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Gibb v. Dorius : Unknown

Utah Supreme Court

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BRIGHAM YOUNG UNIVERSITY
J. Reuben Clark Law School

STATE OF UTAH
DEPARTMENT OF SOCIAL SERVICES

STATE DIVISION OF HEALTH

RULES AND REGULATIONS

FOR APPROVAL TO PERFORM BLOOD ALCOHOL EXAMINATIONS

ADOPTED BY UTAH STATE BOARD OF HEALTH

December 30, 1969

Under Authority of 26-15-5(1) and 26-20-12, UCA 1953, as Amended

and

PERTINENT UTAH LAWS RELATING TO THE STATE DIVISION OF HEALTH LABORATORIES

CERTIFIED OFFICIAL COPY
UTAH STATE BOARD OF HEALTH


By 

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The purpose of these regulations is to provide standards for the approval of laboratories desiring to be approved to conduct examinations for the determination of blood alcohol levels. These regulations were developed with the assistance of the Standard 308 Ad Hoc Technical Advisory Committee for Blood Alcohol.

These rules and regulations have been endorsed also by the State Division of Health Advisory Committee for Laboratory Standards.

Trade names used in the appendix of these rules and regulations are for identification only, and do not represent an endorsement of these products by the Utah State Division of Health.

I. DEFINITIONS

- | | | |
|------------|---|--|
| Chemist | - | Any person conducting the blood alcohol determinations. |
| Director | - | The State Director of Health. |
| Division | - | The State Division of Health. |
| Laboratory | - | Any place in which examinations for the determination of blood alcohol level are performed. |
| Review | - | A visit to a laboratory, by an authorized representative of the director, for the purpose of carrying out these regulations. |
| Reviewer | - | An authorized representative of the director. |
| Supervisor | - | Any person responsible for the performance of blood alcohol determinations, who meets the personnel requirements of these rules and regulations. |

II. AUTHORIZATION AND ADMINISTRATION

A. State Director of Health - Authorization to Approve - Powers and Duties

The State Director of Health, under the powers and duties conferred upon him and the division by the Utah Code, annotated 1953, as amended 1955, 26-15-4 and 1967, 26-15-6 and 26-20-12, upon being assured that a laboratory wishing to become approved or to maintain approval status has satisfied the requirements for approval, as detailed below, shall approve such a laboratory to conduct examinations for the determination of blood alcohol levels.

B. Responsibilities - Utah State Division of Health

It shall be the responsibility of the division to assist any medical laboratory in the State which desires to obtain approval to conduct examinations for the determination of blood alcohol levels to gain and maintain such approval. Toward this end, the laboratory section of the division will offer training, laboratory reviews, procedure evaluation studies and reference materials to any laboratory requesting such services.

C. Requirements for Approval

Any laboratory desiring to be approved to provide blood alcohol determinations must have official approval of the Utah State Division of Health. Approval is conditional on meeting the herein specified minimum standards for personnel and facilities, as well as the herein specified minimum technical standards for the procedures used to examine specimens submitted to that laboratory for the presence or absence of alcohol in the blood.

The satisfactory achievement of these minimum standards shall be determined by an initial and, subsequently, not less than biennial review of the laboratory by an authorized representative of the Utah State Division of Health. The laboratory must also participate in any pertinent performance evaluation studies offered or authorized by the Division of Health.

Failure to meet the minimum requirements, as determined by review and/or performance evaluation, shall be sufficient grounds for withdrawal of approval until such time as the minimum standards can be met.

D. Initial Approval - Provisional Approval

A laboratory that has not had prior approval, but wishes to be considered for approval, must request in writing a review of its facilities. The purpose of the review will be to determine whether the laboratory and the affected personnel meet the minimum standards as established below. The reviewer shall report his findings to the director or to an advisory committee whom the director may designate to evaluate the report of the reviewer and recommend action to be taken. Provisional approval may be granted for thirty (30) days if conditions for meeting the standards appear to be met.

E. Full Approval - Period During Which Approval is Valid

After evaluation of the report of the reviewer, the director may grant approval to the laboratory for one calendar year, subject to annual renewal, providing such laboratory continues to perform satisfactorily and continues to meet minimum standards as determined by procedural evaluation and/or on site observations of both physical facilities and technical performance. (Each approved laboratory shall be visited by a reviewer at least once every two years except that, in the absence of proficiency testing specimens, an annual technical review shall be conducted.)

The approved laboratory shall notify the director in writing when changes of personnel occur and shall submit a curriculum vitae on new personnel performing duties in the chemistry-toxicology laboratory. This notification shall be submitted within ten (10) days of the status change.

F. Renewal of Approval - Maintenance of Approval Status

A laboratory wishing to maintain approval status must continue to meet the requirements for approval as listed above and as determined by a not less than biennial review and satisfactory performance in a proficiency testing program offered by or approved by the division.

G. Revocation of Approval

Approval of any laboratory will be revoked automatically and immediately if:

1. The laboratory changes to a method other than that for which it has been approved unless prior approval has been obtained from the division or
2. any person other than the person or persons approved to perform the testing is permitted to perform and report the results of blood alcohol determinations,
3. results of proficiency testing indicate a lack of ability to perform at satisfactory levels,
4. required minimum standards for performance of the examination(s) are not maintained.

H. Reinstatement of a Laboratory Disapproved

A laboratory that has lost approval because of a change in procedures or through the loss of approved personnel may have approval reinstated by:

1. Requesting a laboratory review during which processing of specimens and testing procedures will be observed by the reviewer,
2. providing all necessary information for the evaluating of credentials of new personnel assigned to the laboratory section in which blood alcohol determinations are made,

3. continuing to participate, satisfactorily, in the proficiency testing program.

A laboratory that has lost approval through an unacceptable performance in proficiency testing studies may request a review to determine and correct the reason(s) for unacceptable performance. Within ten (10) days of completion of this review, the reviewer shall submit his report to the director.

Formal notice of action to be taken to correct deficiencies may be submitted by the laboratory to the director with a request for a new review any time after thirty (30) days from the date of the last review. Upon being assured that corrections leading to satisfactory and acceptable performance have been made, the director may reinstate approval based on compliance with the above rules and regulations.

1. Publishing Lists of Approved Laboratories - Reports - Reports Confidential

The State Division of Health shall publish or cause to be published at least annually a list of laboratories meeting the minimum standards established under these rules and regulations. Included on the list shall be the name and location of the laboratory, the name of the director, supervisor (if any) and the chemist(s) qualified to perform the examinations. This list shall be sent to all municipal, county, and state law enforcement agencies and laboratory directors in the State of Utah. The division may publish semi-annual amendments to the list in a newsletter, but must immediately notify all concerned parties of deletions from this list.

The division shall keep the director of any approved laboratory informed also of any discrepancies which might lead to revocation of approval and shall furnish each participating laboratory with an annual summary of any proficiency testing or evaluation studies. In such a report each participant will be referred to by code and every precaution will be taken at all times to obscure the identity of any participating laboratory or chemist.

III. MINIMUM STANDARDS - METHODS TO BE EMPLOYED

The following minimum standards shall serve as the basis for approval of a laboratory to conduct examinations for the determination of blood alcohol levels.

A. Personnel Qualifications

Minimum educational requirements for a person or persons performing chemical examinations for the determination of blood alcohol levels shall be a recognized Bachelor of Arts or Bachelor of Science degree or equivalent degree issued after a full course of resident instruction in one or more established and accredited institutions of higher education, with major work for such a degree in one or more fields of chemistry, as shown by a transcript of credits. Major work in the biological sciences may be accepted where related work experience has been acquired and providing that the earned degree includes a minimum of twenty-five (25) quarter hours of courses in chemistry. In addition to the baccalaureate degree or equivalent, the supervising chemist shall have demonstrated proficiency in blood alcohol determinations as gained by attendance at pertinent courses or the equivalent in practical clinical chemical laboratory training and experience.

Persons who have successfully completed a regular four years course in an established and accredited college or university, with major work leading to a degree in medical technology, providing such a course shall have included not less than twenty-five (25) quarter hours of chemistry, may also meet the minimum personnel requirements, providing subsequent training has been acquired in the field of clinical chemistry.

A person who is and who has been performing blood alcohol determinations for not less than two years at the time of the adoption of these standards, but who does not meet the above requirements, may also be qualified providing that, as determined by the Advisory Committee for Laboratory Standards, such person has completed not less than one year of pertinent education beyond the high school level, or has received training through an acceptable training program, providing such a person is shown to be competent to perform these examinations as demonstrated by an examination and satisfactory participation in a proficiency testing program offered or authorized by the Division of Health, and providing that such a person is employed under the full-time supervision of a person meeting the qualifications presented in the preceding paragraphs.

Registration by nationally recognized certifying boards may be accepted by the director, on recommendation of the Advisory Committee for Laboratory Standards, in lieu of the baccalaureate degree.

Technical personnel unable to meet these requirements may assist in the preparation and processing of specimens but may not be responsible for any of the definitive analyses.

B. Required and Recommended Minimum Standards for Laboratory Facilities

The facilities provided for blood alcohol determinations shall meet reasonable standards for the procedure selected. There shall be sufficient space to process and examine the specimens commensurate with the total work load of the laboratory. Facilities shall be clean, well lighted, properly ventilated and with adequate temperature control to meet the requirements for the test(s) performed by the laboratory. Adequate and proper storage facilities shall be available for the reagents used in the testing and shall be convenient to the area in which the tests are performed.

C. Laboratory Equipment and Supplies

All equipment, reagents, and glassware necessary for the satisfactory performance of blood alcohol determinations shall be on hand or readily available on the premises. Equipment shall be in good working order. Included in this equipment shall be all items specified for the procedure selected as recorded in techniques published in recognized professional publications. (See D below).

All the above shall be available for use of the laboratory and in keeping with the work load of the laboratory.

D. Minimum Technical Standards

A laboratory shall select, subject to the provisions of the concluding paragraph of this subsection (D), one of the following methods for approval to perform blood alcohol determinations on the basis of evaluation as to specificity for ethanol, sensitivity and reproducibility:

1. The gas chromatography method of Cadman and Johns (see appendix).
2. Enzymatic methods (see appendix).
 - a. Boehringer Mannheim
 - b. Sigma

Realizing that the standardization of methodology for blood alcohol determinations is a new concept, the Director may accept other methods, if published in professionally recognized journals and the methodology is included in a manual of procedures used by the laboratory. All other criteria for approval must be met also, including on-site review of technical performance to determine strict adherence to the method(s) chosen and continuing satisfactory performance in proficiency testing programs offered by the State Division of Health.

IV. APPENDIX

LEGAL BASIS FOR LABORATORY APPROVAL

26-15-4. State Department of Health - Powers and Duties. The state department of health shall have and exercise the following powers and duties in addition to all other powers and duties imposed on it by law:

- (2) To protect and promote physical and mental health of the people.
- (3) To administer and enforce state health laws, regulations and standards.
- (4) To investigate and control the causes of epidemic, infectious, communicable and other disease affecting the public health, and to provide for the detection, reporting, prevention, and control of communicable, infectious, acute, chronic, or any other disease or health hazard considered dangerous or important or which may affect the public health.
- (6) To develop and carry out reasonable health programs, not inconsistent with law, that may be deemed necessary or desirable for the protection of the public health and the control of disease.
- (19) To establish and appoint as may be deemed necessary or advisable special advisory committees to advise and confer with the department concerning the public health. Members of any special advisory committee shall serve without compensation but may be allowed actual and necessary travel and subsistence expenses when in attendance at meetings away from their places of residence.

26-15-6. Powers and Duties of Director of the Division of Health. The director of the division of health shall have and exercise the following powers and duties in addition to all other powers and duties imposed upon him by law:

- (1) To be the chief executive and administrative officer of the division of health, and the secretary and executive officer of the board.
- (2) Succeed to all powers and discharge all duties and perform all functions which by existing and continuing law are conferred upon or required to be discharged or performed by the State Health Commissioner or the Secretary of the State Board of Health.
- (5) To approve payment of traveling and subsistence expenses to employees actually and necessarily incurred in the performance of their official duties when absent from their places of residence.

26-15-5. Board of Health - Powers and Duties - Rules, Regulations and Standards - Reports. The board of health shall have the following powers and duties:

- (1) By the affirmative vote of a majority of its members, adopt, amend,

carry out the provisions and purposes of this act, and to enable the division of health to administer and enforce the public health laws of this state. However, for the control of hospitals, the board may adopt only rules and regulations recommended by the hospital advisory council. The regulations so established shall be part of the Public Health Code, shall have the force and effect of law, and may deal with any matters affecting the security of health or the preservation and improvement of public health in the state of Utah, and with any matters as to which jurisdiction is hereinafter conferred upon the division of health. Every regulation adopted by the board of health shall state the date on which it takes effect, and a copy thereof, duly signed by the secretary of the board of health, shall be filed as a public record in the division of health and a copy thereof shall be sent to each health officer within the state, and shall be published in such manner as the director of the division of health may from time to time determine. Certified copies of the Public Health Code and its amendments shall be furnished for a fee sufficient to cover cost of production and distribution, and such certified copies shall be received in evidence in all courts or other judicial proceedings in the state. The board shall provide public hearings prior to the adoption of any rule, regulation or standard. Hearings may not be provided for measures adopted in the administration of the division. All rules, regulations, and standards, heretofore adopted by the state board of health or any board, office, department or bureau whose duties are transferred to the board of health or the division of health shall remain in full force and effect until superseded by rules, regulations or standards duly adopted by the board of health.

26-20-12. Additional Powers of Division and Board of Health. In addition to the powers and duties of the division of health and the board of health provided by this act and otherwise by law, the division and board may:

(1) Establish and promulgate rules and regulations necessary or appropriate to effectively carry out the provisions of this act.

(2) Arrange for the Medical Examiner officer to perform toxicologic analyses for public or private institutions either in Utah, or elsewhere, and fix the terms for such services.

(3) Co-operate in training law enforcement personnel in the techniques of criminal investigation as related to medical and pathological matters.

I. REFERENCE:

Cadman and Jones, J. Forensic Sci. 5, 369, (1960)

II. GAS CHROMATOGRAPH:

Beckman GC-2 Column 6 ft. packed with 42-60 mesh C-22 firebrick impregnated with 15 parts Flexon 8N8 and 10 parts diisodecylphtholate and 3 parts polyethylene Glycol 600, 28 grams of this mixture to 100 gm firebrick. Beckman #70025 Helium carrier gas and thermocouple detector was used.

III. EXTRACTION:

1.0 gm potassium carbonate is preweighed into 11 x 75 mm tubes and rubber stoppered. At the time of extraction, 2 ml of n-propyl acetate (Eastman #747) is added to the tubes and 1 ml of blood (serum, urine, or tissue homogenate) is added. The tube is stoppered and shaken on a Vortex mixer for 1.0 minute and centrifuged 10 minutes at 2000 RPM. The supernate is used.

IV. INSTRUMENT OPERATION:

Temperature 100°C	Attenuation 1-200
Flow rate 60 cc/min (28 psig)	Sample size 0.020 ml
Current 330 mA	Carrier gas helium

The attenuation is set at X2 for the alcohols, and for the impurity, and X 200 for the solvent.

V. STANDARDIZATION:

Standards are prepared in alcohol-free blood, containing 4.7 gm. sodium fluoride/pint.

1. Prepare a 2.00% alcohol solution W/V by adding 2.53 ml of absolute ethanol to about 90 ml of blood with shaking and make to 100 ml.
2. Since Utah law is based on percent by weight the following standards are made by adding the following amounts of 2.00% of alcohol-blood W/V into a tared polyethylene bottle and adding sufficient blank blood to equal 100 g. net total.

% EtOH Standard (W/W)	ml of 2.00 W/V blood alcohol
0.04 -----	2.0
0.08 -----	4.0
0.16 -----	8.0
0.24 -----	12.0
0.32 -----	16.0
0.40 -----	20.0

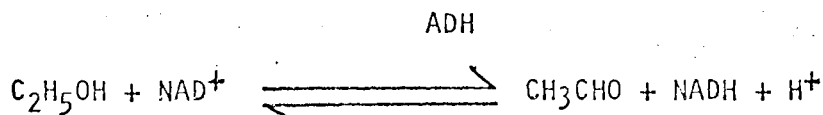
After preparation, standards are stored in the refrigerator. One set of standards may be used several times and are stable at least 3 months.

The height of the impurity peak in graph units is divided into the height of the alcohol peak to obtain the OCA, which is plotted against concentration.

BLOOD ALCOHOL ENZYMATIC METHOD #1
BOEHRINGER MANNHEIM

I. Principle

The ADH method is based on the following enzymatic reaction:



where alcohol dehydrogenase (ADH) catalyzes the oxidation of ethanol to acetaldehyde by nicotinamide-adenine dinucleotide (NAD). The equilibrium of this reaction is very much in favor of ethanol and NAD. It can, however, be completely displaced in favor of acetaldehyde and reduced nicotinamide-adenine dinucleotide (NADH) in alkaline medium with an excess of NAD and by trapping the acetaldehyde with semicarbazide. The NADH formed in the above reaction is equal to the amount of ethanol. NADH is a measure of the activity and can be determined on the basis of its absorption at 366 nm or 340 nm.

II. Reagents

1. Buffer (0.075 N pyrophosphate buffer, pH 8.7; 0.075 M semicarbazide; 0.021 M glycine): Dissolve 10 g sodium pyrophosphate ($\text{Na}_4\text{P}_2\text{O}_7 \cdot 10 \text{H}_2\text{O}$), 2.5 g semicarbazide hydrochloride (absolutely free from alcohol) and 0.5 g. glycine in 250 ml. redist. water, mix with 5 ml. 4N NaOH and make up to 300 ml. with redist. water. Stable for several weeks at approximately $+4^\circ \text{C}$.
2. Nicotinamide-adenine dinucleotide (0.024 M NAD): Dissolve contents of one bottle "Nicotinamide-adenine dinucleotide" with 2.85 ml redist. water. Stable for four weeks at approximately $+4^\circ \text{C}$.
3. Alcohol dehydrogenase (30 mg. ADH/ml.): Use contents of bottle "Alcohol dehydrogenase" undiluted. Stable for six months at approximately $+4^\circ \text{C}$.
4. Perchloric acid (approx. 0.33 M): Dilute perchloric acid PCL-33, ART. No.: 15900 or 2.85 ml. 70% (3.6 ml. 60%) perchloric acid with redist. water to give 100 ml. Stable indefinitely.
5. Ethanol standard solutions: Use standard solutions (standards a-d) containing 0.5, 1.0, 2.0 or 3.0 mg. ethanol ml. (corresponding to 0.05%, 0.100%, 0.200% or 0.300% ethanol).

II. Procedure

A. Deproteinization:

Pipette into 10 ml. centrifuge tubes the following:

1. 4.0 ml. perchloric acid
2. 0.50 ml blood or standard solutions

Mix thoroughly with a glass rod, close centrifuge tube with a rubber stopper and centrifuge at approximately 3000 r.p.m. for 5 minutes. Remove supernatant into a dry test tube, stopper and recentrifuge. Use 0.1 ml. of the supernatant for the determination.

B. Spectrophotometric measurements:

Pipette into test tubes as follows:

<u>Blank</u>	<u>Standards</u>	<u>Sample</u>
4.80 ml. buffer	4.80 ml. buffer	4.80 ml. buffer
0.10 ml. NAD	0.10 ml. NAD	0.10 ml. NAD
0.10 ml. perchloric acid	0.10 ml. supernatant	0.10 ml. supernatant
0.02 ml. ADH	0.02 ml. ADH	0.02 ml. ADH

Mix thoroughly, close test tubes with clean stopper or parafilm. Allow to stand in water bath at 25° C for 70 min.

Read absorbance of blank, standards, and sample against water.

C. Calculation:

Subtract the absorbance of the blank from the absorbances of the standards and samples. Plot the corrected absorbances of the standards against the respective ethanol concentrations (in mg%) on graph paper (ordinate: absorbance; abscissa: ethanol concentrations in mg%). The concentration of ethanol is obtained by reading from the standard curve the concentration of the corrected absorbance of the sample. When calculating the concentration of ethanol in whole blood, its content of corpuscular elements and its specific weight have to be considered.

IV. References

The method described is based on information given by Bucher, Th. and H. Redetzki: "Eine spezifische photometrische Bestimmung von Aethylalkohol auf fermentativem Wege", Klin. Wschr. 29 615 (1951).

Notes:

1. Timing of addition of NAD and ADH It is important that the sequence of initial and final readings be maintained. Using a stop watch is recommended.
2. Time reagent blank the same as standards and samples.
3. Accuracy is enhanced when a recorder is used over visual readings.
4. Suggest 100 lambda pipettes for measuring 0.10 ml. supernatants.

ENZYMATIC METHOD #2
THE DETERMINATION OF ETHYL ALCOHOL
IN BLOOD, SERUM, OR OTHER FLUIDS at 340 mμ

INTRODUCTION

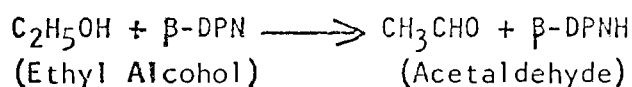
Sigma has been supplying reagents to research laboratories for many years, for the enzymatic determination of Ethyl Alcohol. However, since the usage was limited, no Technical Bulletin or Reagent "Kit" was offered. In recent years, however, interest in accurate Ethyl Alcohol determinations, particularly in legal cases, has risen sharply, so this simple procedure is offered. It is probably the most specific method available for the determination of Ethyl Alcohol in Blood or other fluids since it is based upon the use of the enzyme, Alcohol Dehydrogenase (1)

INSTRUMENT

An ultraviolet spectrophotometer is required. A Colorimetric procedure may be offered in the near future.

PRINCIPLE

The enzyme, Alcohol Dehydrogenase (ADH), catalyzes the following reaction:



This is an equilibrium reaction that can also go in the opposite direction. However, this reversal is prevented by the addition of Semicarbazide which reacts with the Acetaldehyde (CH_3CHO) as it is formed.

Under proper conditions the OD_{340} of the $\beta\text{-DPNH}$ formed is an accurate measure of the amount of ethyl alcohol that was present.

Methyl Alcohol does not react in this system (6).

SPECIMEN COLLECTION

Whole blood, serum, plasma, urine, or other fluids may be used in this procedure. Potassium oxalate (2 mg per ml) may be used as an anticoagulant for whole blood. Citrate may also be used as an anticoagulant. In general, well stoppered and refrigerated specimens may be kept for several days without appreciable loss of Ethanol (2)

The use of Ethanol for sterilization of instruments or the skin prior to obtaining a blood sample is to be avoided.

The use of a 1:1000 Mercuric Chloride Solution for sterilization of the skin has been suggested (2). No doubt other non-alcoholic sterilizing solutions can be used.

PROCEDURE

1. Pipette into Centrifuge Tube:
2.0 ml 2% Perchloric Acid
0.5 ml Blood (or other fluid)
Break up any lumps with small glass rod. Mix well.
 - a) Seal with a rubber stopper; centrifuge approx. 5 min. at about 3000 RPM
2. Pipette the following into a DPN-ADH Vial (Stock No. 330-1).
3.0 ml Pyrophosphate Buffer (Stock No. 330-30).
Cap and shake well to dissolve contents.
 - a) Pour into a Cuvette of 1 cm light path (glass or silica).
 - b) Read and record Optical Density at 340 mμ, using water in reference cuvette. This is the "Initial OD"
3. Pipette:
 - a) 0.1 ml Supernatant Fluid (from Step 1) into the Cuvette
Mix by inversion.
 - b) Read and record the OD₃₄₀ of this Cuvette, using water as reference. Continue readings until the "Maximum OD" is reached. (Approximately 30 minutes required at 25° ± 5° C.)

CALCULATIONS

Maximum OD minus Initial OD = Corrected OD.

0.111 x corrected OD = % ethanol (wgt/vol) in original sample

NOTES

1. The above calculations are applicable only when readings are made in cuvettes of 1 cm light path and on an instrument which obeys Beer's Law at 340 mμ. Instruments such as Beckman Models DU, B, DB, DK, DK-2 would fall in this category as would similar Spectrophotometers of other instrument makers. The Bausch and Lomb Spectronic 20 would not fall in this category but can still be used for this procedure by constructing a calibration curve based on observed Corrected OD's obtained with known concentrations of Ethanol.
2. If the Maximum OD exceeds 1.6, repeat the assay using 0.05 ml of the Supernatant in (Step 3). Multiply the result by 2. If necessary, even smaller aliquots may be used.
3. To check the accuracy of your reagents and procedure or to prepare a Calibration Curve, Sigma offers Ethanol Control, Stock No. 330-20. It may be used as a sample of known Ethanol concentration and substituted for blood in step 1 of the procedure. The label shows its Ethanol concentration when packaged. After repeated usage the Ethanol concentration may gradually decrease due to evaporation of the Ethanol.

4. Approximately 30 minutes is required to reach the Maximum OD_{340} when the reaction is conducted at $25^{\circ} \pm 5^{\circ} C$. This amount of time is required because of the relatively slow rate at which the Semicarbazide reacts with the Acetaldehyde. The use of a higher concentration of Alcohol Dehydrogenase will not necessarily shorten the reaction time.

5. Explanation of Calculations

OD_{340} of a solution containing $1 \mu M$ B-DPNH/ml = 6.22

Therefore, if we have $1 \mu M$ in 3 ml, the OD_{340} will be 2.07.

The molecular weight of Ethanol is 46.

$1 \mu M$ (0.000046 gm) Ethanol will produce $1 \mu M$ B-DPNH in 3 ml, resulting in an OD_{340} of 2.07.

Since the assay used only 0.02 ml of blood, a "Corrected OD" of 2.07 will result from $\frac{0.000046 \text{ gm of Ethanol}}{0.02}$ or 0.0023 gm/ml which = 0.23% (wgt/vol)

Ethanol in original blood:

Any other concentration of Ethanol is proportional to the corrected OD_{340} :

$\frac{\text{Corrected } OD_{340} \times 0.23\%}{2.07} = 0.111 \times \text{Corrected } OD_{340} = \% \text{ Ethanol (wgt/vol)}$

$\frac{2.07}{2.07}$
= $\frac{\text{grams Ethanol}}{100 \text{ ml Blood}}$

- a) In Step (2) of the procedure, approximately 0.1 ml of Buffer is "lost" in the transfer to the Cuvette. Therefore, the "Initial OD" is read on only 2.9 ml whereas the "Maximum OD" is for 3.0 ml. Since the error amounts to less than 0.0001% Ethanol in the original sample, it may generally be ignored.

REAGENTS

DPN-ADH Single Determination Vial, Stock No. 330-1

Stable over 1 year when stored in desiccator box below $0^{\circ} C$.

Ethanol Control, Stock No. 330-20

See label of package for Ethanol concentration.

Stable over 6 months if kept tightly capped.

Pyrophosphate Buffer, pH 9.2, Stock No. 330-30

Stable over 1 year at $0-5^{\circ} C$

Perchloric Acid - 2% Solution

As this item is not mailable, please obtain locally. Usually available as 70% Solution. Prepare 2% solution:

2.9 ml 70% Perchloric Acid. Dilute to 100 ml with water.

Caution: always thoroughly flush glassware and work surfaces copiously with water after exposure to Perchloric Acid. When dry, this reagent can be explosive. Perchloric Acid is available from Sigma only on special order.

REFERENCES

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6. Bonnichsen, R. K., & Theorell, H., "An Enzymatic Method for the Determination of Ethanol", Scan. J. Clin. Lab. Invest., 3, 58, (1951).

ATTACHMENT B

highway safety program manual



vol 8 alcohol in relation to highway safety

 **U.S. DEPARTMENT OF TRANSPORTATION : Federal Highway Administration : National Highway Safety Bureau**

U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL HIGHWAY ADMINISTRATION

NATIONAL HIGHWAY SAFETY BUREAU

HIGHWAY SAFETY PROGRAM MANUAL

VOLUME 8 Alcohol in Relation to Highway Safety	TRANSMITTAL 9
CHAPTER IV. Program Development and Operations	January 17, 1969

(42-01)

- Par. 1. Introduction
2. Planning
3. Chemical Tests
4. Behavioral Tests
5. Technical Qualifications of Operative Personnel
6. Tests Following Fatal Crashes
7. Implied Consent

1. INTRODUCTION

This chapter deals with the major elements which should constitute a Statewide program of alcohol in relation to highway safety.

2. PLANNING

The establishment, development, and operation of an effective program require careful and continuing planning. Such planning should include the following:

- a. Definition of objectives.

The objectives should be derived from the Standard and this Manual, supplemented by State executive, legislative, and judicial policy and current information.

- b. Determination of program scope and content.

This element should be based on the current and projected needs, evaluated in the context of the Standard and this Manual, in light of resources available for the support of the program.

- c. Determination of legislative needs to implement the program.

A review of the current statutes should be made to ascertain what new legislation is needed.

d. Determination of manpower and organization necessary to administer the program.

The State agency selected to administer this program should be capable of providing effective management and administration.

e. Determination of necessary facilities and financial resources to support the program.

There should be a thorough assessment of existing facilities and financial resources and a determination of what new ones must be created.

3. CHEMICAL TESTS

This section deals with chemical tests* which can be used to measure alcohol in materials of body origin and to detect signs of alcoholic impairment.

a. Scientific and technical regulations.

An appropriately qualified State agency** such as the Health Department, Office of the Medical Examiner, or Department of Public Safety, should have overall scientific and technical control of chemical testing for alcohol throughout the State. The responsible State agency should have the following responsibilities:

(1) Promulgate regulations concerning the collection, identification, custody, preservation, and storage of blood, breath, and other body materials obtained for analysis for alcohol content.***

(a) The regulations should limit the analyses to specimens of blood, breath, or urine in the case of living subjects.

(b) Choice of postmortem specimens from subjects of autopsies should be at the discretion of the responsible physician; specimens of blood should be drawn from areas not likely to be contaminated with alcohol from the gastrointestinal tract or by diffusion therefrom.

* Chemical tests include all scientific methods used for testing for alcohol concentration.

** The term "responsible State agency" will hereinafter be used to refer to the agency described in this paragraph.

*** Procedures should include evidentiary safeguards relating to identification and chain of custody of such materials.

(2) Select or develop, and implement a suitable program for periodic performance evaluation of laboratories, agencies, and individuals performing chemical tests for alcohol. Performance reports should be prepared and maintained as public records.

(3) Provide information and advice relevant to testing for alcohol to law enforcement agencies and other interested parties through the State traffic records system.

(4) Provide for appropriate training in the performance of alcohol analyses and for accreditation of qualified individuals meeting the performance requirements established.

b. Analysis of blood.

Reliability criteria, including accuracy, precision, and specificity of the methods of analysis and preservation of the specimens, must be established by the responsible State agency.

(1) Procedures for blood analysis should include the following controls in conjunction with each batch of samples analyzed:

(a) A system blank analysis.

(b) Analysis of a suitable reference or control blood sample of known alcohol content within the range 0.10 to 0.30% W/V; the result of which analysis must coincide with the known blood alcohol value of the reference specimen within $\pm 0.01\%$ W/V if validity is to be assigned to the results for the batch analyzed.

(2) Replicate analyses are recommended in order to minimize the possibility of undetected errors.

(3) Results should be expressed in terms of % W/V, that is, grams of alcohol per 100 milliliters of blood, rounded downward, to the second decimal place; for example, 0.237% found should be reported as 0.23%.

(4) Analytical procedure for determining alcohol in blood should meet the following performance requirements:

(a) The accuracy and sensitivity of the procedure should be such as consistently to attain results within $\pm 0.01\%$ W/V of the known value over the range of 0 to 0.30% W/V in analyses of appropriate reference materials of known ethyl alcohol concentration.

(b) The precision of the procedure should be such as consistently to attain a standard deviation not greater than 0.003% W/V in replicate analyses.

(c) The blank values yielded by the procedure in analyses of alcohol-free blood specimens consistently should be not greater than 0.01% W/V.

(d) The specificity of the procedure should be adequate and appropriate for the analysis of biological specimens for the determination of the blood alcohol concentration in traffic law enforcement and highway crash investigations.

1 Procedures for the analysis of biological specimens from living subjects should respond only to ethyl alcohol and the other lower aliphatic alcohols and should not be susceptible to significant unrecognized interference by other substances.

2 Procedures for the analysis of postmortem biological specimens should respond only to ethyl alcohol and should not be susceptible to significant unrecognized interference by other substances.

c. Analysis of breath.

The chemical test of breath should be performed with the equipment and techniques which meet the reliability criteria, including accuracy, precision, and specificity established by the responsible State agency.

(1) Breath specimens collected for analysis should be substantially in equilibrium, with respect to alcohol, with pulmonary arterial blood, i.e., should be essentially alveolar in composition.

(2) Procedures for breath alcohol analysis for the indirect determination of the blood alcohol concentration should include the following controls in conjunction with the testing of each subject:

(a) Continuous observation of the subject for at least fifteen (15) minutes prior to collection of the breath specimen, during which period the subject must not have ingested alcohol, regurgitated, or vomited.

(b) A system blank analysis.

(c) Analysis of a suitable reference or control sample of known alcohol concentration, such as air equilibrated with a reference solution of known alcohol content at known temperature, the result of which analysis must coincide with the predicted blood alcohol value of the reference sample within $\pm 0.01\%$ W/V.

(3) Results of analyses of breath for alcohol should be expressed in terms of % W/V, that is, grams of alcohol per 100 milliliters of blood, to the second decimal place as found; for example, 0.237% found should be reported as 0.23%.

(4) The quantity of breath analyzed for its alcohol content should be established only by direct volumetric measurement, or by collection and analysis of a fixed breath volume at constant known temperature.

d. Analysis of urine.

Reliability criteria, including accuracy, precision, and specificity of the methods of analysis and preservation of the specimens must be acceptable to the responsible State agency. Because of various problems in the interpretation of the results of analysis of urine for alcohol which cannot be readily overcome in law enforcement practice, urine analysis to determine equivalent alcohol concentration in blood is discouraged, except under strictly controlled conditions (e. g., hospitalized subject), or for the limited purpose of demonstrating recent ingestion of alcohol. Chemical tests of blood or breath are preferred.

e. Specimen collection and preservation.

Every specimen should be collected in such a manner and with such precautions as to maintain the original identity, integrity, and composition with respect to alcohol.

(1) All liquid biological specimens not analyzed immediately upon collection should promptly be so treated and preserved as to maintain the original identity, integrity, and composition with respect to alcohol of each specimen without significant alteration for a minimum period of 30 days, when kept at normal room temperature.

(2) Solid tissue should be deep-frozen.

f. Public record.

The results and full procedural details of all chemical testing for alcohol should be matters of public record.

4. BEHAVIORAL TESTS

Observations for impairment should be made on all drivers involved in crashes investigated by the police. To the extent practicable, behavioral tests should be made on a person where there is reasonable grounds to believe that he was driving while impaired and on all drivers who are arrested on any charge of driving while under the influence of alcohol.

a. Performance tests include but are not limited to the following:

- (1) Balance.
- (2) Walking.
- (3) Turning.
- (4) Finger-to-nose.
- (5) Fetching coins.

b. Observation of the suspect should include appearance, odor of breath, clarity of speech, general attitude, and other actions or unusual conditions.

(1) The manual entitled, Driving Under the Influence of Alcohol or Drugs,* is recommended for training in recognizing "under-the-influence" offenses and as a guide for enforcement action.

(2) The alcoholic influence report form** developed by the National Safety Council should be the minimum guide used in examining, interpreting, and recording the results of such tests.

c. The use of photographs, motion pictures, video tapes, and sound recordings to document behavior is strongly encouraged.

* Publication No. 2071, Traffic Institute, Northwestern University.

** See Appendix F.

5. TECHNICAL QUALIFICATIONS OF OPERATIVE PERSONNEL

This section deals with the technical qualifications of personnel involved in chemical testing for alcohol.

a. Scientific direction.

A scientific director should be in overall charge of each program of chemical testing for alcohol. The director should have at least a master's degree in one of the natural sciences or other appropriate field and should have specialized knowledge of chemical tests for alcohol. It is recommended that the scientific director be affiliated with a local institution of higher learning so as to be informed of and engaged in research bearing on chemical testing, and to assure his own continuing education.

b. Qualifications and training of technical personnel.

To implement a sound chemical testing program properly trained and qualified individuals should be available in each State in adequate numbers.*

(1) Blood, urine, and body material analysis.

The qualifications and training of the laboratory director and laboratory analysts in any laboratory that carries out direct analysis of blood and body materials other than breath should meet the minimum educational and experience requirements for equivalent personnel set forth in the regulations for Conditions for Coverage of Services of Independent Laboratories Under the Federal Health Insurance for the Aged Act.**

(2) Breath analysis.

Chemical testing of breath should be supervised in each laboratory or agency engaged in breath alcohol analysis by a technical supervisor.

(a) The responsibilities of the technical supervisor should include:

1 Field inspection.

* In States where adequate numbers of trained and qualified personnel are not available, the initial phase of implementing a chemical testing program should be the development of, or utilization of, training programs to provide the necessary personnel.

** See Appendix G.

2 Maintenance and calibration of breath testing equipment.

3 Training and reevaluation of the breath test technicians under his jurisdiction.

4 Periodic reexamination of the operators under his jurisdiction to ensure maintenance of technical knowledge and competence.

(b) The minimum qualifications for a technical supervisor should be:

1 High school graduation or its equivalent.

2 Accreditation as an operator of the chemical breath analysis method he is to supervise, or possession of equivalent knowledge to qualify him as such.

3 Satisfactory completion of a technical supervisor's course, which should, minimally, include:

a Advanced survey of current information concerning alcohol and its effects on the human body.

b Operational principles and theories applicable to the program.

c Instrument maintenance and calibration.

d Legal aspects of chemical testing.

e Principles of instruction.

c. Technicians.

Each State should have enough trained technicians, operating under technical supervisors, to provide necessary Statewide coverage. The recommended course of instruction for these technicians includes at least the following:

(1) A minimum of three (3) hours of instruction on the effects of alcohol on the human body.

(2) A minimum of three (3) hours of instruction on operational principles of the selected testing method, which should include a functional description and a detailed operational description of the method with demonstration.

(3) A minimum of five (5) hours of instruction on the legal aspects of chemical tests generally, and of the particular method to be employed.

(4) A minimum of three (3) hours of instruction on supplemental information which should include nomenclature appropriate to the field of chemical tests for alcohol.

(5) A minimum of ten (10) hours of laboratory participation using appropriate equipment. Laboratory practice should include the use of the reference standard, as well as the testing of drinking subjects.

(6) A minimum of one (1) hour of formal examination for purposes of determining competency and qualification.

d. Accreditation of personnel.

Each State should establish formal criteria for accreditation and/or certification procedures for personnel authorized to supervise and conduct chemical tests for alcohol.

(1) This process should be administered by the responsible State agency. The State may delegate accreditation authority to municipalities or counties but should retain supervisory control to ensure that uniform requirements are being met.

(2) A specific time expiration limit, not to exceed two years, should be set for the accreditation or certification.

6. TESTS FOLLOWING FATAL CRASHES

This section deals with the tests that should be performed in each State following fatal crashes:

a. State requirements.

For the purpose of continuous evaluation of the role that alcohol plays in fatal crashes, the allocation of program resources, and the determination of countermeasure efficacy, each State:

(1) Should perform chemical tests on the bodies of at least 90 percent of the drivers and pedestrians over 15 years of age who die within four hours of the time of fatal crashes. Investigations should:

(a) Include chemical testing requiring both the availability and utilization of trained professional personnel and the use of sensitive equipment and procedures.

(b) Use only professionally trained coroners or medical examiners and accredited laboratories in implementing this program.

(2) Is encouraged to provide that no person having custody of the body of such a deceased person shall perform any internal embalming procedure until authorized to do so by the individual who has performed, or who will perform, the postmortem investigation.

(3) Is encouraged to provide that analysis of the specimens obtained in such deaths be conducted by a procedure which is considered specific for ethyl alcohol and which therefore distinguishes among ethyl alcohol, isopropyl alcohol, methyl alcohol, formaldehyde, acetone, and other volatile reducing substances.

(4) Should, to the extent practicable, conduct blood or breath tests on all surviving drivers in crashes fatal to others.

b. Test data.

The data collected in each State in relation to each such test should include at least the following:

- (1) Time and date of crash.
- (2) Time and date of death.
- (3) Role (driver or pedestrian) of each such fatally injured person.
- (4) Name, age, and address of each such fatally injured person.
- (5) Time and kind of each specimen taken.
- (6) Alcohol concentration of each specimen taken.
- (7) Method used to determine alcohol concentration.
- (8) Circumstances surrounding death, including such additional information as may be necessary to permit easy linkage to police, hospital, and other reports dealing with the same crash.

c. Summary data.

Each State should tabulate and publish at least annually, preferably monthly, data on the extent of alcohol involvement in fatal crashes. As a minimum these data should include the following:

- (1) Total number of fatal crashes
- (2) Total number of fatalities, including all categories of persons.
- (3) Total number of drivers and pedestrians 15 years of age or older who died within four hours of the crashes in which they were injured.
- (4) Total number of such drivers and of such pedestrians tested.
- (5) The percentages of drivers and of pedestrians tested with blood alcohol concentrations in each of the following ranges:
 - (a) Negative or less than 0.01% W/V.
 - (b) 0.01 - 0.04% W/V.
 - (c) 0.05 - 0.09% W/V.
 - (d) 0.10 - 0.14% W/V.
 - (e) 0.15 - 0.24% W/V.
 - (f) 0.25% and over W/V.

d. Data form.

The data tabulation should be reported on the current version of the form developed by the National Safety Council entitled Standard Report of Alcohol Involvement in Fatal Motor Vehicle Traffic Accidents.*

e. Local jurisdictions.

In collecting the foregoing data, each State should obtain similar tabulations on a monthly basis from all local jurisdictions in the State.

* This form is presented as Appendix H.

7. IMPLIED CONSENT

Each State should have "implied consent" legislation which provides that a person's operator's permit shall be revoked if he is arrested upon reasonable grounds for belief that he has committed an alcohol-related driving offense and subsequently refuses, on request, to submit to a chemical blood-alcohol test. States should establish an "implied consent" statute which conforms essentially to the appropriate sections of the Uniform Vehicle Code.*

* Appendix I of this volume reproduces sections of the Uniform Vehicle Code dealing with "implied consent."