A
*0972391	0.052%	0.099%	0.151%	0.0017	0.0016	0.0047	0.0026		1		A
*0972392	0.053%	0.102%	0.152%	0.0035	0.0034	0.0048	0.0039	1	2		A
*0972393	0.052%	0.104%	0.153%	0.0016	0.0034	0.0039	0.0029	1	3	printer	U
*0972394	0.050%	0.104%	0.154%	0.0033	0.0037	0.0044	0.0038	2	2		A
*0972395	0.051%	0.101%	0.156%	0.0035	0.0026	0.0034	0.0031		4	printer	U
*0972405	0.047%	0.097%	0.146%	0.0025	0.0016	0.0029	0.0023		4		A
*0972407	0.050%	0.103%	0.152%	0.0026	0.0066	0.0048	0.0046	2	2		U
*0972410	0.051%	0.102%	0.149%	0.0034	0.0025	0.0045	0.0034		1		A
*0972411	0.050%	0.097%	0.149%	0.0032	0.0023	0.0032	0.0029				A

*EXCESS DEV. at 0.100% - the number of tests performed which results were out of the range of -0.010%, +0.009% on a 0,100% simulator

**EXCESS DEV. at o.150% - the number of tests performed which results were out of the range of -0.005%, +0.005% on a 0.150% simulator.

+ not MSP property

								0.100% *	0.150%**		UNACCEPTABLE
1272465	0.052%	0.103%	0.153%	0.0039	0.0039	0.0029	0.0035	1	2		A
1272466	0.051%	0.103%	0.150%	0.0023	0.0064	0.0025	0.0037	1			A
1272467	0.052%	0.100%	0.151%	0.0022	0.0028	0.0023	0.0024				A
1272468	0.046%	0.093%	0.138%	0.0021	0.0009	0.0024	0.0018		10		U
1272469	0.050%	0.099%	0.154%	0.0034	0.0011	0.0058	0.0034		3	acid damage	U
1272470	0.050%	0.101%	0.151%	0.0020	0.0034	0.0045	0.0033		1		A
1272473	0.050%	0.098%	0.146%	0.0018	0.0014	0.0042	0.0024		5		A

*EXCESS. DEV. at 0.100% - the number of tests performed which results were out of the range of -0.010%, +0.009% on a 0.100% simulator.

**EXCESS. DEV. at 0.150% - the number of tests performed which results were out of the range of -0.005%, +0.005% on a 0.150% simulator.

APPENDIX

STANDARD FOR DEVICES TO MEASURE BREATH ALCOHOL

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

HIGHWAY SAFETY PROGRAMS

Standard for Devices to Measure Breath Alcohol

The purpose of this notice is to publish the details of a program for development of a qualified products list for use by the National Highway Traffic Safety Administration, and by State and local governments using Federal funds for purchasing evidential breath-testing equipment.

The Highway Safety Act of 1966 provides that each State shall have a highway safety program designed to reduce motor vehicle accidents and deaths, injuries and property damage resulting therefrom. The Secretary of Transportation is charged with the responsibility for developing uniform standards for highway safety programs, pursuant to section 402(a) of the Act, and for carrying out a research and demonstration program, pursuant to section 403 of the Act. From the outset of the program, development of a broadly-based alcohol countermeasures program has been a high priority. Highway Safety Program Standard No. 8 covers Alcohol in Relation to Highway Safety, and establishes requirements for the alcohol-related aspects of the State programs. The standard includes requirements for legislative actions (such as development of implied consent laws, and laws establishing presumptive levels of intoxication), as well as for development of breath testing and other law enforcement capabilities. The NHTSA has also conducted a vigorous research and demonstration effort to advance the available technology in this field.

In these efforts it has been clear that development and use of accurate testing devices is essential. All jurisdictions covered by the Act now have implied consent statutes. All but four have statutes establishing a 0.10 percent blood alcohol level or lower as a presumptive level of intoxication. Some States have also recently adopted statutes establishing a certain blood alcohol level as illegal "per se", for a person in control of a motor vehicle.

In addition to a requirement in Standard No. 8 for development of controls relating to breath-testing activities, Volume 8 of the Highway Safety Program Manual provides additional guidelines for assisting States in implementing programs. Section IV, paragraph 3 of the Manual deals with chemical tests for alcohol impairment. The requirements with respect to breath tests are further specified in subsection 3(c), "Analysis of Breath". This section provides certain specifications for the accuracy of breath-testing equipment to be used in the law enforcement process. With the rapidly advancing breath-sensing technology there has been a proliferation of new devices being offered on the market for use by police in enforcement programs. As a result of these developments there is a need for an extension of the requirements currently provided in Volume 8 of the Manual. Officials from State and local governments have requested guidance in making purchases: court developments have highlighted the importance of accuracy; and the continuing use of Federal funds for purchasing breath-testing equipment makes it important to ensure effective expenditure of the funds.

To meet this need a variety of standards are being developed by the National Bureau of Standards (NBS) for the NHTSA. The first of these standards covers evidential breath-testing devices. The development of this standard included a review of the current state of the art in breath-testing devices to develop a performance standard against which devices could be tested and a qualified products list developed. The effort began initially in the Committee on Alcohol and Drugs of the National Safety Council (NSC) and has been carried through by the NHTSA in close collaboration with the National Bureau of Standards. Since many manufacturers may wish to sell products to the NHTSA and State and local governments using Federal funds it was decided that a comment and assistance on the standards would be sought from manufacturers as well as from scientific and other technological experts. In December 1972, manufacturers were sent copies of the draft standard for review. The NBS mailed a draft of the standard, with a request for comments or suggestions, to 22 manufacturers, 52 State governors' representatives and highway safety coordinators (with a request that they forward an additional enclosed copy of the draft to their State official responsible for selecting or purchasing breath-testing equipment), and 21 other experts in the field, most of whom were members of the Executive Board of the Committee on Alcohol and Drugs, National Safety Council. Replies have been received from 12 manufacturers, 30 State officials, and 6 other experts. Comments were also received from an ad hoc review subcommittee of the National Safety Council Committee on Alcohol and Drugs.

Generally the letters approved of the draft, although most letters contained suggestions for change. Subjects most frequently mentioned were the system of units, the definition of blood alcohol equivalent (BAQ) and the specificity test using alcohol-free subjects.

As a result of these suggestions, the units for blood alcohol concentration were changed from mg/ml to the more familiar percent weight by volume (percent W/V) based upon grams of alcohol per 100 milliliters of blood. The definition of BAQ was eliminated. The name of the specificity test was changed to "Blank Reading" test. The scope of the standard was also changed to include mobile evidential breath testers.

Three letters suggested that the precision and accuracy tolerances were too tight and three others (including the Committee on Alcohol and Drugs) suggested that these tolerances were too loose. After restudying the data, NBS decided not to change these tolerances, which are based on a chi-square test at the 95-percent confidence level using data from 90 tests at NBS with three different breath testers at the three concentration levels.

Notice of the availability of the draft for review was also published in the Commerce Business Daily in December 1972.

The result of this review and deliberation is the standard testing procedure set forth below. Items meeting the standard will be included on a qualified products list that will be used to determine acceptability for purchase by the Federal Government in its efforts and for

purchase by the State and local governments with funds available pursuant to section 402(a) of the Act.

Qualification testing to these standards, of products submitted by manufacturers, will be conducted by the DOT Transportation Systems Center (TSC), 55 Broadway, Cambridge, Massachusetts 02142. The National Bureau of Standards will act as consultants to the Transportation Systems Center in the conduct of these tests. Tests will be conducted semiannually. Manufacturers wishing to submit devices for evaluation must apply for a test date to the Department Systems Center not later than 4 weeks after publication of this notice. Normally, at least 30 days will be required from the date of notification until the test can be scheduled. One week prior to the scheduled initiation of the testing program, the manufacturer will deliver two units of his equipment to TSC. In addition to the Operator's Manual and the Maintenance Manual normally supplied with the purchase of this equipment, the manufacturer shall deliver to TSC specifications and drawings which fully describe these units. Proprietary information will be respected.

The two units submitted must be a prototype model. One of the two units will be returned to the manufacturer at the end of the testing period. The United States will reserve the right to purchase the remaining device at its discretion. The manufacturer will have the right to check his units between the arrival in Cambridge and the start of the test, but will have no access to the units during the tests. Any malfunction of the device which results in failure to complete any of the tests satisfactorily will result in failure of the qualification program. If a device fails, it may be resubmitted for next testing series.

All testing is expected to be completed within 3 months of the date of publication of this notice. The test results will be transmitted to each manufacturer. On the basis of these results, the NHTSA will develop a qualified products list covering the evidential breath-testing equipment. It is expected that within 6 months of the publication of this notice an NHTSA Directive will be issued amending Volume 8 of the Highway Safety Program Manual to include the qualified products list as a funding criteria. Only devices appearing on this list will be purchased with Federal funds available under sections 402 (a) or 403 of the Act. However, units not on the list may be purchased by DOT or NBS for experimental or developmental testing.

Retesting of devices will be conducted under several circumstances. First, it is expected that annual periodic testing will be conducted using devices purchased on the open market. Second, the NHTSA intends to modify and improve these standards as new data and test procedures become available. It is intended, for example, to add to the standards another section defining means of checking for the capability of a device to collect deep lung air by the use of rebreathing techniques. It is also intended to increase the requirements for accuracy and precision if warranted by cost-effectiveness considerations. A requirement may be added for instruments to produce a permanent record of the test results. Comments and recommended revisions are invited from all interested parties. Suggestions should be addressed to the Associate Administrator, Traffic Safety Programs, National Highway Traffic Safety Administration, DOT, 400 7th Street, SW, Washington, D.C. 20590. Notification will be provided in the FEDERAL REGISTER of each such modification. The manufacturers whose equipment has already been tested to the standard will be notified to resubmit the equipment for testing to the new specification only.

Third, if at any time a manufacturer changes the design of a device currently on the NHTSA qualified products list, the manufacturer should submit the proposed changes to the DOT Transportation Systems Center for review. Based on this review, the NHTSA will decide whether the change will require retesting of the unit. Normally, such retesting will be accomplished at the next annual testing period. In special cases, however, the NHTSA may, at its option, permit an earlier retesting of the device.

Fourth, the DOT Transportation Systems Center will, on behalf of NHTSA, establish a Standards Compliance Information System (SCIS) for the purpose of eliciting information on the performance of devices listed on the NHTSA qualified products list. Reports will be solicited from State and local agencies on their acceptance testing. In addition, field performance data will be obtained from law enforcement agencies using the equipment. User reports will be elicited to assure that (1) devices continue to perform according to the NHTSA standard, and (2) experience in field use does not indicate an excessive breakdown rate or maintenance problems.

If information gathered through the SCIS indicates that an instrument on the qualified products list is not performing in accordance with the NHTSA standard, the Transportation Systems Center will initiate a special investigation. This study may include visits to users and additional tests of the device obtained from the open market. If this investigation indicates that the devices actually sold on the market are not meeting the NHTSA standard, then the manufacturer will be notified that the instrument may be dropped from the qualified products list. In this event the manufacturer shall have 30 days to reply.

Based on the DOT Transportation Systems Center investigation and the data presented in reply by the manufacturer, the NHTSA will make a determination as to whether the instrumentation should remain on the qualified products list. Devices dropped from the list may not be resubmitted for reconsideration for a period of 1 year. Upon resubmission, the manufacturer must submit a statement describing what has been done to overcome the problems which led to the dropping of the device in question from the list.

The primary objective of these standards is to ensure that Federal funds provided to the States under Section 402 of the Highway Safety Act are expended only for effective breath test equipment. A second objective of these standards is to assist the State and local communities by providing a centralized qualification test program for breath-testing devices designed to collect evidence in law enforcement programs. These standards are not intended to replace the current qualification programs required in certain States for this equipment or to directly regulate the manufacture of breath-testing equipment. However, some States may wish to make use of this program in addition to setting their own requirements. Finally, it is hoped that these standards can assist industrial organizations in producing breath test equipment by establishing a minimum national performance standard against which they can develop their designs.

Accordingly, the DOT performance standard for evidential breath testers to measure alcohol content shall be as set forth below.

(23 U.S.C. 402, 403.)

Issued on: October 30, 1973.

WILLARD Y. HOWELL,
Acting Associate Administrator, Traffic Safety Programs, National Highway Traffic Safety Administration.

EVIDENTIAL BREATH TESTERS FOR ALCOHOL CONTENT

1. *Purpose and Scope.* The purpose of this standard is to establish performance requirements and methods of test for evidential breath testers. Evidential breath testers (EBT) are instruments which measure the alcohol content of deep lung samples of breath with sufficient accuracy for evidential purposes. The standard as a whole is intended primarily for use in qualification testing of EBT.

2. *Classification.*

2.1 *Mobility.*

2.1.1 *Mobile evidential breath testers.* EBT which are designed to be transported to nonfixed operational sites in the field.

2.1.2 *Nonmobile evidential breath testers.* EBT which are designed for operation at a fixed location.

2.2 *Power source.*

2.2.1 *Battery powered evidential breath testers.* EBT which are powered by batteries.

2.2.2 *A.C. powered evidential breath testers.* EBT which are powered from the a.c. power lines.

3. *Definitions.*

3.1 *Alcohol.* Ethanol; ethyl alcohol.

3.2 *Blood alcohol concentration (BAC).* Blood alcohol concentration, expressed in percent weight by volume (percent w/v) based upon grams of alcohol per 100 milliliters of blood in accordance with the Uniform Vehicle Code[1]

[1] Copies of the Uniform Vehicle Code Supplement 1 1972 are available from the National Committee on Uniform Traffic Laws and Ordances, 955 North L'Enfant Plaza, SW., Washington, D.C. 20024.

§ 11-902.1(a) (Supplement 1, 1972). A BAC of 0.10 percent w/v is equivalent to 0.10 grams of alcohol per 100 milliliters of blood (0.10g/100ml or 1.0mg/ml).

Alcohol concentrations in either breath or in vapor mixtures are expressed in milligrams of alcohol per liter of vapor (mg/l). For convenience, an equivalent BAC will be given in percent w/v in parentheses. To convert a vapor concentration in units of mg/l to units of percent w/v, multiply by 0.21.

3.3 *Qualification tests.* Tests performed to check the compliance of a product with the requirements of a standard in advance of, and independent of, any specific procurement action.

3.4 *Standard deviation.* A common indication of precision among repeated measurements of a single quantity given by:

$$\text{Standard Deviation} = \sqrt{\frac{\text{Sum } (X-\bar{X})^2}{N-1}}$$

where:

N = the number of measurements,
X = the value of a single measurement, and
$\bar{X}$ = the mean of all X's.

An equivalent formula which is often more convenient for performing calculations is:

$$\text{Standard Deviation} = \sqrt{\frac{SS}{N-1}}$$

where $SS = \text{Sum of } X^2 - \frac{(\text{Sum of } X)^2}{N}$

3.5 *Systematic error.* The difference between the mean measured value and the known value, expressed as a percentage of the known value.

4. *Requirements.*

4.1 *Precision.* Evidential breath testers shall measure the alcohol content of vapor mixtures with an average standard deviation of no more than 0.02 mg/l (0.004 percent W/V) when tested in accordance with 5.1.

4.2 *Accuracy.* Evidential breath testers shall measure the alcohol content of vapor mixtures with a systematic error of no more than plus or minus 10 percent at an ethanol vapor concentration of 0.24 mg/l (0.050 percent W/V), and no more than plus or minus 5 percent at concentrations of 0.48 mg/l (0.10 percent W/V) and 0.72 mg/l (0.15 percent W/V), when tested in accordance with 5.2.

4.3 *Blank reading.* Evidential breath testers shall indicate an average instrument reading of no more than 0.048 mg/l (0.010 percent W/V) when breath from alcohol-free subjects is tested in accordance with 5.3.

4.4 *Breath sampling.* Since the breath/blood correlation will be poor if an improper breath sample is taken, the instrument reading shall be compared with direct measurements of capillary or venous whole blood samples, in accordance with 5.4, to test for deep-lung sampling performance.

NOTE.—The use of this test in the standard does not imply that direct blood measurements are necessarily the only possible means for checking the deep-lung sampling performance of the instrument. If an acceptable performance test which involves breath alcohol measurement alone is developed, revision of this standard will be considered.

4.4.1 The limits to bias in breath/blood correlation shall be zero and −0.020 percent W/V as determined by the value of $\hat{Y}$, the evidential breath tester reading corresponding to a BAC of 0.10 percent W/V on the breath/blood correlation line drawn in accordance with 5.4.13. That is, the value of $\hat{Y}$ shall be between 0.08 and 0.10 percent W/V.

4.4.2 At least seven of the eight breath-alcohol data points calculated in 5.4.10 shall not depart from the breath/blood correlation line by more than ±0.020 percent W/V. That is, at least seven of the eight breath-blood points plotted in accordance with 5.4.12 shall lie between the two lines drawn in accordance with 5.4.14 parallel to the breath/blood correlation line and passing through the points $\hat{Y}+0.020$ and $\hat{Y}-0.020$ percent W/V.

4.5 *Power.*

4.5.1 When a.c. powered evidential breath testers are operated at a.c. line voltages of 108 volts and 123 volts (rms) in accordance with 5.5, the systematic errors shall not exceed plus or minus 5 percent, and the standard deviations shall not exceed 0.02 mg/l (0.004 percent W/V).

4.5.2 Battery powered evidential breath testers shall have an indicator which warns when the accuracy and precision requirements (4.1 and 4.2), cannot be met because of battery condition.

4.5.3 The operator's manual supplied with battery powered evidential breath testers shall state the approximate number of breath tests which can be performed before battery replacement or recharging is necessary.

4.6 *Ambient conditions.*

4.6.1 Evidential breath testers shall meet the requirements of this standard when operated within the following ambient conditions.

(a) Temperature: 20°C (68°F) to 30°C (85°F).

(b) Pressure: 635 mm (25 in) to 787 mm (31 in) Hg.

(c) Relative Humidity: 10–90 percent.

4.6.2 When an evidential breath tester is designed for operation at temperatures outside the limits specified in 4.6.1.a, the instrument shall be tested in accordance with 5.6 at each of the specified limits outside the range 20°C to 30°C. The systematic errors shall not exceed plus or minus 5 percent and the standard deviations shall not exceed 0.02 mg/l (0.004 percent W/V).

4.6.3 If a temperature correction is required, this correction shall not exceed 20 percent of the uncorrected value.

4.7 *Vibration stability of mobile EBT.* Evidential breath testers shall measure the alcohol content of vapor mixtures with a systematic error of no more than plus or minus 5 percent and a standard deviation of no more than 0.02 mg/l (0.004 percent W/V) after they have been subjected to the vibration test in accordance with 5.7.

4.8 *Electrical safety.* Evidential breath testers shall meet the following requirements of the American National Standard Electrical Safety Requirements, ANSI C 39.5-1964:[3] 3.1, Shock Hazard; 3.1.1, Grounding; 3.4, Flammability; 4.1.1, Marking of Terminals; 4.1.3, Male Plugs; 4.2.1, Internal (Wiring and Cabling); and 4.4, Over-Current Protection.

4.9 *Operator's manual.* An operator's manual shall be supplied by the manufacturer or distributor with each evidential breath tester. This manual shall clearly state the instructions for operation and maintenance of the instrument, and shall include the following information.

(a) The ranges of temperature, atmospheric pressure and relative humidity within which the instrument is designed to be operated.

(b) Any temperature corrections to compensate for ambient temperatures outside the range given in 4.6.1.a.

5. *Test methods.* The ambient conditions of temperature, pressure, and humidity shall be within the ranges specified in 4.6.1 during the tests described in 5.1, 5.2, 5.3, 5.4, 5.5, and 5.7.

5.1 *Precision test using known ethanol vapor concentrations.*

5.1.1 Connect a device which supplies known concentrations of ethanol vapor to the evidential breath tester in accordance with the instructions in the operator's manual. The device and the ethanol mixture used therein shall meet the requirements of the standard for breath tester calibrating units.

5.1.2 Flush the sampling assembly of the instrument completely with the alcohol vapor sample as described in the operator's manual.

5.1.3 Using the evidential breath tester, measure each of the three known ethanol vapor concentrations listed below ten times:

(a) 0.24 mg/l (0.050 percent W/V).
(b) 0.48 mg/l (0.10 percent W/V).
(c) 0.72 mg/l (0.15 percent W/V).

5.1.4 For each of the three sets of ten measurements made in accordance with 5.1.3, calculate the standard deviation. (See sample calculation in appendix A.) Add the three standard deviations and divide by 3 to obtain the average standard deviation.

5.2 *Accuracy test using known ethanol vapor concentrations.* Use the test

[2] This conversion factor is based on a commonly used value recommended by the Committee on Alcohol and Drugs of the National Safety Council: that is, 2.1 liters of "deep lung" air at 34°C contains approximately the same quantity of ethanol as 1 ml of circulating pulmonary arterial blood. See, for example, R. N. Harger, R. B. Forney and R. S. Baker, "Estimation of the Level of Blood Alcohol from Analysis of Breath," Quarterly Journal of Studies on Alcohol, 17, 1–18 (1956).

[3] Copies of this ANSI publication may be obtained from the American National Standards Institute, Inc., 1430 Broadway, New York, New York 10018.

data obtained in accordance with 5.1 to calculate the systematic error at each of the three known vapor concentrations.

5.3 *Blank test using alcohol-free test subjects.*

5.3.1 Select five test subjects in generally good physical condition. The test subjects shall have consumed no alcoholic beverage during the 2-day period prior to testing and no more than the equivalent of 3 ounces of 100-proof liquor during the 4-day period prior to testing.

5.3.2 At least two of the five subjects selected shall be smokers and shall smoke at least once during the 2-hour period preceding the start of testing, but shall stop at least 20 minutes before the start of testing.

5.3.3 Take a breath sample from each test subject and obtain an instrument reading, allowing sufficient instrument recovery time (i.e., the time necessary to properly clear the evidential breath tester when following the operating instructions) between measurements.

5.3.4 Repeat 5.3.3 to obtain a total of ten measurements.

5.4 *Breath sampling test.*

5.4.1 Select eight test subjects in generally good physical condition.

5.4.2 The subjects' body temperatures measured orally shall be between 97.0° F and 99.5° F just prior to the start of testing.

5.4.3 Alcoholic beverages (mixed if desired with a non-alcoholic beverage) shall be consumed by the eight subjects over a period of 1 to 2 hours. A very light meal consisting of one sandwich and a non-alcoholic beverage shall be offered to the subjects before the start of the drinking period. Smoking shall be permitted if desired during the drinking period.

5.4.4 The eight subjects shall be divided into two groups of four. Each subject shall be given a different amount of alcoholic beverage to drink, to ensure that there is a distribution of BAC's within each group, and that Group I BAC's are within the range 0.04 to 10 percent W/V and Group II BAC's are within the range 0.1 to 0.2 percent W/V. Table 1 shall be used as a guide to calculate the consumption of alcoholic beverages necessary for a subject to reach a particular BAC. No constraints on body weight of subjects is implied in table 1. However, the listed amounts of liquor should be adjusted for light and heavy subjects.

TABLE 1

BAC, percent W/V	Amount of 100-proof liquor consumed	Body weight, pounds
a 05–a 07	3 ounces	175–180
a 10–a 12	4½ ounces	175–180
a 20–a 22	10 ounces	175–180

5.4.5 A waiting period preceding the taking of a breath sample from each subject in accordance with 5.4.7.1 shall begin when he has consumed all of the alcoholic beverage given him. The duration of this waiting period shall be at least 90 minutes if capillary blood samples are to be drawn, and 120 minutes if venous blood samples are to be drawn. During the waiting period the subjects shall not consume any alcoholic beverages. Those subjects who smoke may do so, but shall stop at least 20 minutes before the testing begins.

5.4.6 Blood samples, to be taken by a medically qualified person, shall be either venous blood from the cubital arm vein or capillary blood from the finger tip.

5.4.7 Instruct each subject individually as to the manner in which a breath specimen is to be delivered to the instrument under test, in accordance with the operator's manual. The test shall then proceed as follows.

5.4.7.1 Take the subject's breath sample and obtain the instrument reading.

5.4.7.2 Take a blood sample within 2 minutes after taking the breath sample.

5.4.7.3 Repeat 5.4.7.1 taking care that the breath testing instrument has had sufficient recovery time, but allowing no more than 6 minutes between the taking of the first and second breath samples.

The blood samples shall be analyzed within 72 hours after being taken, using a method of analysis which meets the requirements of 5.8. No less than two determinations of alcohol concentration shall be made on each blood sample.

5.4.8.1 A reference sample of known concentration of ethanol in whole blood in the range between 0.05 and 0.20 percent W/V shall be prepared by the analyzing laboratory, and five determinations of the reference sample ethanol concentration shall be made concurrently with the analysis of the blood samples.

5.4.8.2 The analysis of the reference sample and the blood samples shall be considered acceptable only if—

(a) The standard deviation of the five determinations of the reference sample concentration does not exceed 0.005 percent W/V; and

(b) The systematic error of the five determinations of the reference sample concentration does not exceed plus or minus 5 percent.

5.4.9 Calculate the average of the BAC measurements for each test subject. Let the letter X equal this average BAC, and use the subscripts 1 to 8 to designate the test subjects in ascending order of alcohol concentration (i.e., $X_1, X_2, \cdots, X_8$).

5.4.10 Calculate the averages of the duplicate instrument readings made in accordance with 5.4.7 for each test subject. Convert if necessary to the same units used in 5.4.9 (percent W/V) by means of the conversion factor 0.21 (see footnote 2). Designate each average instrument reading with the letter Y and the same subscript used to identify the subject in accordance with 5.4.9.

5.4.11 Compute the following averages, and designate them as indicated.[1]

(a) X_H, as the average of X_1, X_7 and X_8.

(b) X_L, as the average of X_1, X_2 and X_3.

(c) Y_H, as the average of Y_6, Y_7 and Y_8.

(d) Y_L, as the average of Y_1, Y_2 and Y_3.

(e) $\overline{X}$, as the average of all eight X values.

(f) $\overline{Y}$, as the average of all eight Y values.

5.4.12 Plot on graph paper the points corresponding to $(\overline{X}, \overline{Y})$, (X_H, Y_H), (X_L, Y_L) and the eight breath-blood points corresponding to (X_1, Y_1), (X_2, Y_2), $\cdots$ (X_8, Y_8) (see figure in appendix B).

5.4.13 Draw a straight line, referred to as the "breath, blood correlation line" through the point $(\overline{X}, \overline{Y})$ and parallel to a line (not drawn in the graph) joining the points (X_L, Y_L) and (X_H, Y_H).

5.4.14 Draw two lines parallel to the breath/blood correlation line and passing through the points $\hat{Y}+0.020$ and $\hat{Y}-0.020$% W/V.

5.5 *Power line voltage test.*

5.5.1 Apply line power to the a.c. powered EBT under test through a variable autotransformer having a nominal input voltage of 117 volts a.c. and an output adjustable between 0 and 130 volts, and having a current rating as required by the instrument under test. Any voltage regulating device used with the instrument shall be connected between the variable autotransformer and the instrument under test.

5.5.2 Monitor the autotransformer output voltage with an rms a.c. voltmeter having an accuracy of plus or minus 2 percent in the range of 105 to 125 volts.

5.5.3 Adjust the voltage of the EBT to 108 volts. After at least one-half hour, check the voltage and readjust if necessary. Then immediately measure a known ethanol vapor concentration of 0.48 mg/l (0.10% W/V) ten times as in the precision test (5.1).

5.5.4 Increase the voltage to 123 volts, and at least one-half hour later readjust the voltage if necessary and again measure a known ethanol vapor concentration of 0.48 mg/l (0.10% W/V) ten times.

5.5.5 Calculate the systematic errors and the standard deviations for each of the two sets of ten measurements (obtained with line voltages of 108 volts and 123 volts).

5.6 *Ambient temperature test.*

5.6.1 The test temperatures shall be constant and accurate within plus or minus 3°C throughout the duration of the testing period.

5.6.2 Allow at least 1 hour for the instrument to come to temperature equilibrium after each test temperature change.

5.6.3 Perform steps 5.1.1 and 5.1.2. Measure a known ethanol vapor concentration of 0.48 mg/l (0.10 percent W/V) ten times at each test temperature.

5.6.4 Calculate the average value of the ethanol vapor concentration measured at each test temperature. Apply any temperature corrections specified by the operator's manual to obtain the adjusted average values.

5.6.5 Using the adjusted average values, calculate the systematic error for each set of ten measurements. Also calculate the standard deviation for each set of ten measurements.

[1] See appendix B for a sample calculation. An additional example may be found on pages 6–27, paragraph 6–4.3.2 of NBS Handbook 91, "Experimental Statistics," available from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402.

5.7 *Vibration test for mobile EBT.*[1]

5.7.1 Subject the mobile EBT to vibrations of simple harmonic motion having an amplitude of 0.015 inches (total excursion 0.03 inches) applied initially at a frequency of 10 Hz and increased at a uniform rate of 30 Hz in 2½ minutes, then decreased at a uniform rate to 10 Hz in 2½ minutes.

5.7.2 Subject the unit to vibrations of simple harmonic motion having an amplitude of 0.0075 inches (total excursion 0.015 inches) applied initially at a frequency of 30 Hz and increased at a uniform rate to 60 Hz in 2½ minutes, then decreased at a uniform rate to 30 Hz in 2½ minutes.

5.7.3 Repeat 5.7.1 and 5.7.2 in each of three directions, namely in the directions parallel to both axes of the base and perpendicular to the plane of the base.

5.7.4 Perform steps 5.1.1 and 5.1.2. Measure a known ethanol vapor concentration of 0.48 mg/l (0.10 W/V) ten times, and calculate the systematic error and the standard deviation.

5.8 *Blood alcohol methodology test.* The analytical measurement system for the blood alcohol concentration determination shall be checked in the testing laboratory at least once prior to that laboratory performing the analysis required in 5.4.8.

5.8.1 The determination of the ethanol concentrations of the reference blood alcohol samples shall be performed by the same laboratory personnel who determine the ethanol concentrations of the test subject blood samples taken in accordance with 5.4. The analysis of the reference samples shall closely parallel the analysis of the test subject blood samples, especially with respect to laboratory conditions and analytical technique.

5.8.2 Prepare with an accuracy of plus or minus 1 percent, a blank (an alcohol-free blood sample), and three reference blood alcohol samples having ethanol concentrations within plus or minus 10 percent of 0.05, 0.100 and 0.200 percent W/V, by adding known quantities of ethanol to alcohol-free whole blood containing a suitable preservative.

5.8.3 Determine the ethanol concentrations of each of the three reference samples and the blank five times.

5.8.4 Compute the means, standard deviations, and systematic errors for each of the four sets of five determinations.

5.8.5 The method of analysis shall be considered acceptable if:

(a) The apparent ethanol concentration of the blank (alcohol-free blood) does not exceed 0.002 percent W/V.

(b) The average of the standard deviations from the analyses of the three reference samples does not exceed 0.005 percent W/V.

(c) The systematic error of the analysis of the 0.05 percent W/V reference sample does not exceed plus or minus 10 percent; and

(d) The systematic errors of the analyses of the 0.100 and 0.200 percent W/V reference samples do not exceed plus or minus 5 percent.

[1] This test was taken from EIA Standard RS-204-A (July 1972) which is available from Electronic Industries Association, Engineering Department, 2001 Eye Street NW., Washington, D.C. 20006.

APPENDIX A

SAMPLE CALCULATIONS OF PRECISION AND ACCURACY

The results of ten simple measurements made in accordance with 5.1 at three known ethanol vapor concentration levels are as follows:

Measurement	0.24 mg/l (0.050 percent W/V)	0.48 mg/l (0.10 percent W/V)	0.72 mg/l (0.15 percent W/V)
1	0.045	0.092	0.149
2	.046	.097	.151
3	.049	.101	.153
4	.050	.105	.156
5	.048	.093	.145
6	.051	.094	.147
7	.047	.095	.152
8	.050	.102	.147
9	.047	.093	.151
10	.046	.091	.152
Average	.047	.097	.149
S.D.	.0018	.0042	.0029
Average S.D.		.0030	
S.E.	−6.0	−3.0	−0.7

APPENDIX B

SAMPLE CALCULATIONS IN THE DEEP LUNG SAMPLING TEST

B.1 Breath and blood alcohol concentration measurements have been made for each of eight subjects in accordance with 5.4. The average of the BAC measurements for each subject is entered in the X column of Table 3. The average of the duplicate instrument readings for each subject is entered in column Y of Table 3.

TABLE 3

Blood X % W/V	*Breath* Y % W/V
X_1=0.0510	Y_1=0.0510
X_2=0.0640	Y_2=0.0648
X_3=0.0820	Y_3=0.0717
X_4=0.0890	Y_4=0.0899
X_5=0.1250	Y_5=0.1164
X_6=0.1500	Y_6=0.1294
X_7=0.1900	Y_7=0.1577
X_8=0.2030	Y_8=0.1647

B.2 The average values computed in accordance with 5.4.11 for the above data are

$\bar{X}_L$=0.06567% W/V $\bar{Y}_L$=0.06250% W/V

$\bar{X}_H$=0.18400% W/V, $\bar{Y}_H$=0.1506% W/V

$\bar{X}$=0.12025% W/V $\bar{Y}$=0.10570% W/V

B.3 The data points and breath/blood correlation line are entered in the sample graph (Figure 1) as required in 5.4.12 and 5.4.13.

B.4 The value of $\hat{Y}$, as defined in 4.4.1, is equal to 0.091% W/V.

B.5 All eight of the breath/blood points lie between the two lines drawn parallel to the breath/blood correlation line and through the points

$\hat{Y}+0.020$% W/V=0.111% W/V and

$\hat{Y}-0.020$% W/V=0.071% W/V.

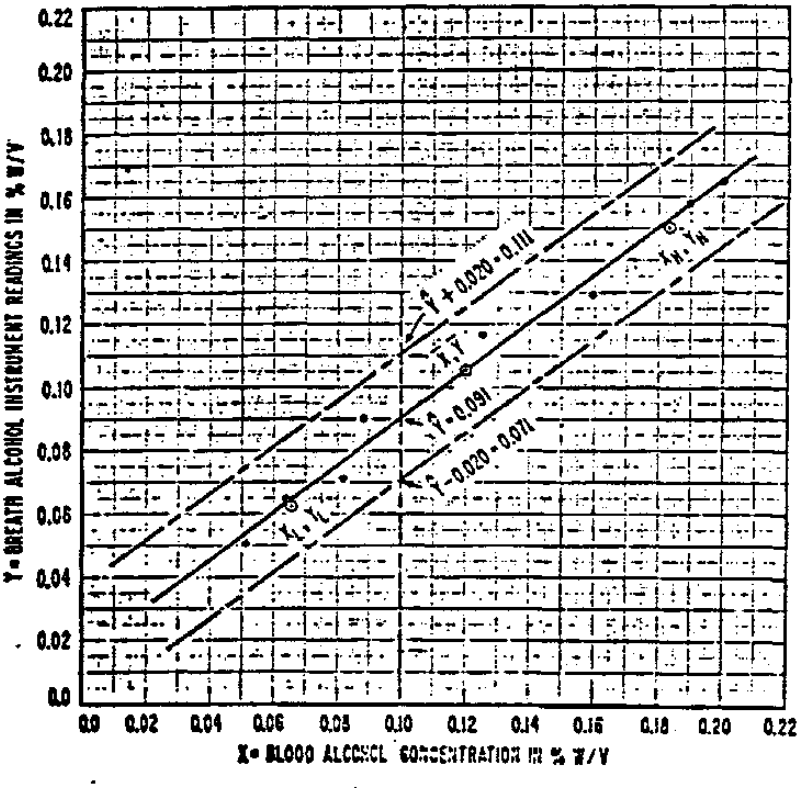
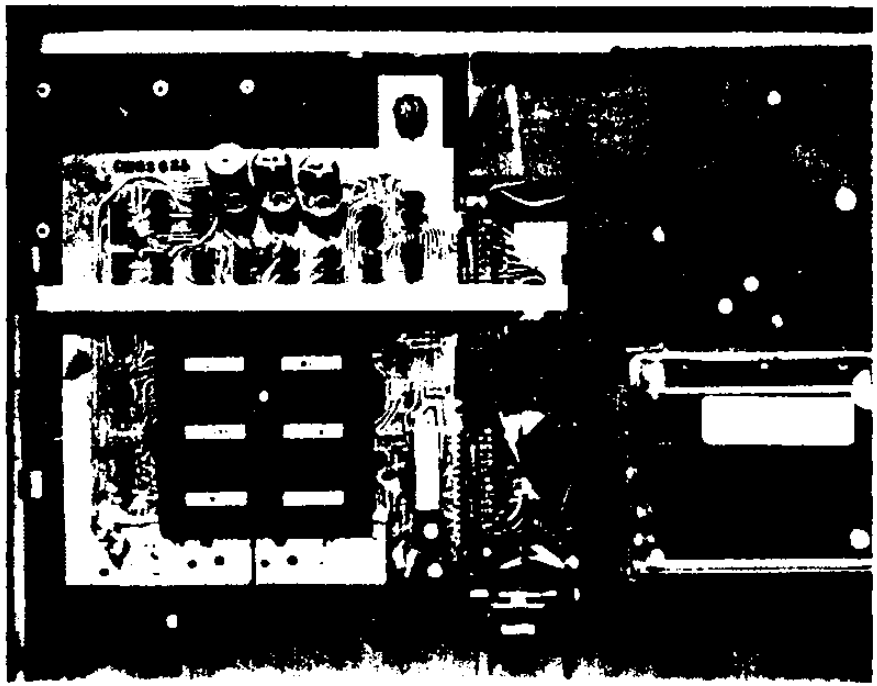


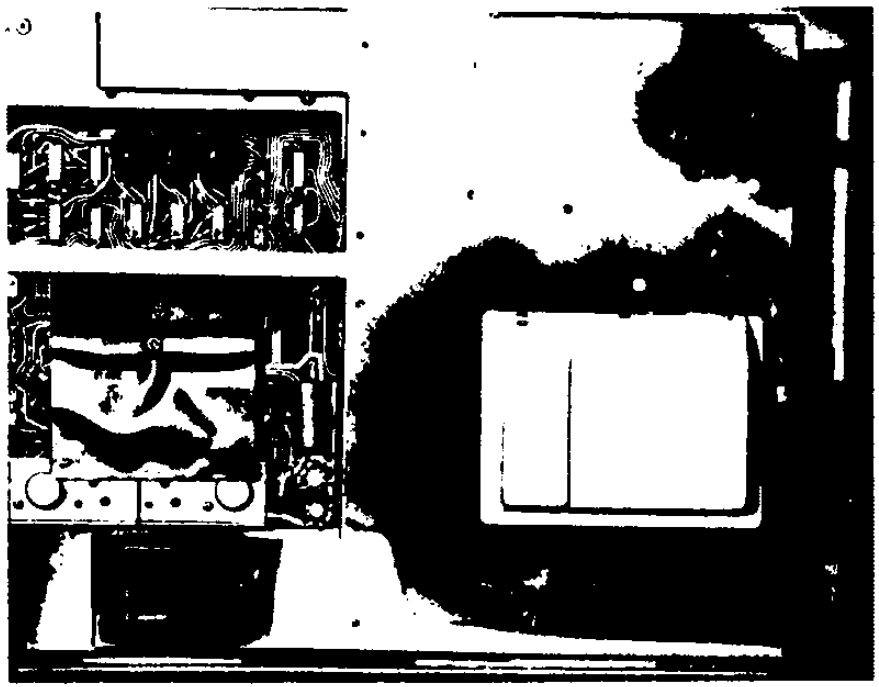
Figure 1 - Sample Data from Deep Lung Sampling Test

[FR Doc.73-23369 Filed 11-2-73;8:45 am]

NEW

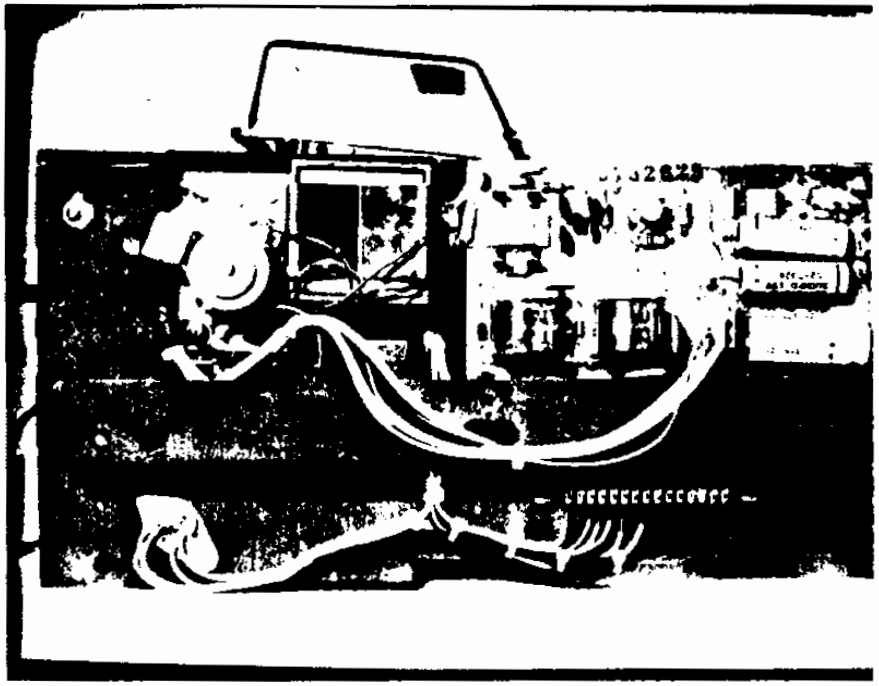
OLD





TOP VIEW SHOWING CONTROL BOARD AND AMPOUL COMPARTMENT COVER

NEW



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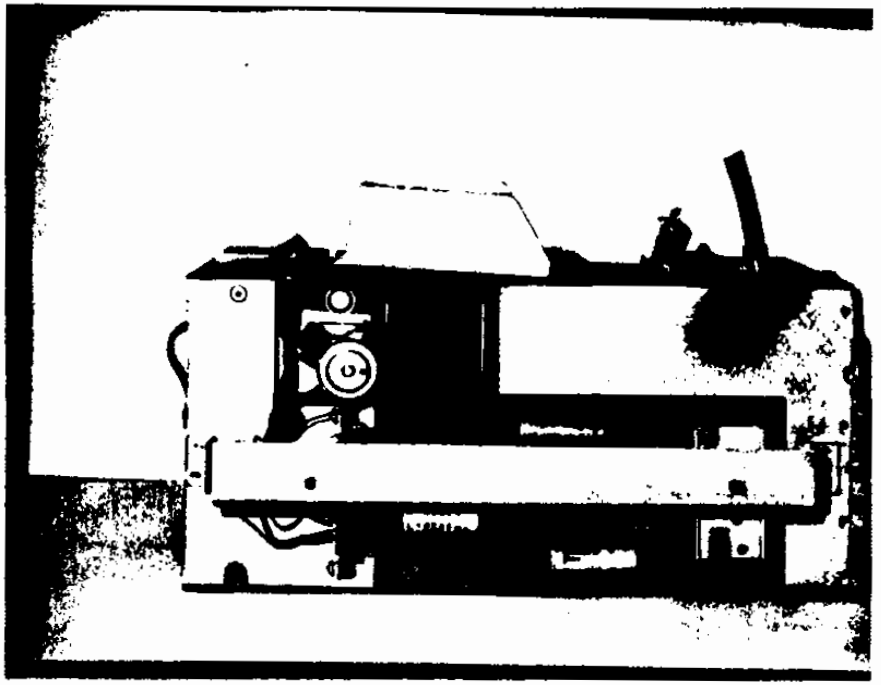
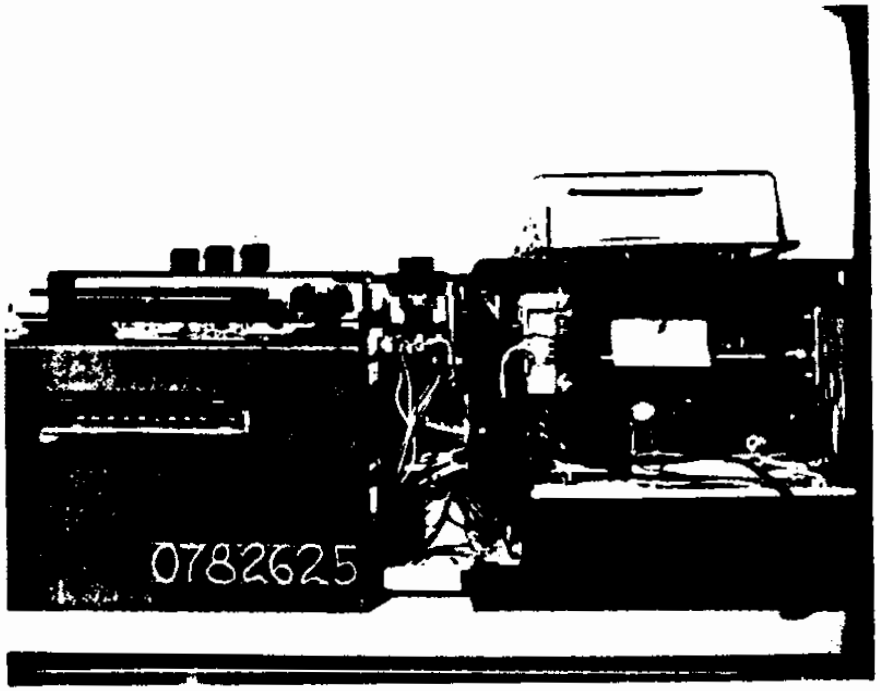
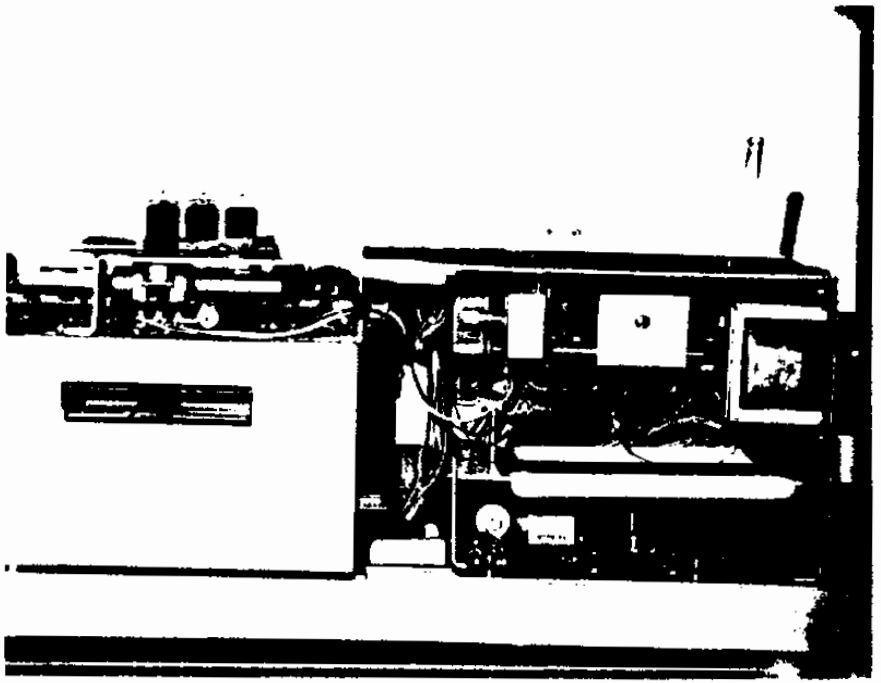


RIGHT SIDE VIEW SHOWING SERVO BOARD ASSEMBLY,
LIGHT CARRIAGE MOTOR AND PHOTO CELL HOUSING

NEW



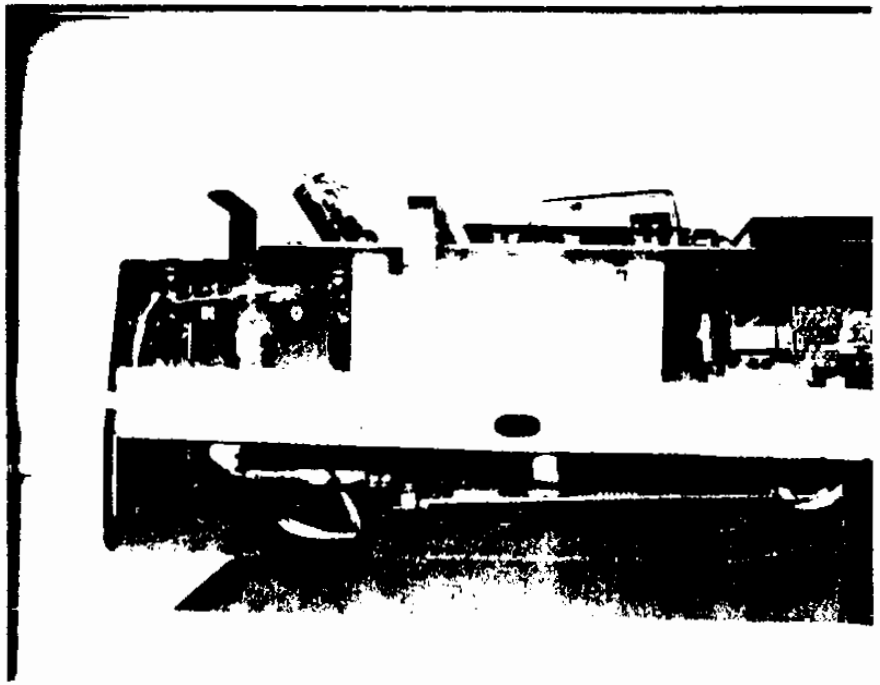
OLD

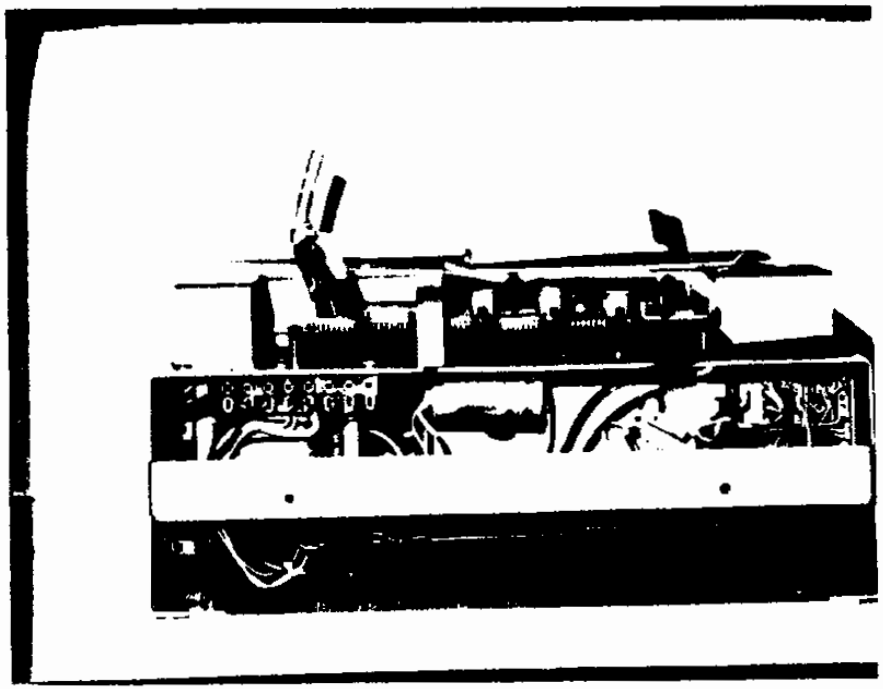


FRONT VIEW SHOWING LIGHT CARRIAGE ASSEMBLY
ON RIGHT AND PRINTER ON LEFT

NEW

OLD

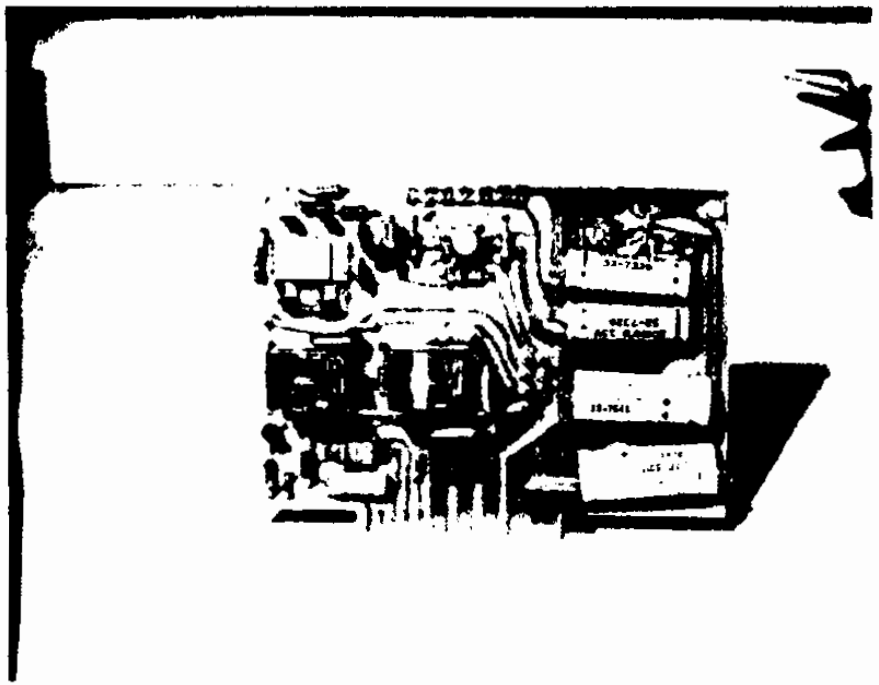


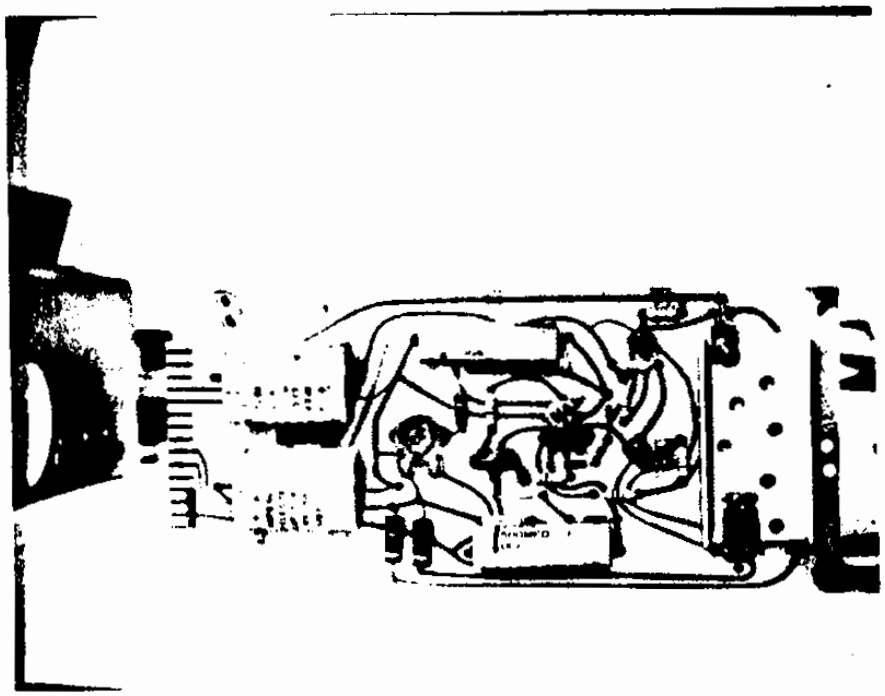


LEFT SIDE VIEW SHOWING EDGE OF PRINTER BOARD

NEW

OLD

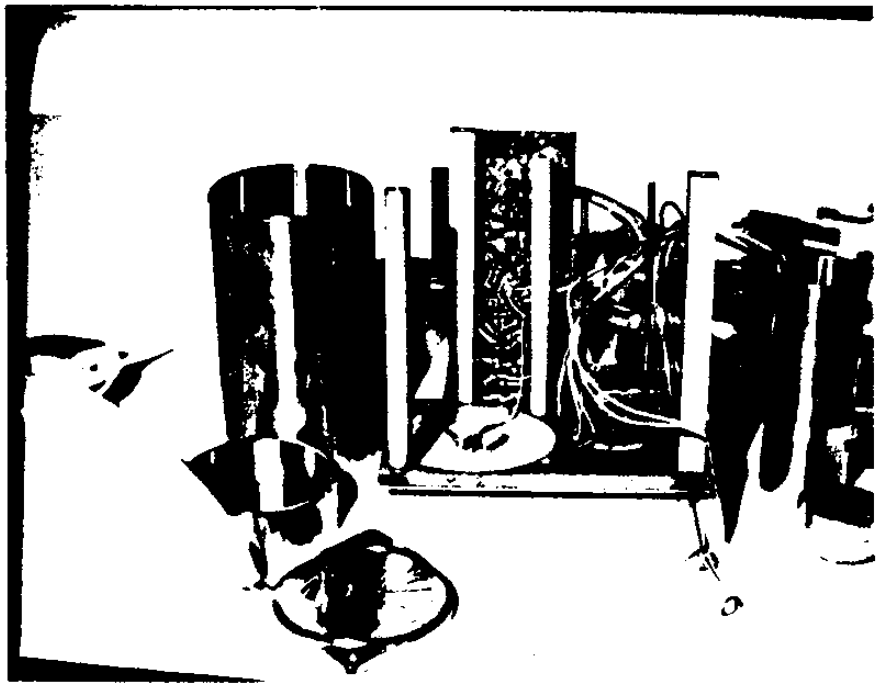


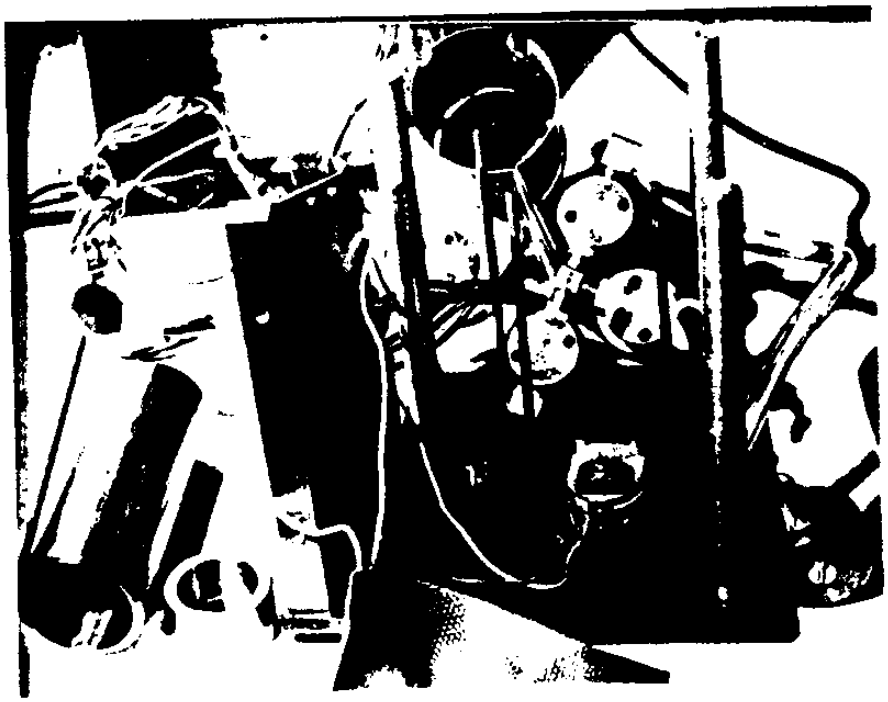


SERVO CONTROL BOARD

NEW

OLD

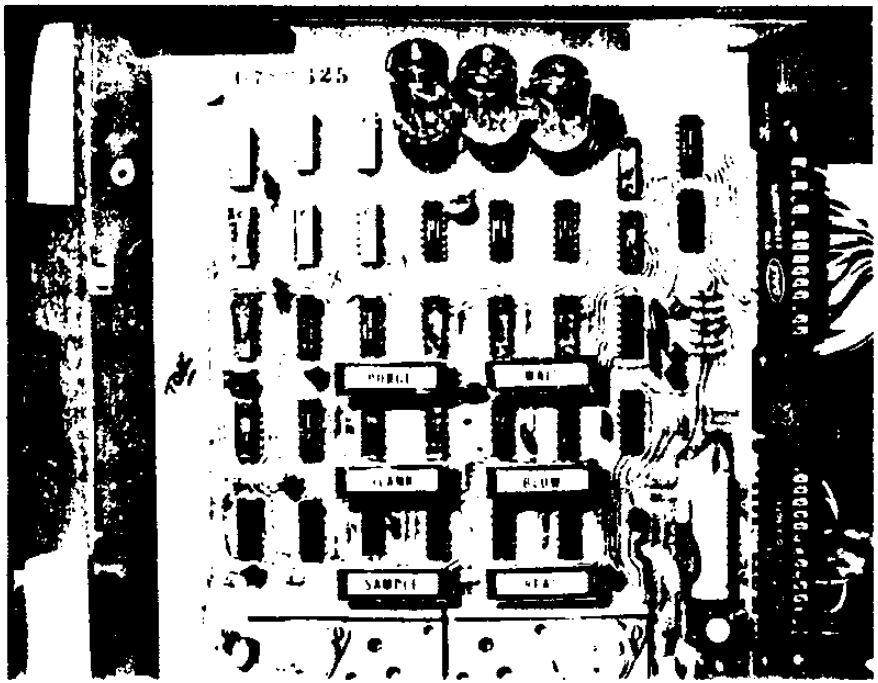


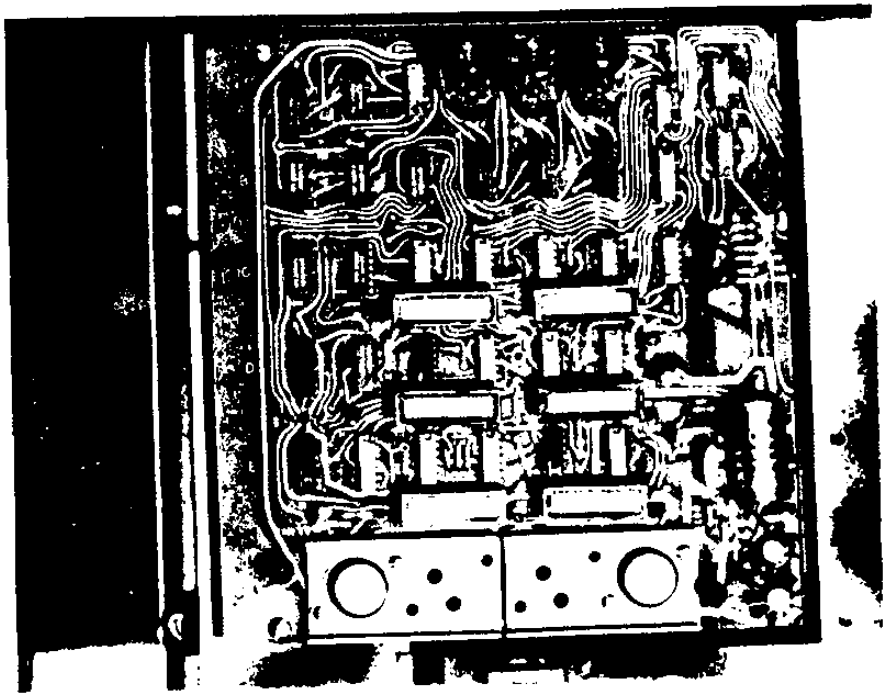


BREATH CYLINDER ASSEMBLY (DISASSEMBLED VIEW)

NEW

OLD





CONTROL BOARD ASSEMBLY

APPENDIX B

QUALITY ASSURANCE REVIEW OF FACTORY AND MANUFACTURING PROCESS SMITH AND WESSON BREATHALYZER FACTORY

Quality Assurance Review of Factory and Manufacturing Process

Smith and Wesson Breathalyzer Factory

Fred Seekell/DTS-722

April 6, 1979

In general, Breathalyzer's plant at Pittsburgh appeared quiet, very orderly and showed very good housekeeping.

Organization charts to the contrary, there seemed to be no one person whose day-long concern was product quality. This responsibility is presently identified among product line managers and engineers or test personnel.

The Receiving area was neat and secure (wire cage). It was stocked to the point of seeming to need expansion. Stock was marked only as to part number; vendors were not identifiable, unless by trademark. Some parts rejected from production had red tags indicating the kind of defect. Disposition was "return to vendor." One lot of switches was rejected by the Receiving Clerk for defective epoxy sealing of the leads. A substantial quantity of component drawings were in the area and in control of the Receiver.

In-process assembly was in a bright and pleasant area. Operators were performing assembly of simple and complex sub-units and harnesses. Most work-in-process was done in stages; when one stage (or subassembly) was finished for an order, fixtures were changed and the group worked on the next higher level. Interim testing was done as necessary by production personnel; any needed rework was also done in this area. Some subassemblies were waiting to be corrected. Most discomfiting was the general lack of evidence of status to be found with the parts (inspect, tested, other); they were not segregated to prevent confusion with acceptable units. Some printed circuit boards were marked with initials

to indicate completion and/or acceptance for the next operation. Pencil marks can provide paths of low leakage currents between sensitive components; some removable form of marking would be better.

In this area photocells were tested and put together in matched pairs when within a tolerable range. The remainder, tested (with readings) and untested, were put back (boxed) on the same shelves as the mated pairs. Evidence of their status was not outstanding, the test instrument was without standard or evident calibration. Some scopes had calibration stickers on them.

The Final test area for built-up printed circuit boards had a number of customized test kits which exercised the various functions of units for which they were designed. The test kits had no standards to indicate when they were not operating properly. Instruments returned for factory service were also tested here.

In a laboratory area used for engineering tests and evaluations, a number of well marked defective units were waiting disposition. A graduated hole gage used to sort calibration wheels by increments of .005" was observed. Were this gage to become damaged or worn, there is no systematic procedure to detect this change.

Master drawings were kept in a central file under the care of the Chief Engineer/Production Manager (Vince Martin). There was said to be very little drawings activity (changes, print issue, etc.), indeed there were few drawings or specs. to be seen anywhere in the plant except at Receiving. There was no evidence of change activity since

1974. There may have been activity which was simply not pointed out. It was stated there are "almost" no changes which would require a model number change or "qualification" testing.

Conclusions:

1) The writer fully appreciates the financial and productivity constraints that a small firm must work under; yet the Quality Assurance responsibility is diffused and viewed as having been "everybody's job" at this Smith and Wesson division.

2) Elements of the production process which are now areas of concern and which would pay back the cost of a more disciplined approach are:

   a) Product identity and status: There are many places in the manufacturing sequence where one is unsure of the product having been inspected or tested, whether it is finished, waiting rework, or which vendor made the part.

   b) Standards and calibration: Several test and inspection measurements could drift or change and go undetected for some time.

   c) Inspections/tests: Where these activities are already being done, methods, characteristics and criteria can change due to the spaced occasions when they are activated.

   d) Failure feedback: Information from several sources (field failures, shipping damage, production defect problems) can easily be viewed as only a present problem and not anticipated (methodically) as a potential future problem.

Recommendations:

Reasonable means of control for these elements might all be obtained under a "junior quality engineer" or "chief inspector" working for the plant manager or plant engineer. His output should be "low key" and worked into existing operations and functions.

a) Identification by way of marked shelves, dedicated or prominently colored or labeled containers could help resolve concern in the assembly or test areas, especially photocells. Some identity mechanism should clearly show status (inspected, tested, unfinished, to be reworked, source, etc.) and product line.

b) Test and measuring equipment should definitely have special, stable and protected units to use as standards or, better, calibrated devices or instruments which can be checked periodically against national standards. These should be supported by procedures for their use and for defining allowable intervals between rechecks to anticipate possible expected changes.

c) Inspection "specifications" should be written for whatever product has experienced quality problems and which have hampered production or compromised outgoing products. These should be brief, simple sketches as needed, and they should identify the characteristics to inspect or test. They should be reviewed at Receiving as a product is received or in-process when production begins or is to be tested. These are especially useful with new products (like the anticipated printers).

d) Failure information from field or factory problems can be routed and corrected so as to prevent or minimize reoccurrence. A procedure should be coordinated with Sales and Field Service for reporting customer problems and in-service failures--including recording of circumstances/conditions of failure, results of examining equipment, failure analysis, etc. Findings and recommendations of failures must be factored into inspection and test procedures, product improvements, vendor actions, calibration, design reviews, inventory decisions and drawings or specification changes.

APPENDIX C

DATA FORMS

NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION

Breath Alcohol Tester Field Survey

Instrument Tested _____ Ser.# _____ Date _____

Agency _____ Contact _____

_____ Title _____

_____ Factory Rep. _____

_____ Address _____

_____

Director of Breath Testing _____ Tel. # _____

Sample Chamber Output _____ Cycle Thru All Modes? _____

Light Alignment _____ Wait Light Goes Out at _____

Sample Chamber Temp. _____ Sample Delivery Time _____

.050 BAC			.100 BAC			.150 BAC		
Sim _____			Sim _____			Sim _____		
Amp	Sim Temp	Reading	Amp	Sim Temp	Reading	Amp	Sim Temp	Reading

DO NOT WRITE
IN THIS SPACE

Comments including general condition of instrument on reverse.

Signature _____

APPENDIX D

SITE VISIT REPORT

UNITED STATES GOVERNMENT

Memorandum

U.S. DEPARTMENT OF TRANSPORTATION
RESEARCH AND SPECIAL PROGRAMS DIRECTORATE
TRANSPORTATION SYSTEMS CENTER
KENDALL SQUARE
CAMBRIDGE, MA 02142

SUBJECT: Field Performance Test on Breathalyzer 1000

DATE:

FROM: Officer Floyd Wing
Metropolitan Police
Washington, D.C.

In reply refer to: NTS-14

TO: Arthur Flores
DOT/Transportation Systems Center

From August 1979 to November 1979 Sergeant Joseph Jacob and the undersigned were contracted to run a series of compliance tests on the Breathalyzer 1000 to determine if the those instruments in the field meet the standards originally established by U.S. Department of Transportation.

To compile this data a total of six (6) States were visited. They are as follows: Illinois, Ohio, West Virginia, North Carolina, Arkansas and Alleghency County, Pennsylvania.

In conducting this survey a total of thirty (30) instruments were tested. The manner in which these test were made is as follows; each instrument was physically inspected by checking for cleanliness, breath chamber volume, light alignment, cycle time, temperature control, sample chamber time, sample

TSC F 1325.4 (1/78)

delivery time, Numitron read outs and a visual inspection of components. Each instrument was then tested with a known alcohol in-air sample having equivaling blood alcohol concentrations of (W/V%) of 0.050, 0.100 and 0.150. Each concentration was administered five (5) times to each instrument when possible. It should be noted that these tests and or inspections, were affected after removing the housing of each instrument. The Alcohol solutions and three simulators were obtained from the DOT/Transportation Systems Center. Each simulator serial number and solution temperature was recorded.

The ampoules used in this survey were recorded by lot number, and each Ampoule gauged for content prior to using. Discrepancies in all tested instruments were noted with appropriate maintenance action taken.

(Each agency visited was requested to complete a questionnaire setting forth the following information: 1) Type of maintenance program utilized in their State or agency, 2) the frequency that their instruments are checked for accuracy; 3) if problems exist, who provides the maintenance services 4) length of the training both of operators and maintenance personnel; 5) recertification programs of personnel and equipment; 6) their opinion

of the Breathalyzer 1000 compared to other breath testing devices; 7) their opinion as to whether they are adequately informed of problems encountered and remedies and/or modifications to the instrument. Maintenance files were inspected when available. Both Sgt. Jacob and the undersigned corrected various problems when detected, and able to be corrected.

Of the thirty instruments tested: eleven (11) checked within DOT specifications, one (1) had a bad printer and three (3) had minor correctable problem which were repaired after the first few tests. Six (6) had at least one (1) test out over .010 and nine (9) were within range or within .010. Six (6) instruments also had minor problems which attempts were made to correct either prior to or after the first few tests. Two (2) instruments were training instruments and not certified for use. Two (2) had major acid spills. One (1) had a wheat germ light out and one (1) had major board problems. The latter four were at stations for use. Of all instruments tested, five (5) were new insttuments not yet placed in service.

Most agencies visited calibrate their instruments with a simulator concentration of 0.100 (w/V%) and attempt to keep their breathalyzer readings in a close grouping under

0.100 for use in court.

A list of the problems found is as follows:

(A) Twenty four (24) of the instruments tested had been returned to the dealer and/or factory prior to being placed in service or shortly thereafter.

(B) Thirteen (13) had a major or minor acid spilled in the photo-meter areas (two (2) of which met DOT specifications during testing).

(C) Sixteen (16) instruments had problems with either the servo system and/or the photo-meter section, four (4) of which had loose half nuts and two (2) with sticking relays on the servo board.

(D) Three (3) instruments had faulty printers two (2) of there instruments were new from the factory and had not been placed in service yet.

(E) Six (6) instruments had no problems with the exception of a minor acid spill.

Each State's breathalyzer program varied. Ohio and North Carolina have a senior operator. The senior operator's responsibilities are to run monthly accuracy checks on the breathalyzer and to provide minor maintenance cleaning of the breath chamber etc. Arkansas has a senior operator who only provides accuracy checks to the instrument.

Alleghency county, Pennsylvania has a maintenance tech who provides these services monthly although this program does not exist throughout the State of Pennsylvania.

Illinois has a State inspector who provides accuracy checks and minor maintenance checks monthly.

West Virginia accuracy checks are not a standard procedure!

Ohio, West Virginia, Arkansas and North Carolina have a State inspector that provides accuracy and minor maintenance at random intervals.

All jurisdictions return their instruments to the dealer or to Smith and Wesson for major repairs.

It was the opinion of all agency's visited that there is a quality control problem with the Breathalyzer 1000 judging by the condition of new instruments purchased and instruments received back after repair. The majority of these problems being that the photo-meter, servo and printer fail to work properly.

Nine persons interviewed felt that they could not rely on the instrument when they had tests to be run. Most all agencies felt that the Breathalyzer 1000 needs a lot of attention to keep it in operating condition. Most feel a stronger and better understanding of the mechanics

of the instrument and more qualified maintenance personnel would help.

All agency's feet that they are not properly advised of various modifications to the instrument nor have a proper trouble shooting list.

All agency's feel that the time their instrument is down and returned to the dealer or factor for repair is a setback and is entirely too long.

It is the opinion of both Sergeant Joseph Jacob and the undersigned that:

1. The major problem from the reporting jurisdictions is one of quality control.
2. Qualified maintenance personnel are needed but are not available.
3. Lack of proper and frequent test both for accuracy and mechanical condition.
4. Inadequate repair facilitys and/or equipment to provide repairs.
5. The majority of the problems found with the Breathalyzer where to the photo-metric system and servo system. It is flet by both Sergeant Jacobs and the undersigned that a more simplified system should be devised.

Another serious problem seen was that of acid spills. The avoidance of the spilling of acid is the responsibility of the operator. It is felt that an alarm system could be installed to minimize the spilling of the acid.

It is also felt that a uniform program be set up to inform all agencies of what is happening in the breath test world and to discuss various problems and corrections of these problems.

Sgt. Jacob and the undersigned feel that these surveys have been both beneficial in advancing their knowledge of the alcohol programs in other States and the maintenance programs utilized by other jurisdictions.

We hope and feel that the information compiled will both benefit Smith and Wesson and the U.S. Department of Transportation in various problems related to the Breathalyzer 1000.

The State of Compliance of the Smith and Wesson Breathalyzer Model 1000

A Follow-Up Report

A. L. Flores

Transportation Systems Center

September 1983

Prepared for

U. S. Department of Transportation

National Highway Traffic Safety Administration

Office of Alcohol Countermeasures

Washington, DC 20590

1.0 Introduction

The Smith and Wesson Breathalyzer model 1000 breath alcohol tester was placed on the National Highway Traffic Safety Administration (NHTSA) Qualified Products List for evidential breath testers (EBT) in 1975. This action followed evaluation of that device by Transportation Systems Center (TSC) under the existing NHTSA EBT Standard [1]. In addition to specifying minimum performance requirements for precision and accuracy under several operating conditions, the Standard provides for the re-evaluation of listed EBT's on the basis of unsatisfactory performance in field use.

Following reports of unsatisfactory performance from several police agencies, and at the request of NHTSA, TSC conducted an investigation into the state of compliance of the Breathalyzer model 1000 device. A report was submitted to NHTSA in February 1980 (appended). This report below is the result of a follow-up investigation on this device.

2.0 Summary of Previous Findings and Recommendations

The report submitted in February 1980 presented data from a number of police agencies as well as laboratory data. Two hundred and six Breathalyzers model 1000 comprised the basis from which performance data and malfunction information were obtained from Maryland, Pennsylvania, North Carolina, Ohio, Illinois, Arkansas, West Virginia and the District of Columbia. In addition, laboratory tests were performed on seven new, unused devices obtained from several police sources and from the manufacturer. A quality control inspection was made at the manufacturing plant.

Failure to meet minimum performance standards for precision and accuracy were found for 42 of 125 devices specifically tested for precision and accuracy which represents a 34% failure rate. In addition, malfunction rates encountered were judged high enough to impair the effective use of the device.

3.0 Present Findings

The data of this follow-up investigation were collected by Officer Floyd Wing, Traffic Enforcement Branch, Metropolitan Police Department, Washington, D.C. Officer Wing is an expert in the design, maintenance, and use of the Breathalyzer model 1000 device. Site visits were made to device stations in Pennsylvania and Arkansas during May and October 1982 and May 1983. Sixteen devices were tested for precision and accuracy. Test results are shown in Table 1. The performance criteria used to determine pass or fail are the same as that of the NHTSA Standard, i.e.: for accuracy systematic error must be within $\pm$ 10% at 0.050 BAC, and within $\pm$ 5% at 0.100 and 0.150 BAC; for precision the average standard deviation must not be greater than 0.004 BAC. Using these criteria, 11 of the devices, or 69%, failed to meet one or more of the performance criteria including two devices which were borderline failures. In addition to these specific test failures, 3 of the devices required servicing before the tests could be performed. However, two of these three were used only for operator training.

In addition to the performance test summary, the table lists additional information useful to assessing the effectiveness of the device such as: number of tests performed per year, total number of break downs and total down time. Unfortunately, this information was largely not available or unknown at the time of the site visits. The non-availability of this information is significant since one feature of an adequate maintenance program would seem to be documentation of such information in order that program effectiveness can be monitored.

4.0 Conclusion and Recommendations

The conclusion of the February 1980 report was that a substantial fraction of the Breathalyzers model 1000 then in use failed to be in compliance with the NHTSA Standard. It was pointed out that while the underlying principle on which the instrument is based is straight forward, the actual design of it is complex; a fact which may contribute to the problem seen. It was recommended that use of the device be supported by a maintenance effort sufficient to overcome these performance problems. It was pointed out then that the device is an effective evidential breath tester when operating properly. It was also recommended that the manufacturers improve the state of quality control at the factory for both manufacturing and repair operations and to consider design simplification in order to improve performance and reduce the frequency of malfunction. It was finally recommended that the device be removed from the Qualified Products List.

The findings of the present report do not indicate a change in the state of compliance of this device. Therefore, the recommendations of the present report are basically unchanged.

The only significant change in the previous situation is that, as of January 1, 1983, Smith and Wesson has stopped production of this device. Thus, there would no longer be any purpose to de-listing the device since the original intent of the Qualified Products List (making available NHTSA funds to the states only for devices which meet minimum performance standards) is met by removal of the device from the market by Smith and Wesson.

Reference

1. Federal Register Vol. 38, No. 212, Nov. 5, 1973.

Table 1. Smith and Wesson Breathalyzer Model 1000.

1982-83 Compliance Survey Data

Instrument	Systematic Error at .05	.10	.15	Ave. Std. Dev.	Pass Fail	#Tests Per Year	# Break downs	Down Time	Note
1. 1272441RFI, Milton PA	-5	2	-13	.0187	F	-	unknown	1 yr	out for 1 yr. following RFI fit
2. 1240916 RFI Lower Paxton PA	2	1	-3	.0021	P	175	10-12	3 wk	
3. 0250955 Harrisburgh PA	-7	-5	-8	.0056	F	-	unknown	-	S, T
4. 0262039 RFI Columbia Boro PA	-2	0	-9	.0030	F	50	unknown	1 yr	S, R
5. 1072437 RFI Lewisburgh PA	3	-9	-9	.0101	F	50	unknown	unknown	R
6. 0462084 RFI Wilmore PA	-2	-4	-5	.0019	P	550	unknown	3-6 wks	
7. 0382542 RFI Johnstown PA	11	3	3	.0027	F*	-	16	-	
8. 2962 East Taylor PA	1	3	3	.0013	P	-	9	-	
9. 0372306 RFI Sesquehanna Twp PA	-1	-10	-1	.0033	F	150	10	-	
10. 0672319 RFI Pottsville PA	-1	-2	-2	.0017	P	-	unknown	-	G
11. 0872321 RFI Schuykill Haven PA	-1	-8	-1	.0048	F	-	unknown	-	
12. 0272284 RFI Pottsville PA	-12	-6	-7	.0037	F	100	8	-	G
13. 0362047 RFI Bryant AR	0	5	6	.0017	F*	-	5	-	G
14. 0520161 RFI Benton AR	14	20	9	.077	F	-	unknown	-	decertified
15. 0640686 Little Rock Ar	-22	-11	-7	.0057	F	-	unknown	-	S, T
16. 0362078 Little Rock Ar	-10	-5	-3	.0026	P	-	unknown	-	T

* - Borderline Failure
G - Good appearance of instrument and test area
S - Service required before instrument could be tested
R - RFI retrofit suspected as source of malfunction