

Minnesota Attorney General: Administrative Rules Proceedings

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Version 3
August 20, 2018

CBE

RULE REVIEW CHECKLIST

File No. 1596 — Docket No. 05-0009.1430

DATE RECEIVED 4-26-89 — ADOPTED W/O HEARING X

REVIEW DATE 5-5-89 — EMERGENCY RULE _____

DUE DATE 5-10-89 — REVISOR APPROVED ✓

APPROVED 5/10/89 JEA — REVISOR DISAPPROVED _____

DISAPPROVED _____ — FILED W/SEC. OF STATE 5/11/89

WITHDRAWN _____ — RETURNED TO AGENCY 5/11/89

gen accredit. Licensure

✓ ✓ Rule as adopted (4 copies)

_____ ✓ Notice to Solicit Outside Information/Opinion (if applicable) Relating to licensure
8-17-87 Date published in State Register
None Comments

_____ ~~Petition for Adoption of a Rule (if applicable)~~

_____ ~~Board's Authorizing Resolution~~
_____ ~~Date adopted~~

✓ ✓ Proposed Rule
yes Revisor's Certificate

✓ Notice of Intent to Adopt Rule
144.07-18, 953 Statutory Authority
yes Small Business Statement
No Expenditure of public money statement
yes Signature

✓ ✓ Statement of Need and Reasonableness (if applicable)
yes yes Small Business Statement
yes n/a Fees - § 16A.128

✓ Affidavit of Mailing Notice of Intent to Adopt Rule
10/24/88 Date 30/25 days before adoption
OK Notice attached
_____ ~~Copy of rule or summary attached~~

✓ Publication in State Register
10/31/88 Date 30/25 days before adoption

_____ 180-day deadline from:
See notes. Effective date of law requiring rule (14.12) (both rules)
11/30/88 end of comment period (§ 14.26) (rules without hearing)
_____ ~~effective date of statutory authority (§ 14.29) (emergency rules)~~

_____ ~~Resolution Adopting~~
_____ ~~Date adopted~~

✓ Findings of Fact, Conclusions & Order Adopting
4/19/89 Date

✓ Written requests, submissions or comments

✓ Declaration of attorney
P. Zerby Name of SAAG representing agency

_____ ~~Notice of Submission to Atty. Gen. (if applicable)~~

_____ ~~Aff. of Mailing Notice to Atty. Gen. (if applicable)~~

FILE COPY

DEPARTMENT : ATTORNEY GENERAL

STATE OF MINNESOTA

Office Memorandum

DATE : May 11, 1989

TO : PAUL A. ZERBY
Special Assistant Attorney General
2829 University Ave. S.E., Minneapolis

FROM : JACKIE E. ALBRIGHT
Special Assistant Attorney General
515 Transportation Building

PHONE : 6-9715

SUBJECT : In the Matter of the Adopted Permanent Rules Relating to Drug and Alcohol Testing Laboratories: Licensing

The above-referenced rule has been approved as to its legality by the Attorney General on May 10, 1989.

Enclosed is the agency's copy of the approved rule. Thos office has already filed two copies with the Secretary of State who will forward one copy to the Revisor of Statutes. The fourth is being retained by this division of the Attorney General's Office for its records.

Also enclosed are any petitions, requests, submissions or comments received by the agency and any extra copies of documents which the agency submitted to the Attorney General.

In order for a permanent rule without a hearing to become effective, your agency must publish a notice of adoption in the State Register in accordance with Minn. Stat. § 14.27. An emergency rule becomes effective five working days after approval by the Attorney General; however, the agency must publish a notice in the State Register in accordance with Minn. Stat. § 14.34.

If you have any questions in this regard, please contact me.

JEA:bbl
Enclosures

cc: William Brown
Maryanne Hruby

Department of Health

Adopted Permanent Rules Relating to General Accreditation Requirements for Laboratories

Rules as Adopted

CHAPTER 4740
DEPARTMENT OF HEALTH
LABORATORIES; ACCREDITATION REQUIREMENTS

4740.0100 PURPOSE AND SCOPE.

The rules in chapter 4740 contain accreditation procedures and standards for laboratories that perform tests or analyses as required by state or federal law.

4740.0110 DEFINITIONS.

Subpart 1. **Scope.** The terms used in parts 4740.0100 to 4740.0170 have the meanings given them in this part.

Subp. 2. **Accreditation.** "Accreditation" means licensure or certification of a laboratory to perform specific tests.

Subp. 3. **Certification.** "Certification" means written acknowledgment of the laboratory's demonstrated capability to perform tests for a specific purpose.

Subp. 4. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 4a. **Etiologic agent.** "Etiologic agent" means a viable microorganism, or its toxin, which causes or may cause human disease.

Subp. 4b. **Histologic.** "Histologic" means a body tissue.

Subp. 5. **Laboratory.** "Laboratory" means a person, corporation, or other entity, including a governmental entity, which examines, analyzes, or tests samples.

Subp. 6. **Licensure.** "Licensure" means authorization to perform laboratory tests for a purpose defined by statute.

Subp. 7. **Out-of-control quality control result.** "Out-of-control quality control result" means a result from an internal quality control sample that does not fall within a

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statistically acceptable range.

Subp. 8. **Sample.** "Sample" means a substance derived from a nonhuman source and collected for the purpose of analysis or a tissue, blood, excretion, or other bodily fluid specimen obtained from a human for the detection of a chemical, etiologic agent, or histologic abnormality.

4740.0120 APPLICATION PROCEDURES.

Subpart 1. **Standards.** To obtain accreditation, the laboratory must comply with subparts 2 to 5 and with the technical standards that apply to the specific laboratory test for which accreditation is sought, as specified in rule.

Subp. 2. **Contents.** The application shall include:

A. the address of the principal place of business or headquarters;

B. the address and phone number of the laboratory that seeks accreditation, if different than in item A;

C. the names of officers and the laboratory director;

D. written assurance that the laboratory meets the standards of parts 4740.0100 to 4740.0170 and the standards that apply to the specific test for which laboratory accreditation is sought, as specified in rule;

E. the signatures of two officers or managing agents of the laboratory and proof of the signatories' authority to bind the laboratory; and

F. other reasonable information necessary to determine compliance with accreditation requirements.

Subp. 3. **Documentation.** At the time of application, the laboratory shall submit or have available for inspection the following documents:

A. a current laboratory manual;

B. criteria for accepting and rejecting samples for testing;

C. proficiency testing results;

D. internal quality assurance records;

E. corrective action for out-of-control quality

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control results;

F. sample receipt and storage records;

G. equipment calibration and standardization records;

H. equipment repair and preventive maintenance records;

I. personnel education and training requirements;

J. laboratory safety policies; and

K. written chain-of-custody procedures.

Subp. 4. **Fee.** The laboratory shall submit with its application a nonrefundable fee, in the amount established by the specific rule for the purpose or type of test for which accreditation is sought.

Subp. 5. **Inspection.** The laboratory must demonstrate compliance with accreditation requirements through an inspection conducted by persons designated by the commissioner. Inspections ~~shall~~ may be unannounced and at a frequency established by the rule specific to the purpose or type of test for which accreditation is sought.

4740.0130 PROVISIONAL ACCREDITATION.

A laboratory that meets accreditation application requirements shall receive written provisional accreditation until an on-site inspection is completed. Upon demonstration, through inspections, of compliance with standards specific to the purpose or type of testing for which accreditation is sought, full accreditation shall be granted in writing showing the date of expiration.

4740.0140 TERM OF ACCREDITATION.

Laboratories shall be accredited for a term of one year, which shall include any period of provisional accreditation. Unless a laboratory submits a timely application for renewal of the accreditation, the accreditation expires without notice at the end of the term.

4740.0150 COMPLIANCE.

All accredited laboratories shall immediately inform the

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commissioner of any changes to the information required by part 4740.0120 and the rules specific to the laboratory test for which accreditation is sought. The laboratory director must inform the commissioner in writing of any changes in test methodology, instrumentation, key personnel, or laboratory ownership and submit revisions to the documents listed in part 4740.0120, subpart 3, within 14 calendar days of the change.

4740.0160 ACCREDITATION RENEWAL.

A laboratory shall submit an application for renewal of accreditation with the applicable renewal fee, no later than 30 days before the expiration date of the current accreditation. The renewal application shall contain the same information required for an initial application in part 4740.0120, subpart 2. At the time of application for a renewal of its accreditation, the laboratory shall also submit or have available for inspection the documents listed in part 4740.0120, subpart 3. Unless a laboratory submits a timely application for accreditation renewal, the accreditation expires without further notice at the end of the term.

4740.0170 ACCREDITATION; SUSPENSION AND REVOCATION.

The commissioner may, pursuant to Minnesota Statutes, chapter 14, suspend, revoke, refuse to renew, condition, or limit the accreditation of a laboratory upon finding that the laboratory has ~~repeatedly~~ violated provisions of parts 4740.0100 to 4740.0160 or has ~~repeatedly~~ failed to meet standards defined under the rule applicable to the specific laboratory test for which the laboratory is accredited.

Approved
by Revisor _____

APPROVED AS TO FORM AND LEGALITY

May 10 19 89

HUBERT H. HUMPHREY, III
ATTORNEY GENERAL

BY Jacqueline E. Albright
SPECIAL ASSISTANT ATTORNEY GENERAL

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED

MAY 11 1989

Joan Anderson Growe
Secretary of State

1:55 PM

Department of Health

Adopted Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing

Rules as Adopted

DRUG AND ALCOHOL TESTING OF EMPLOYEES

4740.1010 DEFINITIONS.

Subpart 1. **Scope, application.** The following terms used in parts 4740.1020 to 4740.1080 have the meanings given them in this part.

Subp. 2. **Alcohol.** "Alcohol" means ethyl alcohol.

Subp. 3. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 4. **Confirmatory test.** "Confirmatory test" means a drug or alcohol test, run on a sample that was positive on the initial screening test. Techniques for a confirmatory test are described in part 4740.1070, subparts 5 and 6.

Subp. 5. **Department.** "Department" means the Department of Health.

Subp. 6. **Drug.** "Drug" means a controlled substance as defined in Minnesota Statutes, section 152.02, and as updated yearly by rules of the Board of Pharmacy.

Subp. 7. **Employee.** "Employee" means a person, independent contractor, or person working for an independent contractor who performs services for compensation, in whatever form, for an employer.

Subp. 8. **Employer.** "Employer" means a person, independent contractor, or entity located or doing business in this state and having one or more employees, and includes the state of Minnesota and all political or other governmental subdivisions of the state.

Subp. 9. **Initial screening test.** "Initial screening test" means a drug or alcohol test ~~that can detect the~~, the results of which indicate presumptive presence of a drug, drug metabolite,

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or alcohol in a sample. Techniques for an initial screening test are described in part 4740.1070, subparts 5 and 6.

Subp. 10. **Initial screening test minimum detection level.** "Initial screening test minimum detection level" means the level at which a laboratory is capable of detecting a drug or drug metabolite using a screening test. The values are derived from the NIDA initial cutoff levels in Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines; Notice, paragraph 2.4(e)(1), as provided by the Federal Register, Volume 53, Number 69, page 11983, Monday, April 11, 1988.

Subp. 11. **Job applicant.** "Job applicant" means a person, independent contractor, or person working for an independent contractor who applies to become an employee of an employer, and includes a person who has received a job offer that is contingent on the person passing drug or alcohol testing.

Subp. ~~11.~~ 12. **Laboratory.** "Laboratory" means a person, corporation, or other entity, including a governmental entity, that examines, analyzes, or tests samples.

Subp. ~~12.~~ 13. **NCCLS.** "NCCLS" means the National Committee for Clinical Laboratory Standards, Villanova, Pennsylvania.

Subp. ~~13.~~ 14. **NIDA.** "NIDA" means the National Institute ~~for~~ on Drug Abuse, of the Alcohol, Drug Abuse, and Mental Health Administration, United States Health and Human Services Department.

Subp. ~~14.~~ 15. **Positive test result.** "Positive test result" means a finding of the presence of drugs, alcohol, or their metabolites in the sample tested by a confirmatory test in levels at or above the threshold detection levels set by the commissioner under part 4740.1080.

Subp. ~~15.~~ 16. **Presumptive presence.** "Presumptive presence" means some indication of the presence of a drug, drug metabolite, or alcohol that, in the judgment of the laboratory director or the laboratory director's designee, provides a reasonable basis for conducting a confirmatory test. The presumptive presence of a drug, drug metabolite, or alcohol is

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not a positive test result.

Subp. ~~16.~~ 17. **Sample.** "Sample" means a substance derived from a nonhuman source and collected for the purpose of analysis or a tissue, blood, excretion, or other bodily fluid specimen obtained from a human for the detection of a chemical, etiologic agent, or histologic abnormality.

Subp. ~~17.~~ 18. **Threshold detection level.** "Threshold detection level" means ~~that~~ the level at which the presence of a drug, drug metabolite, or alcohol ~~could~~ can be reasonably ~~be~~ expected to be detected ~~in a sample~~ by a confirmatory test performed by a laboratory that meets the standards of parts 4740.1010 to 4740.1090. The threshold detection level is neither meant to indicate impairment nor any relationship between the time of the test and the time of use of a drug or alcohol by the employee or applicant. The threshold detection level simply indicates the level at which a valid conclusion can be drawn that the drug or alcohol is present in the employee's or applicant's sample.

4740.1020 LICENSE REQUIRED FOR LABORATORIES PERFORMING DRUG AND ALCOHOL TESTING FOR EMPLOYERS.

A laboratory that performs drug and alcohol laboratory tests of employees and job applicants for Minnesota employers must possess a valid license to do so. A laboratory must obtain a license according to the procedures in parts 4740.0100 to 4740.0170, as proposed at 13 State Register 1079 and as subsequently adopted. In addition to the information required on an application for a license, a laboratory that performs only initial drug and alcohol screening tests must disclose on its application the name of the licensed laboratory that performs its confirmatory tests.

4740.1025 EXCEPTION.

A medical clinic, hospital, or other medical facility need not be licensed under parts 4740.1010 to 4740.1080 to perform a breath test as an initial screening test for alcohol if:

A. the medical clinic, hospital, or other medical

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facility is not owned or operated by the employer; and

B. the results of the breath test are confirmed by a blood test performed by a laboratory licensed under parts 4740.1010 to 4740.1080.

4740.1040 RECIPROCITY.

A license shall be granted to a laboratory located in another state, if the requirements of Minnesota Statutes, section 181.953, subdivision 1, paragraph (c), are met.

4740.1050 TERM OF LICENSE.

Laboratories shall be licensed for a term of one year ~~beginning on July 1 and ending June 30~~. Unless a laboratory submits a timely application for license renewal, the license expires without further notice at the end of the term.

4740.1060 FEES.

Subpart 1. **Annual license fee required.** The laboratory must pay an annual license fee and other required costs with the initial application for license and with each renewal application. The amount of the fee and other required costs is determined under subpart 3. ~~It is based upon the number of samples taken from Minnesota employees, that the laboratory tests.~~ A laboratory must pay the fees and costs required under this part before a license is issued.

Subp. 2. **Information required to determine fee.** The laboratory must submit an estimate of the ~~number of annual Minnesota employee samples to be tested for drugs and alcohol~~ laboratory annual receipts during the current accounting year with the application for a license or license renewal. The laboratory must submit to the department quarterly reports of the ~~volume of actual employee drug and alcohol testing samples~~ laboratory annual receipts and the results of proficiency testing results for the past quarter. The statistics from these reports are used to adjust the license fee collected from the laboratory on its next license renewal application to reflect actual ~~sample volume~~ laboratory annual receipts.

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Subp. 3. **License fee schedule.** The annual license ~~fees are determined according to the following schedule:~~ fee is made up of an application fee and inspection fee as described in items A and B. The fees are nonrefundable.

~~License fee = (a) $1,200 +~~

~~(b) Total annual alcohol samples + drug samples X $3/sample~~

~~taken from Minnesota employees~~

~~2~~

~~A sample obtained for both alcohol and drug testing is considered as one alcohol sample and one drug sample for fee purposes. The $1,200 in part (a) of the schedule is nonrefundable.~~

A. The application fee is determined as follows:

Laboratory Annual Receipts	License fee
less than $500,000	$ 600
$500,000 to $2,000,000	1,200
$2 million to $10 million	1,800
more than $10 million	2,400; and

B. The inspection fee is $1,200 per year per lab.

C. Laboratories located outside Minnesota are assessed actual cost of additional labor, travel, and lodging expenses the department incurs in the laboratory inspection.

4740.1065 ANNUAL INSPECTION.

The commissioner shall conduct periodic inspections of laboratories licensed for drug and alcohol testing of employees. Inspections ~~shall~~ may be unannounced and occur at least annually.

4740.1070 PERFORMANCE METHODS REQUIRED FOR ISSUANCE OF A LICENSE.

Subpart 1. **Standards required.** To qualify for a license to conduct drug and alcohol testing for Minnesota employees and job applicants, the officers or the owner of a laboratory must use the performance methods described in subparts 2 to 8.

Subp. 2. **Test samples.** The usual sample for drug testing

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is freshly voided urine. A breath, urine, or blood sample may be used for initial screening tests. When the breath test is used as the initial screening test for alcohol, a blood sample shall be obtained for the confirmatory test. The blood sample shall be collected immediately after the breath test. When an initial positive urine test indicates the presence of drugs, a blood ~~test may~~ or urine sample shall be used for the confirmatory test.

The sample volume must be adequate to allow for the initial screening test, a confirmatory test, and a confirmatory retest.

Subp. 3. **Collection of urine samples; procedures.** The laboratory must have written procedures for collecting urine samples. The collection procedures must contain paragraphs 6 and 11 to 16 of the specimen collection procedures in Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies, NIDA, as provided by the Federal Register, volume 52, pages 30639 and 30640, Friday, August 14, 1987. Paragraphs 1 to 5 and 7 to 10 of these procedures are optional. The site where the sample is collected must have a stall or partitioned area that allows the individual being tested to provide the individual's urine specimen in privacy. The collection site person must sign and date either the tape sealing the sample container or the sample container label.

Subp. 4. **Collection of blood samples; procedures.** The laboratory must have written procedures for collection of blood samples. The procedure must address identification of the employee or job applicant, necessary collection supplies, seating or positioning of the employee or job applicant during sample collection, cleansing of the skin at the venipuncture site, and verification that the sample and paperwork are from the individual from which the sample was collected. NCCLS Guidelines H3-A2, Procedures for Collection of Diagnostic Blood Specimens by Venipuncture, 2nd Edition, Approved Standard, 1984, is an acceptable guide for the collection of blood samples. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford

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Building, 117 University Avenue, Saint Paul, Minnesota 55155.

The collection site person must sign either the tape sealing the sample container or the sample container label.

Subp. 5. **Techniques for drug testing.** For an initial screening test for drugs or drug metabolites, the laboratory must use a chromatographic technique or an immunoassay method. Samples that show the presumptive presence of a drug or drug metabolite must be confirmed by the gas chromatography/mass spectrometry (GC/MS) technique.

Subp. 6. **Techniques for alcohol testing.** A breath test, alcohol dehydrogenase reaction, microdiffusion, or oxidation of distillate with potassium dichromate may be used as a method to initially test for the presence of alcohol. The presumptive presence of alcohol must be confirmed using gas chromatography.

Subp. 7. **Confirmatory tests required.** A laboratory that performs only initial testing must obtain confirmatory results from a licensed laboratory that performs confirmatory tests.

Subp. 8. **Chain-of-custody procedures for handling samples.** The laboratory must follow written chain-of-custody procedures that, at a minimum, meet the requirements of items A to C.

A. Possession of a sample must be traceable to the employee from whom the sample is collected, from the time the sample is collected through the time the sample is tested, the test result reported, the sample retested, and the sample stored.

B. At all times, the sample must be in the possession of, in view of, or placed in a secured area by a person authorized to handle the sample.

C. A sample must be accompanied by a written chain-of-custody record. Individuals relinquishing or accepting possession of the sample must record the time the possession of the sample was transferred and must sign and date the chain-of-custody record at the time of transfer.

Subp. 9. **Storage of positive samples.** All confirmed positive samples shall be stored frozen for at least six months. The sample container must be sealed and labeled. The

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freezer must be locked or be located in a secure area.

Subp. 10. **Requirements for directors.** The director of the laboratory must be a full-time employee of the laboratory, must possess a doctoral, medical doctor, or a master's degree in a biological or medical science, and must have at least three years' experience in an analytical toxicology laboratory.

Subp. 11. **Proficiency testing required.** Satisfactory participation in a proficiency testing program is required of a laboratory applying for or renewing a license. The Forensic Urine Drug Testing surveys conducted by the College of American Pathologists and the American Association for Clinical Chemistry and the NIDA Performance Test Program are acceptable proficiency testing programs. The laboratory must participate at the appropriate screening and confirmatory test levels for which an application for license is submitted.

Subp. 12. **Procedures for proficiency testing.** Before applying for or renewing a license, a laboratory must participate in and report the results of three cycles of proficiency testing. The laboratory must mail proficiency testing results to the commissioner.

The procedures for handling and testing proficiency test samples after receipt by the laboratory must be identical to the procedures for normal laboratory samples.

Laboratory personnel shall not be informed that these samples are part of a performance test to the extent possible.

A licensed laboratory may also be subjected to blind proficiency testing. Performance on blind testing samples is required at the same level as for the open proficiency testing.

A false-positive result from a confirmatory test sample is unsatisfactory performance. Two false-positive results from a screening test sample during a one-year period constitute unsatisfactory performance. The laboratory must inform the commissioner, in writing, of any false-positive test result on a proficiency testing sample, with a plan of corrective action. The commissioner will be informed within 14 days of receipt of the proficiency testing report.

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Subp. 13. **Laboratory procedure manual.** The laboratory must possess and follow a laboratory procedure manual. The laboratory manual must describe the individual test procedures performed by the laboratory. The manual must have a table of contents and numbered pages. The manual must be reviewed annually. The description of the test procedures must include sections addressing the sample used for the test, reagents, supplies and materials, equipment calibration, quality control, the step-by-step procedure, calculations, reporting results, special notes, safety precautions, limitations of the procedure, references, and flow diagrams. Changes in a procedure must be reviewed and dated. Clinical Laboratory Procedure Manuals; Approved Guidelines, GP2-A, National Committee for Clinical Laboratory Standards, 1984, is an acceptable guide to writing a laboratory manual. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford Building, 117 University Avenue, Saint Paul, Minnesota 55155.

4740.1075 INITIAL SCREENING TEST; MINIMUM DETECTION LEVELS.

The minimum levels that need to be detectable by a screening test are as follows:

A. marijuana metabolites, 100 ng/ml;

B. cocaine metabolites, 300 ng/ml;

C. opiate metabolites, 300 ng/ml;

D. phencyclidine, 25 ng/ml; and

E. amphetamines, 1,000 ng/ml.

4740.1080 THRESHOLD DETECTION LEVELS.

Threshold detection levels for confirmatory tests of drugs and drug metabolites defined in Minnesota Statutes, section 152.02, and rules of the Board of Pharmacy are 1,000 ng/ml, except as listed in items A to K:

A. marijuana metabolite (delta-9 tetrahydrocannabinol-9-carboxylic acid), 15 ng/ml;

B. cocaine~~,~~ ~~150 ng/ml;~~

~~C.~~ metabolite (benzoylecgonine), 150 ng/ml;

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~~D.~~ C. opiates~~, 300 ng/ml~~;

(1) morphine, 300 ng/ml*; and

(2) codeine, 300 ng/ml*;

~~E.~~ D. phencyclidine, 25 ng/ml;

~~F.~~ E. amphetamines, 500 ng/ml;

~~G.~~ F. fentanyl, 5 ng/ml;

~~H.~~ G. lysergic acid diethylamide (LSD), 5 ng/ml;

~~I.~~ H. 3-4-methylenedioxy amphetamine (MDA), 300 ng/ml;

~~J.~~ I. alcohol (urine), .02 gram percent; and

~~K.~~ J. alcohol (blood), .02 gram percent.

* 300 ng/ml individually or in combination.

4740.1090 VARIANCE AND WAIVERS.

A laboratory may request that the department grant a variance or waiver from the provisions of parts 4740.1000 to 4740.1080. A request for a variance or waiver must be submitted to the department in writing. A request must contain the following information:

A. the specific rules for which the variance or waiver is requested;

B. the reasons for the request;

C. the alternative measures that will be taken if a variance or waiver is granted; and

D. the length of time for which the variance or waiver is sought.

The commissioner shall review information submitted with the request for waiver or variance. If the laboratory proposes alternatives equivalent or superior to those prescribed in the rule and shows that strict enforcement of the rule would cause undue hardship, and the variance would not adversely affect public health or safety, the commissioner shall grant the variance, provided however the variance shall not conflict with statutory provisions. The commissioner shall provide the laboratory with a written decision that states the reasons for granting or denying the request for the variance.

Approved
by Revisor _____

STATE OF MINNESOTA
DEPARTMENT OF STATE
FILED

MAY 11 1989

Joan Anderson Growe

Secretary of State

1:55 PM

APPROVED AS TO FORM AND LEGALITY

May 10 19 89

HUBERT H. HUMPHREY, III
ATTORNEY GENERAL

BY Jacquelyn E. Albright
SPECIAL ASSISTANT ATTORNEY GENERAL

AG Copy

Department of Health

Adopted Permanent Rules Relating to General Accreditation Requirements for Laboratories

Rules as Adopted

CHAPTER 4740
DEPARTMENT OF HEALTH
LABORATORIES; ACCREDITATION REQUIREMENTS

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A. the address of the principal place of business or headquarters;

B. the address and phone number of the laboratory that seeks accreditation, if different than in item A;

C. the names of officers and the laboratory director;

D. written assurance that the laboratory meets the standards of parts 4740.0100 to 4740.0170 and the standards that apply to the specific test for which laboratory accreditation is sought, as specified in rule;

E. the signatures of two officers or managing agents of the laboratory and proof of the signatories' authority to bind the laboratory; and

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A. a current laboratory manual;

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A laboratory that meets accreditation application requirements shall receive written provisional accreditation until an on-site inspection is completed. Upon demonstration, through inspections, of compliance with standards specific to the purpose or type of testing for which accreditation is sought, full accreditation shall be granted in writing showing the date of expiration.

4740.0140 TERM OF ACCREDITATION.

Laboratories shall be accredited for a term of one year, which shall include any period of provisional accreditation. Unless a laboratory submits a timely application for renewal of the accreditation, the accreditation expires without notice at the end of the term.

4740.0150 COMPLIANCE.

All accredited laboratories shall immediately inform the

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commissioner of any changes to the information required by part 4740.0120 and the rules specific to the laboratory test for which accreditation is sought. The laboratory director must inform the commissioner in writing of any changes in test methodology, instrumentation, key personnel, or laboratory ownership and submit revisions to the documents listed in part 4740.0120, subpart 3, within 14 calendar days of the change.

4740.0160 ACCREDITATION RENEWAL.

A laboratory shall submit an application for renewal of accreditation with the applicable renewal fee, no later than 30 days before the expiration date of the current accreditation. The renewal application shall contain the same information required for an initial application in part 4740.0120, subpart 2. At the time of application for a renewal of its accreditation, the laboratory shall also submit or have available for inspection the documents listed in part 4740.0120, subpart 3. Unless a laboratory submits a timely application for accreditation renewal, the accreditation expires without further notice at the end of the term.

4740.0170 ACCREDITATION; SUSPENSION AND REVOCATION.

The commissioner may, pursuant to Minnesota Statutes, chapter 14, suspend, revoke, refuse to renew, condition, or limit the accreditation of a laboratory upon finding that the laboratory has ~~repeatedly~~ violated provisions of parts 4740.0100 to 4740.0160 or has ~~repeatedly~~ failed to meet standards defined under the rule applicable to the specific laboratory test for which the laboratory is accredited.

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Department of Health

Proposed Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing

Rules as Proposed (all new material)

DRUG AND ALCOHOL TESTING OF EMPLOYEES

4740.1010 DEFINITIONS.

Subpart 1. **Scope, application.** The following terms used in parts 4740.1020 to 4740.1080 have the meanings given them in this part.

Subp. 2. **Alcohol.** "Alcohol" means ethyl alcohol.

Subp. 3. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 4. **Confirmatory test.** "Confirmatory test" means a drug or alcohol test, run on a sample that was positive on the initial screening test. Techniques for a confirmatory test are described in part 4740.1070, subparts 5 and 6.

Subp. 5. **Department.** "Department" means the Department of Health.

Subp. 6. **Drug.** "Drug" means a controlled substance as defined in Minnesota Statutes, section 152.02, and as updated yearly by rules of the Board of Pharmacy.

Subp. 7. **Employee.** "Employee" means a person, independent contractor, or person working for an independent contractor who performs services for compensation, in whatever form, for an employer.

Subp. 8. **Employer.** "Employer" means a person or entity located or doing business in this state and having one or more employees, and includes the state of Minnesota and all political or other governmental subdivisions of the state.

Subp. 9. **Initial screening test.** "Initial screening test" means a drug or alcohol test that can detect the presumptive presence of a drug, drug metabolite, or alcohol in a sample. Techniques for an initial screening test are described in part

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4740.1070, subparts 5 and 6.

Subp. 10. **Job applicant.** "Job applicant" means a person, independent contractor, or person working for an independent contractor who applies to become an employee of an employer, and includes a person who has received a job offer that is contingent on the person passing drug or alcohol testing.

Subp. 11. **Laboratory.** "Laboratory" means a person, corporation, or other entity, including a governmental entity, that examines, analyzes, or tests samples.

Subp. 12. **NCCLS.** "NCCLS" means the National Committee for Clinical Laboratory Standards, Villanova, Pennsylvania.

Subp. 13. **NIDA.** "NIDA" means the National Institute for Drug Abuse, of the Alcohol, Drug Abuse, and Mental Health Administration, United States Health and Human Services Department.

Subp. 14. **Positive test result.** "Positive test result" means a finding of the presence of drugs, alcohol, or their metabolites in the sample tested by a confirmatory test in levels at or above the threshold detection levels set by the commissioner under part 4740.1080.

Subp. 15. **Presumptive presence.** "Presumptive presence" means some indication of the presence of a drug, drug metabolite, or alcohol that, in the judgment of the laboratory director or the laboratory director's designee, provides a reasonable basis for conducting a confirmatory test. The presumptive presence of a drug, drug metabolite, or alcohol is not a positive test result.

Subp. 16. **Sample.** "Sample" means a substance derived from a nonhuman source and collected for the purpose of analysis or a tissue, blood, excretion, or other bodily fluid specimen obtained from a human for the detection of a chemical, etiologic agent, or histologic abnormality.

Subp. 17. **Threshold detection level.** "Threshold detection level" means that level at which a drug, drug metabolite, or alcohol could reasonably be expected to be detected in a sample by a confirmatory test.

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4740.1020 LICENSE REQUIRED FOR LABORATORIES PERFORMING DRUG AND ALCOHOL TESTING FOR EMPLOYERS.

A laboratory that performs drug and alcohol laboratory tests of employees and job applicants for Minnesota employers must possess a valid license to do so. A laboratory must obtain a license according to the procedures in parts 4740.0100 to 4740.0170, as proposed at .. State Register .... and as subsequently adopted. In addition to the information required on an application for a license, a laboratory that performs only initial drug and alcohol screening tests must disclose on its application the name of the licensed laboratory that performs its confirmatory tests.

4740.1025 EXCEPTION.

A medical clinic, hospital, or other medical facility need not be licensed under parts 4740.1010 to 4740.1080 to perform a breath test as an initial screening test for alcohol if:

A. the medical clinic, hospital, or other medical facility is not owned or operated by the employer; and

B. the results of the breath test are confirmed by a blood test performed by a laboratory licensed under parts 4740.1010 to 4740.1080.

4740.1040 RECIPROCITY.

A license shall be granted to a laboratory located in another state, if the requirements of Minnesota Statutes, section 181.953, subdivision 1, paragraph (c), are met.

4740.1050 TERM OF LICENSE.

Laboratories shall be licensed for a term of one year beginning on July 1 and ending June 30. Unless a laboratory submits a timely application for license renewal, the license expires without further notice at the end of the term.

4740.1060 FEES.

Subpart 1. **Annual license fee required.** The laboratory must pay an annual license fee with the initial application for

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license and with each renewal application. The amount of the fee is determined under subpart 3. It is based upon the number of samples taken from Minnesota employees, that the laboratory tests.

Subp. 2. **Information required to determine fee.** The laboratory must submit an estimate of the number of annual Minnesota employee samples to be tested for drugs and alcohol with the application for a license or license renewal. The laboratory must submit to the department quarterly reports of the volume of actual employee drug and alcohol testing samples and the results of proficiency testing results for the past quarter. The statistics from these reports are used to adjust the license fee collected from the laboratory on its next license renewal application to reflect actual sample volume.

Subp. 3. **License fee schedule.** Annual license fees are determined according to the following schedule:

$$\text{License fee} = (a)\ \$1{,}200 + (b)\left[\frac{\text{Total annual alcohol samples taken from Minnesota employees} + \text{Total annual drug samples taken from Minnesota employees}}{2}\right] \times \$3/\text{sample}$$

A sample obtained for both alcohol and drug testing is considered as one alcohol sample and one drug sample for fee purposes. The $1,200 in part (a) of the schedule is nonrefundable.

Laboratories located outside Minnesota are assessed actual cost of additional labor, travel, and lodging expenses the department incurs in the laboratory inspection.

4740.1065 ANNUAL INSPECTION.

The commissioner shall conduct periodic inspections of laboratories licensed for drug and alcohol testing of employees. Inspections shall be unannounced and occur at least annually.

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4740.1070 PERFORMANCE METHODS REQUIRED FOR ISSUANCE OF A LICENSE.

Subpart 1. **Standards required.** To qualify for a license to conduct drug and alcohol testing for Minnesota employees and job applicants, the officers or the owner of a laboratory must use the performance methods described in subparts 2 to 8.

Subp. 2. **Test samples.** The usual sample for drug testing is freshly voided urine. A breath, urine, or blood sample may be used for initial screening tests. When the breath test is used as the initial screening test for alcohol, a blood sample shall be obtained for the confirmatory test. The blood sample shall be collected immediately after the breath test. When an initial positive urine test indicates the presence of drugs, a blood test may be used for the confirmatory test.

The sample volume must be adequate to allow for the initial screening test, a confirmatory test, and a confirmatory retest.

Subp. 3. **Collection of urine samples; procedures.** The laboratory must have written procedures for collecting urine samples. The collection procedures must contain paragraphs 6 and 11 to 16 of the specimen collection procedures in Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies, NIDA, as provided by the Federal Register, volume 52, pages 30639 and 30640, Friday, August 14, 1987. Paragraphs 1 to 5 and 7 to 10 of these procedures are optional. The site where the sample is collected must have a stall or partitioned area that allows the individual being tested to provide the individual's urine specimen in privacy. The collection site person must sign and date either the tape sealing the sample container or the sample container label.

Subp. 4. **Collection of blood samples; procedures.** The laboratory must have written procedures for collection of blood samples. The procedure must address identification of the employee or job applicant, necessary collection supplies, seating or positioning of the employee or job applicant during sample collection, cleansing of the skin at the venipuncture site, and verification that the sample and paperwork are from

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the individual from which the sample was collected. NCCLS Guidelines H3-A2, Procedures for Collection of Diagnostic Blood Specimens by Venipuncture, 2nd Edition, Approved Standard, 1984, is an acceptable guide for the collection of blood samples. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford Building, 117 University Avenue, Saint Paul, Minnesota 55155.

The collection site person must sign either the tape sealing the sample container or the sample container label.

Subp. 5. **Techniques for drug testing.** For an initial screening test for drugs or drug metabolites, the laboratory must use a chromatographic technique or an immunoassay method. Samples that show the presumptive presence of a drug or drug metabolite must be confirmed by the gas chromatography/mass spectrometry (GC/MS) technique.

Subp. 6. **Techniques for alcohol testing.** A breath test, alcohol dehydrogenase reaction, microdiffusion, or oxidation of distillate with potassium dichromate may be used as a method to initially test for the presence of alcohol. The presumptive presence of alcohol must be confirmed using gas chromatography.

Subp. 7. **Confirmatory tests required.** A laboratory that performs only initial testing must obtain confirmatory results from a licensed laboratory that performs confirmatory tests.

Subp. 8. **Chain-of-custody procedures for handling samples.** The laboratory must follow written chain-of-custody procedures that, at a minimum, meet the requirements of items A to C.

A. Possession of a sample must be traceable to the employee from whom the sample is collected, from the time the sample is collected through the time the sample is tested, the test result reported, the sample retested, and the sample stored.

B. At all times, the sample must be in the possession of, in view of, or placed in a secured area by a person authorized to handle the sample.

C. A sample must be accompanied by a written chain-of-custody record. Individuals relinquishing or accepting

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possession of the sample must record the time the possession of the sample was transferred and must sign and date the chain-of-custody record at the time of transfer.

Subp. 9. **Storage of positive samples.** All confirmed positive samples shall be stored frozen for at least six months. The sample container must be sealed and labeled. The freezer must be locked or be located in a secure area.

Subp. 10. **Requirements for directors.** The director of the laboratory must be a full-time employee of the laboratory, must possess a doctoral or a master's degree in a biological or medical science, and must have at least three years' experience in an analytical toxicology laboratory.

Subp. 11. **Proficiency testing required.** Satisfactory participation in a proficiency testing program is required of a laboratory applying for or renewing a license. The Forensic Urine Drug Testing surveys conducted by the College of American Pathologists and the American Association for Clinical Chemistry and the NIDA Performance Test Program are acceptable proficiency testing programs. The laboratory must participate at the appropriate screening and confirmatory test levels for which an application for license is submitted.

Subp. 12. **Procedures for proficiency testing.** Before applying for or renewing a license, a laboratory must participate in and report the results of three cycles of proficiency testing. The laboratory must mail proficiency testing results to the commissioner.

The procedures for handling and testing proficiency test samples after receipt by the laboratory must be identical to the procedures for normal laboratory samples.

Laboratory personnel shall not be informed that these samples are part of a performance test to the extent possible.

A licensed laboratory may also be subjected to blind proficiency testing. Performance on blind testing samples is required at the same level as for the open proficiency testing.

A false-positive result from a confirmatory test sample is unsatisfactory performance. Two false-positive results from a

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screening test sample during a one-year period constitute unsatisfactory performance. The laboratory must inform the commissioner, in writing, of any false-positive test result on a proficiency testing sample, with a plan of corrective action. The commissioner will be informed within 14 days of receipt of the proficiency testing report.

Subp. 13. **Laboratory procedure manual.** The laboratory must possess and follow a laboratory procedure manual. The laboratory manual must describe the individual test procedures performed by the laboratory. The manual must have a table of contents and numbered pages. The manual must be reviewed annually. The description of the test procedures must include sections addressing the sample used for the test, reagents, supplies and materials, equipment calibration, quality control, the step-by-step procedure, calculations, reporting results, special notes, safety precautions, limitations of the procedure, references, and flow diagrams. Changes in a procedure must be reviewed and dated. Clinical Laboratory Procedure Manuals; Approved Guidelines, GP2-A, National Committee for Clinical Laboratory Standards, 1984, is an acceptable guide to writing a laboratory manual. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford Building, 117 University Avenue, Saint Paul, Minnesota 55155.

4740.1080 THRESHOLD DETECTION LEVELS.

Threshold detection levels for confirmatory tests of drugs and drug metabolites defined in Minnesota Statutes, section 152.02, and rules of the Board of Pharmacy are 1,000 ng/ml, except as listed in items A to K:

A. marijuana metabolite (delta-9 tetrahydrocannabinol-9-carboxylic acid), 15 ng/ml;

B. cocaine, 150 ng/ml;

C. benzoylecgonine, 150 ng/ml;

D. opiates, 300 ng/ml;

E. phencyclidine, 25 ng/ml;

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F. amphetamines, 500 ng/ml;

G. fentanyl, 5 ng/ml;

H. lysergic acid diethylamide (LSD), 5 ng/ml;

I. 3-4-methylenedioxy amphetamine (MDA), 300 ng/ml;

J. alcohol (urine), .02 gram percent; and

K. alcohol (blood), .02 gram percent.

4740.1090 VARIANCE AND WAIVERS.

A laboratory may request that the department grant a variance or waiver from the provisions of parts 4740.1000 to 4740.1080. A request for a variance or waiver must be submitted to the department in writing. A request must contain the following information:

A. the specific rules for which the variance or waiver is requested;

B. the reasons for the request;

C. the alternative measures that will be taken if a variance or waiver is granted; and

D. the length of time for which the variance or waiver is sought.

The commissioner shall review information submitted with the request for waiver or variance. The commissioner shall provide the laboratory with a written decision that states the reasons for granting or denying the request for the variance.

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Office of the Revisor of Statutes

Administrative Rules

TITLE: Proposed Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing

AGENCY: Department of Health

MINNESOTA RULES: Chapter 4740

INCORPORATIONS BY REFERENCE:

Rule Number: 4740.1070, subpart 4
Material Incorporated: NCCLS Guidelines H3-A2, Procedures for Collection of Diagnostic Blood Specimens by Venipuncture, 2nd Edition, Approved Standard, 1984.

Rule Number: 4740.1070, subpart 13
Material Incorporated: Clinical Laboratory Procedure Manuals; Approved Guidelines, GP2-A, National Committee for Clinical Laboratory Standards, 1984.

The attached rules are approved for publication in the State Register

Kathleen M. Traxler
Assistant Revisor

Department of Health

Adopted Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing

Rules as Adopted

DRUG AND ALCOHOL TESTING OF EMPLOYEES

4740.1010 DEFINITIONS.

Subpart 1. **Scope, application.** The following terms used in parts 4740.1020 to 4740.1080 have the meanings given them in this part.

Subp. 2. **Alcohol.** "Alcohol" means ethyl alcohol.

Subp. 3. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 4. **Confirmatory test.** "Confirmatory test" means a drug or alcohol test, run on a sample that was positive on the initial screening test. Techniques for a confirmatory test are described in part 4740.1070, subparts 5 and 6.

Subp. 5. **Department.** "Department" means the Department of Health.

Subp. 6. **Drug.** "Drug" means a controlled substance as defined in Minnesota Statutes, section 152.02, and as updated yearly by rules of the Board of Pharmacy.

Subp. 7. **Employee.** "Employee" means a person, independent contractor, or person working for an independent contractor who performs services for compensation, in whatever form, for an employer.

Subp. 8. **Employer.** "Employer" means a person, independent contractor, or entity located or doing business in this state and having one or more employees, and includes the state of Minnesota and all political or other governmental subdivisions of the state.

Subp. 9. **Initial screening test.** "Initial screening test" means a drug or alcohol test ~~that can detect the~~, the results of which indicate presumptive presence of a drug, drug metabolite,

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or alcohol in a sample. Techniques for an initial screening test are described in part 4740.1070, subparts 5 and 6.

Subp. 10. **Initial screening test minimum detection level.** "Initial screening test minimum detection level" means the level at which a laboratory is capable of detecting a drug or drug metabolite using a screening test. The values are derived from the NIDA initial cutoff levels in Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines; Notice, paragraph 2.4(e)(1), as provided by the Federal Register, Volume 53, Number 69, page 11983, Monday, April 11, 1988.

Subp. 11. **Job applicant.** "Job applicant" means a person, independent contractor, or person working for an independent contractor who applies to become an employee of an employer, and includes a person who has received a job offer that is contingent on the person passing drug or alcohol testing.

Subp. ~~11.~~ 12. **Laboratory.** "Laboratory" means a person, corporation, or other entity, including a governmental entity, that examines, analyzes, or tests samples.

Subp. ~~12.~~ 13. **NCCLS.** "NCCLS" means the National Committee for Clinical Laboratory Standards, Villanova, Pennsylvania.

Subp. ~~13.~~ 14. **NIDA.** "NIDA" means the National Institute ~~for~~ on Drug Abuse, of the Alcohol, Drug Abuse, and Mental Health Administration, United States Health and Human Services Department.

Subp. ~~14.~~ 15. **Positive test result.** "Positive test result" means a finding of the presence of drugs, alcohol, or their metabolites in the sample tested by a confirmatory test in levels at or above the threshold detection levels set by the commissioner under part 4740.1080.

Subp. ~~15.~~ 16. **Presumptive presence.** "Presumptive presence" means some indication of the presence of a drug, drug metabolite, or alcohol that, in the judgment of the laboratory director or the laboratory director's designee, provides a reasonable basis for conducting a confirmatory test. The presumptive presence of a drug, drug metabolite, or alcohol is

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not a positive test result.

Subp. ~~16.~~ 17. **Sample.** "Sample" means a substance derived from a nonhuman source and collected for the purpose of analysis or a tissue, blood, excretion, or other bodily fluid specimen obtained from a human for the detection of a chemical, etiologic agent, or histologic abnormality.

Subp. ~~17.~~ 18. **Threshold detection level.** "Threshold detection level" means ~~that~~ the level at which the presence of a drug, drug metabolite, or alcohol ~~could~~ can be reasonably ~~be~~ expected to be detected ~~in a sample~~ by a confirmatory test performed by a laboratory that meets the standards of parts 4740.1010 to 4740.1090. The threshold detection level is neither meant to indicate impairment nor any relationship between the time of the test and the time of use of a drug or alcohol by the employee or applicant. The threshold detection level simply indicates the level at which a valid conclusion can be drawn that the drug or alcohol is present in the employee's or applicant's sample.

4740.1020 LICENSE REQUIRED FOR LABORATORIES PERFORMING DRUG AND ALCOHOL TESTING FOR EMPLOYERS.

A laboratory that performs drug and alcohol laboratory tests of employees and job applicants for Minnesota employers must possess a valid license to do so. A laboratory must obtain a license according to the procedures in parts 4740.0100 to 4740.0170, as proposed at 13 State Register 1079 and as subsequently adopted. In addition to the information required on an application for a license, a laboratory that performs only initial drug and alcohol screening tests must disclose on its application the name of the licensed laboratory that performs its confirmatory tests.

4740.1025 EXCEPTION.

A medical clinic, hospital, or other medical facility need not be licensed under parts 4740.1010 to 4740.1080 to perform a breath test as an initial screening test for alcohol if:

A. the medical clinic, hospital, or other medical

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facility is not owned or operated by the employer; and

B. the results of the breath test are confirmed by a blood test performed by a laboratory licensed under parts 4740.1010 to 4740.1080.

4740.1040 RECIPROCITY.

A license shall be granted to a laboratory located in another state, if the requirements of Minnesota Statutes, section 181.953, subdivision 1, paragraph (c), are met.

4740.1050 TERM OF LICENSE.

Laboratories shall be licensed for a term of one year ~~beginning on July 1 and ending June 30~~. Unless a laboratory submits a timely application for license renewal, the license expires without further notice at the end of the term.

4740.1060 FEES.

Subpart 1. **Annual license fee required.** The laboratory must pay an annual license fee and other required costs with the initial application for license and with each renewal application. The amount of the fee and other required costs is determined under subpart 3. ~~It is based upon the number of samples taken from Minnesota employees, that the laboratory tests.~~ A laboratory must pay the fees and costs required under this part before a license is issued.

Subp. 2. **Information required to determine fee.** The laboratory must submit an estimate of the ~~number of annual Minnesota employee samples to be tested for drugs and alcohol~~ laboratory annual receipts during the current accounting year with the application for a license or license renewal. The laboratory must submit to the department quarterly reports of the ~~volume of actual employee drug and alcohol testing samples~~ laboratory annual receipts and the results of proficiency testing results for the past quarter. The statistics from these reports are used to adjust the license fee collected from the laboratory on its next license renewal application to reflect actual ~~sample volume~~ laboratory annual receipts.

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Subp. 3. **License fee schedule.** The annual license ~~fees are determined according to the following schedule:~~ fee is made up of an application fee and inspection fee as described in items A and B. The fees are nonrefundable.

~~License fee = (a) $1,200 + (b) Total annual alcohol samples taken from Minnesota employees / 2 + Total annual drug samples taken from Minnesota employees x $3/sample~~

~~A sample obtained for both alcohol and drug testing is considered as one alcohol sample and one drug sample for fee purposes. The $1,200 in part (a) of the schedule is nonrefundable.~~

A. The application fee is determined as follows:

Laboratory Annual Receipts	License fee
less than $500,000	$ 600
$500,000 to $2,000,000	1,200
$2 million to $10 million	1,800
more than $10 million	2,400; and

B. The inspection fee is $1,200 per year per lab.

C. Laboratories located outside Minnesota are assessed actual cost of additional labor, travel, and lodging expenses the department incurs in the laboratory inspection.

4740.1065 ANNUAL INSPECTION.

The commissioner shall conduct periodic inspections of laboratories licensed for drug and alcohol testing of employees. Inspections ~~shall~~ may be unannounced and occur at least annually.

4740.1070 PERFORMANCE METHODS REQUIRED FOR ISSUANCE OF A LICENSE.

Subpart 1. **Standards required.** To qualify for a license to conduct drug and alcohol testing for Minnesota employees and job applicants, the officers or the owner of a laboratory must use the performance methods described in subparts 2 to 8.

Subp. 2. **Test samples.** The usual sample for drug testing

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is freshly voided urine. A breath, urine, or blood sample may be used for initial screening tests. When the breath test is used as the initial screening test for alcohol, a blood sample shall be obtained for the confirmatory test. The blood sample shall be collected immediately after the breath test. When an initial positive urine test indicates the presence of drugs, a blood ~~test may~~ or urine sample shall be used for the confirmatory test.

Confusing - is this another urine test?

The sample volume must be adequate to allow for the initial screening test, a confirmatory test, and a confirmatory retest.

Subp. 3. **Collection of urine samples; procedures.** The laboratory must have written procedures for collecting urine samples. The collection procedures must contain paragraphs 6 and 11 to 16 of the specimen collection procedures in Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies, NIDA, as provided by the Federal Register, volume 52, pages 30639 and 30640, Friday, August 14, 1987. Paragraphs 1 to 5 and 7 to 10 of these procedures are optional. The site where the sample is collected must have a stall or partitioned area that allows the individual being tested to provide the individual's urine specimen in privacy. The collection site person must sign and date either the tape sealing the sample container or the sample container label.

Subp. 4. **Collection of blood samples; procedures.** The laboratory must have written procedures for collection of blood samples. The procedure must address identification of the employee or job applicant, necessary collection supplies, seating or positioning of the employee or job applicant during sample collection, cleansing of the skin at the venipuncture site, and verification that the sample and paperwork are from the individual from which the sample was collected. NCCLS Guidelines H3-A2, Procedures for Collection of Diagnostic Blood Specimens by Venipuncture, 2nd Edition, Approved Standard, 1984, is an acceptable guide for the collection of blood samples. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford

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Building, 117 University Avenue, Saint Paul, Minnesota 55155.

The collection site person must sign either the tape sealing the sample container or the sample container label.

Subp. 5. **Techniques for drug testing.** For an initial screening test for drugs or drug metabolites, the laboratory must use a chromatographic technique or an immunoassay method. Samples that show the presumptive presence of a drug or drug metabolite must be confirmed by the gas chromatography/mass spectrometry (GC/MS) technique.

Subp. 6. **Techniques for alcohol testing.** A breath test, alcohol dehydrogenase reaction, microdiffusion, or oxidation of distillate with potassium dichromate may be used as a method to initially test for the presence of alcohol. The presumptive presence of alcohol must be confirmed using gas chromatography.

Subp. 7. **Confirmatory tests required.** A laboratory that performs only initial testing must obtain confirmatory results from a licensed laboratory that performs confirmatory tests.

Subp. 8. **Chain-of-custody procedures for handling samples.** The laboratory must follow written chain-of-custody procedures that, at a minimum, meet the requirements of items A to C.

A. Possession of a sample must be traceable to the employee from whom the sample is collected, from the time the sample is collected through the time the sample is tested, the test result reported, the sample retested, and the sample stored.

B. At all times, the sample must be in the possession of, in view of, or placed in a secured area by a person authorized to handle the sample.

C. A sample must be accompanied by a written chain-of-custody record. Individuals relinquishing or accepting possession of the sample must record the time the possession of the sample was transferred and must sign and date the chain-of-custody record at the time of transfer.

Subp. 9. **Storage of positive samples.** All confirmed positive samples shall be stored frozen for at least six months. The sample container must be sealed and labeled. The

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freezer must be locked or be located in a secure area.

Subp. 10. **Requirements for directors.** The director of the laboratory must be a full-time employee of the laboratory, must possess a doctoral, medical doctor, or a master's degree in a biological or medical science, and must have at least three years' experience in an analytical toxicology laboratory.

Subp. 11. **Proficiency testing required.** Satisfactory participation in a proficiency testing program is required of a laboratory applying for or renewing a license. The Forensic Urine Drug Testing surveys conducted by the College of American Pathologists and the American Association for Clinical Chemistry and the NIDA Performance Test Program are acceptable proficiency testing programs. The laboratory must participate at the appropriate screening and confirmatory test levels for which an application for license is submitted.

Subp. 12. **Procedures for proficiency testing.** Before applying for or renewing a license, a laboratory must participate in and report the results of three cycles of proficiency testing. The laboratory must mail proficiency testing results to the commissioner.

The procedures for handling and testing proficiency test samples after receipt by the laboratory must be identical to the procedures for normal laboratory samples.

Laboratory personnel shall not be informed that these samples are part of a performance test to the extent possible.

A licensed laboratory may also be subjected to blind proficiency testing. Performance on blind testing samples is required at the same level as for the open proficiency testing.

A false-positive result from a confirmatory test sample is unsatisfactory performance. Two false-positive results from a screening test sample during a one-year period constitute unsatisfactory performance. The laboratory must inform the commissioner, in writing, of any false-positive test result on a proficiency testing sample, with a plan of corrective action. The commissioner will be informed within 14 days of receipt of the proficiency testing report.

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Subp. 13. **Laboratory procedure manual.** The laboratory must possess and follow a laboratory procedure manual. The laboratory manual must describe the individual test procedures performed by the laboratory. The manual must have a table of contents and numbered pages. The manual must be reviewed annually. The description of the test procedures must include sections addressing the sample used for the test, reagents, supplies and materials, equipment calibration, quality control, the step-by-step procedure, calculations, reporting results, special notes, safety precautions, limitations of the procedure, references, and flow diagrams. Changes in a procedure must be reviewed and dated. Clinical Laboratory Procedure Manuals; Approved Guidelines, GP2-A, National Committee for Clinical Laboratory Standards, 1984, is an acceptable guide to writing a laboratory manual. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford Building, 117 University Avenue, Saint Paul, Minnesota 55155.

4740.1075 INITIAL SCREENING TEST; MINIMUM DETECTION LEVELS.

The minimum levels that need to be detectable by a screening test are as follows:

A. marijuana metabolites, 100 ng/ml;

B. cocaine metabolites, 300 ng/ml;

C. opiate metabolites, 300 ng/ml;

D. phencyclidine, 25 ng/ml; and

E. amphetamines, 1,000 ng/ml.

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4740.1080 THRESHOLD DETECTION LEVELS.

Threshold detection levels for confirmatory tests of drugs and drug metabolites defined in Minnesota Statutes, section 152.02, and rules of the Board of Pharmacy are 1,000 ng/ml, except as listed in items A to K:

A. marijuana metabolite (delta-9 tetrahydrocannabinol-9-carboxylic acid), 15 ng/ml;

B. cocaine~~, 150 ng/ml;~~

~~C.~~ metabolite (benzoylecgonine), 150 ng/ml;

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~~D.~~ C. opiates~~, 300 ng/ml~~:

(1) morphine, 300 ng/ml*; and

(2) codeine, 300 ng/ml*;

~~E.~~ D. phencyclidine, 25 ng/ml;

~~F.~~ E. amphetamines, 500 ng/ml;

~~G.~~ F. fentanyl, 5 ng/ml;

~~H.~~ G. lysergic acid diethylamide (LSD), 5 ng/ml;

~~I.~~ H. 3-4-methylenedioxy amphetamine (MDA), 300 ng/ml;

~~J.~~ I. alcohol (urine), .02 gram percent; and

~~K.~~ J. alcohol (blood), .02 gram percent.

* 300 ng/ml individually or in combination.

4740.1090 VARIANCE AND WAIVERS.

A laboratory may request that the department grant a variance or waiver from the provisions of parts 4740.1000 to 4740.1080. A request for a variance or waiver must be submitted to the department in writing. A request must contain the following information:

A. the specific rules for which the variance or waiver is requested;

B. the reasons for the request;

C. the alternative measures that will be taken if a variance or waiver is granted; and

D. the length of time for which the variance or waiver is sought.

The commissioner shall review information submitted with the request for waiver or variance. The commissioner shall provide the laboratory with a written decision that states the reasons for granting or denying the request for the variance.

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Department of Health

Adopted Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing

Rules as Adopted

DRUG AND ALCOHOL TESTING OF EMPLOYEES

4740.1010 DEFINITIONS.

Subpart 1. **Scope, application.** The following terms used in parts 4740.1020 to 4740.1080 have the meanings given them in this part.

Subp. 2. **Alcohol.** "Alcohol" means ethyl alcohol.

Subp. 3. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 4. **Confirmatory test.** "Confirmatory test" means a drug or alcohol test, run on a sample that was positive on the initial screening test. Techniques for a confirmatory test are described in part 4740.1070, subparts 5 and 6.

Subp. 5. **Department.** "Department" means the Department of Health.

Subp. 6. **Drug.** "Drug" means a controlled substance as defined in Minnesota Statutes, section 152.02, and as updated yearly by rules of the Board of Pharmacy.

Subp. 7. **Employee.** "Employee" means a person, independent contractor, or person working for an independent contractor who performs services for compensation, in whatever form, for an employer.

Subp. 8. **Employer.** "Employer" means a person, independent contractor, or entity located or doing business in this state and having one or more employees, and includes the state of Minnesota and all political or other governmental subdivisions of the state.

Subp. 9. **Initial screening test.** "Initial screening test" means a drug or alcohol test ~~that can detect the~~, the results of which indicate presumptive presence of a drug, drug metabolite,

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not a positive test result.

Subp. ~~16.~~ 17. **Sample.** "Sample" means a substance derived from a nonhuman source and collected for the purpose of analysis or a tissue, blood, excretion, or other bodily fluid specimen obtained from a human for the detection of a chemical, etiologic agent, or histologic abnormality.

Subp. ~~17.~~ 18. **Threshold detection level.** "Threshold detection level" means ~~that~~ the level at which the presence of a drug, drug metabolite, or alcohol ~~could~~ can be reasonably ~~be~~ expected to be detected ~~in a sample~~ by a confirmatory test performed by a laboratory that meets the standards of parts 4740.1010 to 4740.1090. The threshold detection level is neither meant to indicate impairment nor any relationship between the time of the test and the time of use of a drug or alcohol by the employee or applicant. The threshold detection level simply indicates the level at which a valid conclusion can be drawn that the drug or alcohol is present in the employee's or applicant's sample.

4740.1020 LICENSE REQUIRED FOR LABORATORIES PERFORMING DRUG AND ALCOHOL TESTING FOR EMPLOYERS.

A laboratory that performs drug and alcohol laboratory tests of employees and job applicants for Minnesota employers must possess a valid license to do so. A laboratory must obtain a license according to the procedures in parts 4740.0100 to 4740.0170, as proposed at 13 State Register 1079 and as subsequently adopted. In addition to the information required on an application for a license, a laboratory that performs only initial drug and alcohol screening tests must disclose on its application the name of the licensed laboratory that performs its confirmatory tests.

4740.1025 EXCEPTION.

A medical clinic, hospital, or other medical facility need not be licensed under parts 4740.1010 to 4740.1080 to perform a breath test as an initial screening test for alcohol if:

A. the medical clinic, hospital, or other medical

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Subp. 3. **License fee schedule.** The annual license ~~fees are determined according to the following schedule:~~ fee is made up of an application fee and inspection fee as described in items A and B. The fees are nonrefundable.

~~License fee = (a) $1,200 +~~

~~(b) Total annual alcohol samples + drug samples x $3/sample~~

~~taken from Minnesota employees~~

~~2~~

~~A sample obtained for both alcohol and drug testing is considered as one alcohol sample and one drug sample for fee purposes. The $1,200 in part (a) of the schedule is nonrefundable.~~

A. The application fee is determined as follows:

Laboratory Annual Receipts	License fee
less than $500,000	$ 600
$500,000 to $2,000,000	1,200
$2 million to $10 million	1,800
more than $10 million	2,400; and

B. The inspection fee is $1,200 per year per lab.

C. Laboratories located outside Minnesota are assessed actual cost of additional labor, travel, and lodging expenses the department incurs in the laboratory inspection.

4740.1065 ANNUAL INSPECTION.

The commissioner shall conduct periodic inspections of laboratories licensed for drug and alcohol testing of employees. Inspections ~~shall~~ may be unannounced and occur at least annually.

4740.1070 PERFORMANCE METHODS REQUIRED FOR ISSUANCE OF A LICENSE.

Subpart 1. **Standards required.** To qualify for a license to conduct drug and alcohol testing for Minnesota employees and job applicants, the officers or the owner of a laboratory must use the performance methods described in subparts 2 to 8.

Subp. 2. **Test samples.** The usual sample for drug testing

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is freshly voided urine. A breath, urine, or blood sample may be used for initial screening tests. When the breath test is used as the initial screening test for alcohol, a blood sample shall be obtained for the confirmatory test. The blood sample shall be collected immediately after the breath test. When an initial positive urine test indicates the presence of drugs, a blood ~~test may~~ or urine sample shall be used for the confirmatory test.

The sample volume must be adequate to allow for the initial screening test, a confirmatory test, and a confirmatory retest.

Subp. 3. **Collection of urine samples; procedures.** The laboratory must have written procedures for collecting urine samples. The collection procedures must contain paragraphs 6 and 11 to 16 of the specimen collection procedures in Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies, NIDA, as provided by the Federal Register, volume 52, pages 30639 and 30640, Friday, August 14, 1987. Paragraphs 1 to 5 and 7 to 10 of these procedures are optional. The site where the sample is collected must have a stall or partitioned area that allows the individual being tested to provide the individual's urine specimen in privacy. The collection site person must sign and date either the tape sealing the sample container or the sample container label.

Subp. 4. **Collection of blood samples; procedures.** The laboratory must have written procedures for collection of blood samples. The procedure must address identification of the employee or job applicant, necessary collection supplies, seating or positioning of the employee or job applicant during sample collection, cleansing of the skin at the venipuncture site, and verification that the sample and paperwork are from the individual from which the sample was collected. NCCLS Guidelines H3-A2, Procedures for Collection of Diagnostic Blood Specimens by Venipuncture, 2nd Edition, Approved Standard, 1984, is an acceptable guide for the collection of blood samples. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford

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Building, 117 University Avenue, Saint Paul, Minnesota 55155.

The collection site person must sign either the tape sealing the sample container or the sample container label.

Subp. 5. **Techniques for drug testing.** For an initial screening test for drugs or drug metabolites, the laboratory must use a chromatographic technique or an immunoassay method. Samples that show the presumptive presence of a drug or drug metabolite must be confirmed by the gas chromatography/mass spectrometry (GC/MS) technique.

Subp. 6. **Techniques for alcohol testing.** A breath test, alcohol dehydrogenase reaction, microdiffusion, or oxidation of distillate with potassium dichromate may be used as a method to initially test for the presence of alcohol. The presumptive presence of alcohol must be confirmed using gas chromatography.

Subp. 7. **Confirmatory tests required.** A laboratory that performs only initial testing must obtain confirmatory results from a licensed laboratory that performs confirmatory tests.

Subp. 8. **Chain-of-custody procedures for handling samples.** The laboratory must follow written chain-of-custody procedures that, at a minimum, meet the requirements of items A to C.

A. Possession of a sample must be traceable to the employee from whom the sample is collected, from the time the sample is collected through the time the sample is tested, the test result reported, the sample retested, and the sample stored.

B. At all times, the sample must be in the possession of, in view of, or placed in a secured area by a person authorized to handle the sample.

C. A sample must be accompanied by a written chain-of-custody record. Individuals relinquishing or accepting possession of the sample must record the time the possession of the sample was transferred and must sign and date the chain-of-custody record at the time of transfer.

Subp. 9. **Storage of positive samples.** All confirmed positive samples shall be stored frozen for at least six months. The sample container must be sealed and labeled. The

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freezer must be locked or be located in a secure area.

Subp. 10. **Requirements for directors.** The director of the laboratory must be a full-time employee of the laboratory, must possess a doctoral, medical doctor, or a master's degree in a biological or medical science, and must have at least three years' experience in an analytical toxicology laboratory.

Subp. 11. **Proficiency testing required.** Satisfactory participation in a proficiency testing program is required of a laboratory applying for or renewing a license. The Forensic Urine Drug Testing surveys conducted by the College of American Pathologists and the American Association for Clinical Chemistry and the NIDA Performance Test Program are acceptable proficiency testing programs. The laboratory must participate at the appropriate screening and confirmatory test levels for which an application for license is submitted.

Subp. 12. **Procedures for proficiency testing.** Before applying for or renewing a license, a laboratory must participate in and report the results of three cycles of proficiency testing. The laboratory must mail proficiency testing results to the commissioner.

The procedures for handling and testing proficiency test samples after receipt by the laboratory must be identical to the procedures for normal laboratory samples.

Laboratory personnel shall not be informed that these samples are part of a performance test to the extent possible.

A licensed laboratory may also be subjected to blind proficiency testing. Performance on blind testing samples is required at the same level as for the open proficiency testing.

A false-positive result from a confirmatory test sample is unsatisfactory performance. Two false-positive results from a screening test sample during a one-year period constitute unsatisfactory performance. The laboratory must inform the commissioner, in writing, of any false-positive test result on a proficiency testing sample, with a plan of corrective action. The commissioner will be informed within 14 days of receipt of the proficiency testing report.

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Subp. 13. **Laboratory procedure manual.** The laboratory must possess and follow a laboratory procedure manual. The laboratory manual must describe the individual test procedures performed by the laboratory. The manual must have a table of contents and numbered pages. The manual must be reviewed annually. The description of the test procedures must include sections addressing the sample used for the test, reagents, supplies and materials, equipment calibration, quality control, the step-by-step procedure, calculations, reporting results, special notes, safety precautions, limitations of the procedure, references, and flow diagrams. Changes in a procedure must be reviewed and dated. Clinical Laboratory Procedure Manuals; Approved Guidelines, GP2-A, National Committee for Clinical Laboratory Standards, 1984, is an acceptable guide to writing a laboratory manual. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford Building, 117 University Avenue, Saint Paul, Minnesota 55155.

4740.1075 INITIAL SCREENING TEST; MINIMUM DETECTION LEVELS.

The minimum levels that need to be detectable by a screening test are as follows:

A. marijuana metabolites, 100 ng/ml;

B. cocaine metabolites, 300 ng/ml;

C. opiate metabolites, 300 ng/ml;

D. phencyclidine, 25 ng/ml; and

E. amphetamines, 1,000 ng/ml.

4740.1080 THRESHOLD DETECTION LEVELS.

Threshold detection levels for confirmatory tests of drugs and drug metabolites defined in Minnesota Statutes, section 152.02, and rules of the Board of Pharmacy are 1,000 ng/ml, except as listed in items A to K:

A. marijuana metabolite (delta-9 tetrahydrocannabinol-9-carboxylic acid), 15 ng/ml;

B. cocaine~~,~~ ~~150 ng/ml,~~

~~C.~~ metabolite (benzoylecgonine), 150 ng/ml;

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~~D.~~ C. opiates~~, 300 ng/ml~~:

(1) morphine, 300 ng/ml*; and

(2) codeine, 300 ng/ml*;

~~E.~~ D. phencyclidine, 25 ng/ml;

~~F.~~ E. amphetamines, 500 ng/ml;

~~G.~~ F. fentanyl, 5 ng/ml;

~~H.~~ G. lysergic acid diethylamide (LSD), 5 ng/ml;

~~I.~~ H. 3-4-methylenedioxy amphetamine (MDA), 300 ng/ml;

~~J.~~ I. alcohol (urine), .02 gram percent; and

~~K.~~ J. alcohol (blood), .02 gram percent.

* 300 ng/ml individually or in combination.

4740.1090 VARIANCE AND WAIVERS.

A laboratory may request that the department grant a variance or waiver from the provisions of parts 4740.1000 to 4740.1080. A request for a variance or waiver must be submitted to the department in writing. A request must contain the following information:

A. the specific rules for which the variance or waiver is requested;

B. the reasons for the request;

C. the alternative measures that will be taken if a variance or waiver is granted; and

D. the length of time for which the variance or waiver is sought.

The commissioner shall review information submitted with the request for waiver or variance. The commissioner shall provide the laboratory with a written decision that states the reasons for granting or denying the request for the variance.

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Office of the Revisor of Statutes

Administrative Rules

TITLE: Adopted Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing

AGENCY: Department of Health

MINNESOTA RULES: Chapter 4740

INCORPORATIONS BY REFERENCE:

Rule Number: 4740.1070, subpart 4
Material Incorporated: NCCLS Guidelines H3-A2, Procedures for Collection of Diagnostic Blood Specimens by Venipuncture, 2nd Edition, Approved Standard, 1984.

Rule Number: 4740.1070, subpart 13
Material Incorporated: Clinical Laboratory Procedure Manuals; Approved Guidelines, GP2-A, National Committee for Clinical Laboratory Standards, 1984.

The attached rules are approved for filing with the Secretary of State

Kathleen M. Traxler
Assistant Revisor

Department of Health

Adopted Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing

Rules as Adopted

DRUG AND ALCOHOL TESTING OF EMPLOYEES

4740.1010 DEFINITIONS.

Subpart 1. **Scope, application.** The following terms used in parts 4740.1020 to 4740.1080 have the meanings given them in this part.

Subp. 2. **Alcohol.** "Alcohol" means ethyl alcohol.

Subp. 3. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 4. **Confirmatory test.** "Confirmatory test" means a drug or alcohol test, run on a sample that was positive on the initial screening test. Techniques for a confirmatory test are described in part 4740.1070, subparts 5 and 6.

Subp. 5. **Department.** "Department" means the Department of Health.

Subp. 6. **Drug.** "Drug" means a controlled substance as defined in Minnesota Statutes, section 152.02, and as updated yearly by rules of the Board of Pharmacy.

Subp. 7. **Employee.** "Employee" means a person, independent contractor, or person working for an independent contractor who performs services for compensation, in whatever form, for an employer.

Subp. 8. **Employer.** "Employer" means a person, independent contractor, or entity located or doing business in this state and having one or more employees, and includes the state of Minnesota and all political or other governmental subdivisions of the state.

Subp. 9. **Initial screening test.** "Initial screening test" means a drug or alcohol test ~~that can detect the~~, the results of which indicate presumptive presence of a drug, drug metabolite,

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or alcohol in a sample. Techniques for an initial screening test are described in part 4740.1070, subparts 5 and 6.

Subp. 10. **Initial screening test minimum detection level.** "Initial screening test minimum detection level" means the level at which a laboratory is capable of detecting a drug or drug metabolite using a screening test. The values are derived from the NIDA initial cutoff levels in Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines; Notice, paragraph 2.4(e)(1), as provided by the Federal Register, Volume 53, Number 69, page 11983, Monday, April 11, 1988.

Subp. 11. **Job applicant.** "Job applicant" means a person, independent contractor, or person working for an independent contractor who applies to become an employee of an employer, and includes a person who has received a job offer that is contingent on the person passing drug or alcohol testing.

Subp. ~~11.~~ 12. **Laboratory.** "Laboratory" means a person, corporation, or other entity, including a governmental entity, that examines, analyzes, or tests samples.

Subp. ~~12.~~ 13. **NCCLS.** "NCCLS" means the National Committee for Clinical Laboratory Standards, Villanova, Pennsylvania.

Subp. ~~13.~~ 14. **NIDA.** "NIDA" means the National Institute ~~for~~ on Drug Abuse, of the Alcohol, Drug Abuse, and Mental Health Administration, United States Health and Human Services Department.

Subp. ~~14.~~ 15. **Positive test result.** "Positive test result" means a finding of the presence of drugs, alcohol, or their metabolites in the sample tested by a confirmatory test in levels at or above the threshold detection levels set by the commissioner under part 4740.1080.

Subp. ~~15.~~ 16. **Presumptive presence.** "Presumptive presence" means some indication of the presence of a drug, drug metabolite, or alcohol that, in the judgment of the laboratory director or the laboratory director's designee, provides a reasonable basis for conducting a confirmatory test. The presumptive presence of a drug, drug metabolite, or alcohol is

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not a positive test result.

Subp. ~~16.~~ 17. **Sample.** "Sample" means a substance derived from a nonhuman source and collected for the purpose of analysis or a tissue, blood, excretion, or other bodily fluid specimen obtained from a human for the detection of a chemical, etiologic agent, or histologic abnormality.

Subp. ~~17.~~ 18. **Threshold detection level.** "Threshold detection level" means ~~that~~ the level at which the presence of a drug, drug metabolite, or alcohol ~~could~~ can be reasonably ~~be~~ expected to be detected ~~in a sample~~ by a confirmatory test performed by a laboratory that meets the standards of parts 4740.1010 to 4740.1090. The threshold detection level is neither meant to indicate impairment nor any relationship between the time of the test and the time of use of a drug or alcohol by the employee or applicant. The threshold detection level simply indicates the level at which a valid conclusion can be drawn that the drug or alcohol is present in the employee's or applicant's sample.

4740.1020 LICENSE REQUIRED FOR LABORATORIES PERFORMING DRUG AND ALCOHOL TESTING FOR EMPLOYERS.

A laboratory that performs drug and alcohol laboratory tests of employees and job applicants for Minnesota employers must possess a valid license to do so. A laboratory must obtain a license according to the procedures in parts 4740.0100 to 4740.0170, as proposed at 13 State Register 1079 and as subsequently adopted. In addition to the information required on an application for a license, a laboratory that performs only initial drug and alcohol screening tests must disclose on its application the name of the licensed laboratory that performs its confirmatory tests.

4740.1025 EXCEPTION.

A medical clinic, hospital, or other medical facility need not be licensed under parts 4740.1010 to 4740.1080 to perform a breath test as an initial screening test for alcohol if:

A. the medical clinic, hospital, or other medical

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facility is not owned or operated by the employer; and

B. the results of the breath test are confirmed by a blood test performed by a laboratory licensed under parts 4740.1010 to 4740.1080.

4740.1040 RECIPROCITY.

A license shall be granted to a laboratory located in another state, if the requirements of Minnesota Statutes, section 181.953, subdivision 1, paragraph (c), are met.

4740.1050 TERM OF LICENSE.

Laboratories shall be licensed for a term of one year ~~beginning on July 1 and ending June 30~~. Unless a laboratory submits a timely application for license renewal, the license expires without further notice at the end of the term.

4740.1060 FEES.

Subpart 1. **Annual license fee required.** The laboratory must pay an annual license fee and other required costs with the initial application for license and with each renewal application. The amount of the fee and other required costs is determined under subpart 3. ~~It is based upon the number of samples taken from Minnesota employees, that the laboratory tests.~~ A laboratory must pay the fees and costs required under this part before a license is issued.

Subp. 2. **Information required to determine fee.** The laboratory must submit an estimate of the ~~number of annual Minnesota employee samples to be tested for drugs and alcohol~~ laboratory annual receipts during the current accounting year with the application for a license or license renewal. The laboratory must submit to the department quarterly reports of the ~~volume of actual employee drug and alcohol testing samples~~ laboratory annual receipts and the results of proficiency testing results for the past quarter. The statistics from these reports are used to adjust the license fee collected from the laboratory on its next license renewal application to reflect actual ~~sample volume~~ laboratory annual receipts.

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Subp. 3. **License fee schedule.** The annual license ~~fees are determined according to the following schedule:~~ fee is made up of an application fee and inspection fee as described in items A and B. The fees are nonrefundable.

~~License fee = (a) $1,200 + (b) Total annual alcohol samples taken from Minnesota employees + drug samples taken from Minnesota employees / 2 x $3/sample~~

~~A sample obtained for both alcohol and drug testing is considered as one alcohol sample and one drug sample for fee purposes. The $1,200 in part (a) of the schedule is nonrefundable.~~

A. The application fee is determined as follows:

Laboratory Annual Receipts	License fee
less than $500,000	$ 600
$500,000 to $2,000,000	1,200
$2 million to $10 million	1,800
more than $10 million	2,400; and

B. The inspection fee is $1,200 per year per lab.

C. Laboratories located outside Minnesota are assessed actual cost of additional labor, travel, and lodging expenses the department incurs in the laboratory inspection.

4740.1065 ANNUAL INSPECTION.

The commissioner shall conduct periodic inspections of laboratories licensed for drug and alcohol testing of employees. Inspections ~~shall~~ may be unannounced and occur at least annually.

4740.1070 PERFORMANCE METHODS REQUIRED FOR ISSUANCE OF A LICENSE.

Subpart 1. **Standards required.** To qualify for a license to conduct drug and alcohol testing for Minnesota employees and job applicants, the officers or the owner of a laboratory must use the performance methods described in subparts 2 to 8.

Subp. 2. **Test samples.** The usual sample for drug testing

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is freshly voided urine. A breath, urine, or blood sample may be used for initial screening tests. When the breath test is used as the initial screening test for alcohol, a blood sample shall be obtained for the confirmatory test. The blood sample shall be collected immediately after the breath test. When an initial positive urine test indicates the presence of drugs, a blood ~~test may~~ or urine sample shall be used for the confirmatory test.

The sample volume must be adequate to allow for the initial screening test, a confirmatory test, and a confirmatory retest.

Subp. 3. **Collection of urine samples; procedures.** The laboratory must have written procedures for collecting urine samples. The collection procedures must contain paragraphs 6 and 11 to 16 of the specimen collection procedures in Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies, NIDA, as provided by the Federal Register, volume 52, pages 30639 and 30640, Friday, August 14, 1987. Paragraphs 1 to 5 and 7 to 10 of these procedures are optional. The site where the sample is collected must have a stall or partitioned area that allows the individual being tested to provide the individual's urine specimen in privacy. The collection site person must sign and date either the tape sealing the sample container or the sample container label.

Subp. 4. **Collection of blood samples; procedures.** The laboratory must have written procedures for collection of blood samples. The procedure must address identification of the employee or job applicant, necessary collection supplies, seating or positioning of the employee or job applicant during sample collection, cleansing of the skin at the venipuncture site, and verification that the sample and paperwork are from the individual from which the sample was collected. NCCLS Guidelines H3-A2, Procedures for Collection of Diagnostic Blood Specimens by Venipuncture, 2nd Edition, Approved Standard, 1984, is an acceptable guide for the collection of blood samples. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford

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Building, 117 University Avenue, Saint Paul, Minnesota 55155.

The collection site person must sign either the tape sealing the sample container or the sample container label.

Subp. 5. **Techniques for drug testing.** For an initial screening test for drugs or drug metabolites, the laboratory must use a chromatographic technique or an immunoassay method. Samples that show the presumptive presence of a drug or drug metabolite must be confirmed by the gas chromatography/mass spectrometry (GC/MS) technique.

Subp. 6. **Techniques for alcohol testing.** A breath test, alcohol dehydrogenase reaction, microdiffusion, or oxidation of distillate with potassium dichromate may be used as a method to initially test for the presence of alcohol. The presumptive presence of alcohol must be confirmed using gas chromatography.

Subp. 7. **Confirmatory tests required.** A laboratory that performs only initial testing must obtain confirmatory results from a licensed laboratory that performs confirmatory tests.

Subp. 8. **Chain-of-custody procedures for handling samples.** The laboratory must follow written chain-of-custody procedures that, at a minimum, meet the requirements of items A to C.

A. Possession of a sample must be traceable to the employee from whom the sample is collected, from the time the sample is collected through the time the sample is tested, the test result reported, the sample retested, and the sample stored.

B. At all times, the sample must be in the possession of, in view of, or placed in a secured area by a person authorized to handle the sample.

C. A sample must be accompanied by a written chain-of-custody record. Individuals relinquishing or accepting possession of the sample must record the time the possession of the sample was transferred and must sign and date the chain-of-custody record at the time of transfer.

Subp. 9. **Storage of positive samples.** All confirmed positive samples shall be stored frozen for at least six months. The sample container must be sealed and labeled. The

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freezer must be locked or be located in a secure area.

Subp. 10. **Requirements for directors.** The director of the laboratory must be a full-time employee of the laboratory, must possess a doctoral, medical doctor, or a master's degree in a biological or medical science, and must have at least three years' experience in an analytical toxicology laboratory.

Subp. 11. **Proficiency testing required.** Satisfactory participation in a proficiency testing program is required of a laboratory applying for or renewing a license. The Forensic Urine Drug Testing surveys conducted by the College of American Pathologists and the American Association for Clinical Chemistry and the NIDA Performance Test Program are acceptable proficiency testing programs. The laboratory must participate at the appropriate screening and confirmatory test levels for which an application for license is submitted.

Subp. 12. **Procedures for proficiency testing.** Before applying for or renewing a license, a laboratory must participate in and report the results of three cycles of proficiency testing. The laboratory must mail proficiency testing results to the commissioner.

The procedures for handling and testing proficiency test samples after receipt by the laboratory must be identical to the procedures for normal laboratory samples.

Laboratory personnel shall not be informed that these samples are part of a performance test to the extent possible.

A licensed laboratory may also be subjected to blind proficiency testing. Performance on blind testing samples is required at the same level as for the open proficiency testing.

A false-positive result from a confirmatory test sample is unsatisfactory performance. Two false-positive results from a screening test sample during a one-year period constitute unsatisfactory performance. The laboratory must inform the commissioner, in writing, of any false-positive test result on a proficiency testing sample, with a plan of corrective action. The commissioner will be informed within 14 days of receipt of the proficiency testing report.

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Subp. 13. **Laboratory procedure manual.** The laboratory must possess and follow a laboratory procedure manual. The laboratory manual must describe the individual test procedures performed by the laboratory. The manual must have a table of contents and numbered pages. The manual must be reviewed annually. The description of the test procedures must include sections addressing the sample used for the test, reagents, supplies and materials, equipment calibration, quality control, the step-by-step procedure, calculations, reporting results, special notes, safety precautions, limitations of the procedure, references, and flow diagrams. Changes in a procedure must be reviewed and dated. Clinical Laboratory Procedure Manuals; Approved Guidelines, GP2-A, National Committee for Clinical Laboratory Standards, 1984, is an acceptable guide to writing a laboratory manual. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford Building, 117 University Avenue, Saint Paul, Minnesota 55155.

4740.1075 INITIAL SCREENING TEST; MINIMUM DETECTION LEVELS.

The minimum levels that need to be detectable by a screening test are as follows:

A. marijuana metabolites, 100 ng/ml;

B. cocaine metabolites, 300 ng/ml;

C. opiate metabolites, 300 ng/ml;

D. phencyclidine, 25 ng/ml; and

E. amphetamines, 1,000 ng/ml.

4740.1080 THRESHOLD DETECTION LEVELS.

Threshold detection levels for confirmatory tests of drugs and drug metabolites defined in Minnesota Statutes, section 152.02, and rules of the Board of Pharmacy are 1,000 ng/ml, except as listed in items A to K:

A. marijuana metabolite (delta-9 tetrahydrocannabinol-9-carboxylic acid), 15 ng/ml;

B. cocaine~~, 150 ng/ml;~~

C. metabolite (benzoylecgonine), 150 ng/ml;

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~~D.~~ C. opiates~~, 300 ng/ml~~:

(1) morphine, 300 ng/ml*; and

(2) codeine, 300 ng/ml*;

~~E.~~ D. phencyclidine, 25 ng/ml;

~~F.~~ E. amphetamines, 500 ng/ml;

~~G.~~ F. fentanyl, 5 ng/ml;

~~H.~~ G. lysergic acid diethylamide (LSD), 5 ng/ml;

~~I.~~ H. 3-4-methylenedioxy amphetamine (MDA), 300 ng/ml;

~~J.~~ I. alcohol (urine), .02 gram percent; and

~~K.~~ J. alcohol (blood), .02 gram percent.

* 300 ng/ml individually or in combination.

4740.1090 VARIANCE AND WAIVERS.

A laboratory may request that the department grant a variance or waiver from the provisions of parts 4740.1000 to 4740.1080. A request for a variance or waiver must be submitted to the department in writing. A request must contain the following information:

A. the specific rules for which the variance or waiver is requested;

B. the reasons for the request;

C. the alternative measures that will be taken if a variance or waiver is granted; and

D. the length of time for which the variance or waiver is sought.

The commissioner shall review information submitted with the request for waiver or variance. The commissioner shall provide the laboratory with a written decision that states the reasons for granting or denying the request for the variance.

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Office of the Revisor of Statutes

Administrative Rules

TITLE: Adopted Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing

AGENCY: Department of Health

MINNESOTA RULES: Chapter 4740

INCORPORATIONS BY REFERENCE:

Rule Number: 4740.1070, subpart 4
Material Incorporated: NCCLS Guidelines H3-A2, Procedures for Collection of Diagnostic Blood Specimens by Venipuncture, 2nd Edition, Approved Standard, 1984.

Rule Number: 4740.1070, subpart 13
Material Incorporated: Clinical Laboratory Procedure Manuals; Approved Guidelines, GP2-A, National Committee for Clinical Laboratory Standards, 1984.

The attached rules are approved for filing with the Secretary of State

Kathleen M. Traxler
Assistant Revisor

Department of Health

Adopted Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing

Rules as Adopted

DRUG AND ALCOHOL TESTING OF EMPLOYEES

4740.1010 DEFINITIONS.

Subpart 1. **Scope, application.** The following terms used in parts 4740.1020 to 4740.1080 have the meanings given them in this part.

Subp. 2. **Alcohol.** "Alcohol" means ethyl alcohol.

Subp. 3. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 4. **Confirmatory test.** "Confirmatory test" means a drug or alcohol test, run on a sample that was positive on the initial screening test. Techniques for a confirmatory test are described in part 4740.1070, subparts 5 and 6.

Subp. 5. **Department.** "Department" means the Department of Health.

Subp. 6. **Drug.** "Drug" means a controlled substance as defined in Minnesota Statutes, section 152.02, and as updated yearly by rules of the Board of Pharmacy.

Subp. 7. **Employee.** "Employee" means a person, independent contractor, or person working for an independent contractor who performs services for compensation, in whatever form, for an employer.

Subp. 8. **Employer.** "Employer" means a person, independent contractor, or entity located or doing business in this state and having one or more employees, and includes the state of Minnesota and all political or other governmental subdivisions of the state.

Subp. 9. **Initial screening test.** "Initial screening test" means a drug or alcohol test ~~that can detect the~~, the results of which indicate presumptive presence of a drug, drug metabolite,

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or alcohol in a sample. Techniques for an initial screening test are described in part 4740.1070, subparts 5 and 6.

Subp. 10. **Initial screening test minimum detection level.** "Initial screening test minimum detection level" means the level at which a laboratory is capable of detecting a drug or drug metabolite using a screening test. The values are derived from the NIDA initial cutoff levels in Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines; Notice, paragraph 2.4(e)(1), as provided by the Federal Register, Volume 53, Number 69, page 11983, Monday, April 11, 1988.

Subp. 11. **Job applicant.** "Job applicant" means a person, independent contractor, or person working for an independent contractor who applies to become an employee of an employer, and includes a person who has received a job offer that is contingent on the person passing drug or alcohol testing.

Subp. ~~11.~~ 12. **Laboratory.** "Laboratory" means a person, corporation, or other entity, including a governmental entity, that examines, analyzes, or tests samples.

Subp. ~~12.~~ 13. **NCCLS.** "NCCLS" means the National Committee for Clinical Laboratory Standards, Villanova, Pennsylvania.

Subp. ~~13.~~ 14. **NIDA.** "NIDA" means the National Institute ~~for~~ on Drug Abuse, of the Alcohol, Drug Abuse, and Mental Health Administration, United States Health and Human Services Department.

Subp. ~~14.~~ 15. **Positive test result.** "Positive test result" means a finding of the presence of drugs, alcohol, or their metabolites in the sample tested by a confirmatory test in levels at or above the threshold detection levels set by the commissioner under part 4740.1080.

Subp. ~~15.~~ 16. **Presumptive presence.** "Presumptive presence" means some indication of the presence of a drug, drug metabolite, or alcohol that, in the judgment of the laboratory director or the laboratory director's designee, provides a reasonable basis for conducting a confirmatory test. The presumptive presence of a drug, drug metabolite, or alcohol is

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not a positive test result.

Subp. ~~16.~~ 17. **Sample.** "Sample" means a substance derived from a nonhuman source and collected for the purpose of analysis or a tissue, blood, excretion, or other bodily fluid specimen obtained from a human for the detection of a chemical, etiologic agent, or histologic abnormality.

Subp. ~~17.~~ 18. **Threshold detection level.** "Threshold detection level" means ~~that~~ the level at which the presence of a drug, drug metabolite, or alcohol ~~could~~ can be reasonably ~~be~~ expected to be detected ~~in a sample~~ by a confirmatory test performed by a laboratory that meets the standards of parts 4740.1010 to 4740.1090. The threshold detection level is neither meant to indicate impairment nor any relationship between the time of the test and the time of use of a drug or alcohol by the employee or applicant. The threshold detection level simply indicates the level at which a valid conclusion can be drawn that the drug or alcohol is present in the employee's or applicant's sample.

4740.1020 LICENSE REQUIRED FOR LABORATORIES PERFORMING DRUG AND ALCOHOL TESTING FOR EMPLOYERS.

A laboratory that performs drug and alcohol laboratory tests of employees and job applicants for Minnesota employers must possess a valid license to do so. A laboratory must obtain a license according to the procedures in parts 4740.0100 to 4740.0170, as proposed at 13 State Register 1079 and as subsequently adopted. In addition to the information required on an application for a license, a laboratory that performs only initial drug and alcohol screening tests must disclose on its application the name of the licensed laboratory that performs its confirmatory tests.

4740.1025 EXCEPTION.

A medical clinic, hospital, or other medical facility need not be licensed under parts 4740.1010 to 4740.1080 to perform a breath test as an initial screening test for alcohol if:

A. the medical clinic, hospital, or other medical

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facility is not owned or operated by the employer; and

B. the results of the breath test are confirmed by a blood test performed by a laboratory licensed under parts 4740.1010 to 4740.1080.

4740.1040 RECIPROCITY.

A license shall be granted to a laboratory located in another state, if the requirements of Minnesota Statutes, section 181.953, subdivision 1, paragraph (c), are met.

4740.1050 TERM OF LICENSE.

Laboratories shall be licensed for a term of one year ~~beginning on July 1 and ending June 30~~. Unless a laboratory submits a timely application for license renewal, the license expires without further notice at the end of the term.

4740.1060 FEES.

Subpart 1. **Annual license fee required.** The laboratory must pay an annual license fee and other required costs with the initial application for license and with each renewal application. The amount of the fee and other required costs is determined under subpart 3. ~~It is based upon the number of samples taken from Minnesota employees, that the laboratory tests.~~ A laboratory must pay the fees and costs required under this part before a license is issued.

Subp. 2. **Information required to determine fee.** The laboratory must submit an estimate of the ~~number of annual Minnesota employee samples to be tested for drugs and alcohol~~ laboratory annual receipts during the current accounting year with the application for a license or license renewal. The laboratory must submit to the department quarterly reports of the ~~volume of actual employee drug and alcohol testing samples~~ laboratory annual receipts and the results of proficiency testing results for the past quarter. The statistics from these reports are used to adjust the license fee collected from the laboratory on its next license renewal application to reflect actual ~~sample volume~~ laboratory annual receipts.

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Subp. 3. **License fee schedule.** The annual license ~~fees are determined according to the following schedule:~~ fee is made up of an application fee and inspection fee as described in items A and B. The fees are nonrefundable.

~~License fee = (a) $1,200 +~~

~~(b) Total annual alcohol samples + drug samples x $3/sample~~

~~taken from Minnesota employees~~

~~2~~

~~A sample obtained for both alcohol and drug testing is considered as one alcohol sample and one drug sample for fee purposes. The $1,200 in part (a) of the schedule is nonrefundable.~~

A. The application fee is determined as follows:

Laboratory Annual Receipts	License fee
less than $500,000	$ 600
$500,000 to $2,000,000	1,200
$2 million to $10 million	1,800
more than $10 million	2,400; and

B. The inspection fee is $1,200 per year per lab.

C. Laboratories located outside Minnesota are assessed actual cost of additional labor, travel, and lodging expenses the department incurs in the laboratory inspection.

4740.1065 ANNUAL INSPECTION.

The commissioner shall conduct periodic inspections of laboratories licensed for drug and alcohol testing of employees. Inspections ~~shall~~ may be unannounced and occur at least annually.

4740.1070 PERFORMANCE METHODS REQUIRED FOR ISSUANCE OF A LICENSE.

Subpart 1. **Standards required.** To qualify for a license to conduct drug and alcohol testing for Minnesota employees and job applicants, the officers or the owner of a laboratory must use the performance methods described in subparts 2 to 8.

Subp. 2. **Test samples.** The usual sample for drug testing

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is freshly voided urine. A breath, urine, or blood sample may be used for initial screening tests. When the breath test is used as the initial screening test for alcohol, a blood sample shall be obtained for the confirmatory test. The blood sample shall be collected immediately after the breath test. When an initial positive urine test indicates the presence of drugs, a blood ~~test may~~ or urine sample shall be used for the confirmatory test.

The sample volume must be adequate to allow for the initial screening test, a confirmatory test, and a confirmatory retest.

Subp. 3. **Collection of urine samples; procedures.** The laboratory must have written procedures for collecting urine samples. The collection procedures must contain paragraphs 6 and 11 to 16 of the specimen collection procedures in Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies, NIDA, as provided by the Federal Register, volume 52, pages 30639 and 30640, Friday, August 14, 1987. Paragraphs 1 to 5 and 7 to 10 of these procedures are optional. The site where the sample is collected must have a stall or partitioned area that allows the individual being tested to provide the individual's urine specimen in privacy. The collection site person must sign and date either the tape sealing the sample container or the sample container label.

Subp. 4. **Collection of blood samples; procedures.** The laboratory must have written procedures for collection of blood samples. The procedure must address identification of the employee or job applicant, necessary collection supplies, seating or positioning of the employee or job applicant during sample collection, cleansing of the skin at the venipuncture site, and verification that the sample and paperwork are from the individual from which the sample was collected. NCCLS Guidelines H3-A2, Procedures for Collection of Diagnostic Blood Specimens by Venipuncture, 2nd Edition, Approved Standard, 1984, is an acceptable guide for the collection of blood samples. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford

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Building, 117 University Avenue, Saint Paul, Minnesota 55155.

The collection site person must sign either the tape sealing the sample container or the sample container label.

Subp. 5. **Techniques for drug testing.** For an initial screening test for drugs or drug metabolites, the laboratory must use a chromatographic technique or an immunoassay method. Samples that show the presumptive presence of a drug or drug metabolite must be confirmed by the gas chromatography/mass spectrometry (GC/MS) technique.

Subp. 6. **Techniques for alcohol testing.** A breath test, alcohol dehydrogenase reaction, microdiffusion, or oxidation of distillate with potassium dichromate may be used as a method to initially test for the presence of alcohol. The presumptive presence of alcohol must be confirmed using gas chromatography.

Subp. 7. **Confirmatory tests required.** A laboratory that performs only initial testing must obtain confirmatory results from a licensed laboratory that performs confirmatory tests.

Subp. 8. **Chain-of-custody procedures for handling samples.** The laboratory must follow written chain-of-custody procedures that, at a minimum, meet the requirements of items A to C.

A. Possession of a sample must be traceable to the employee from whom the sample is collected, from the time the sample is collected through the time the sample is tested, the test result reported, the sample retested, and the sample stored.

B. At all times, the sample must be in the possession of, in view of, or placed in a secured area by a person authorized to handle the sample.

C. A sample must be accompanied by a written chain-of-custody record. Individuals relinquishing or accepting possession of the sample must record the time the possession of the sample was transferred and must sign and date the chain-of-custody record at the time of transfer.

Subp. 9. **Storage of positive samples.** All confirmed positive samples shall be stored frozen for at least six months. The sample container must be sealed and labeled. The

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freezer must be locked or be located in a secure area.

Subp. 10. **Requirements for directors.** The director of the laboratory must be a full-time employee of the laboratory, must possess a doctoral, medical doctor, or a master's degree in a biological or medical science, and must have at least three years' experience in an analytical toxicology laboratory.

Subp. 11. **Proficiency testing required.** Satisfactory participation in a proficiency testing program is required of a laboratory applying for or renewing a license. The Forensic Urine Drug Testing surveys conducted by the College of American Pathologists and the American Association for Clinical Chemistry and the NIDA Performance Test Program are acceptable proficiency testing programs. The laboratory must participate at the appropriate screening and confirmatory test levels for which an application for license is submitted.

Subp. 12. **Procedures for proficiency testing.** Before applying for or renewing a license, a laboratory must participate in and report the results of three cycles of proficiency testing. The laboratory must mail proficiency testing results to the commissioner.

The procedures for handling and testing proficiency test samples after receipt by the laboratory must be identical to the procedures for normal laboratory samples.

Laboratory personnel shall not be informed that these samples are part of a performance test to the extent possible.

A licensed laboratory may also be subjected to blind proficiency testing. Performance on blind testing samples is required at the same level as for the open proficiency testing.

A false-positive result from a confirmatory test sample is unsatisfactory performance. Two false-positive results from a screening test sample during a one-year period constitute unsatisfactory performance. The laboratory must inform the commissioner, in writing, of any false-positive test result on a proficiency testing sample, with a plan of corrective action. The commissioner will be informed within 14 days of receipt of the proficiency testing report.

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Subp. 13. **Laboratory procedure manual.** The laboratory must possess and follow a laboratory procedure manual. The laboratory manual must describe the individual test procedures performed by the laboratory. The manual must have a table of contents and numbered pages. The manual must be reviewed annually. The description of the test procedures must include sections addressing the sample used for the test, reagents, supplies and materials, equipment calibration, quality control, the step-by-step procedure, calculations, reporting results, special notes, safety precautions, limitations of the procedure, references, and flow diagrams. Changes in a procedure must be reviewed and dated. Clinical Laboratory Procedure Manuals; Approved Guidelines, GP2-A, National Committee for Clinical Laboratory Standards, 1984, is an acceptable guide to writing a laboratory manual. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford Building, 117 University Avenue, Saint Paul, Minnesota 55155.

4740.1075 INITIAL SCREENING TEST; MINIMUM DETECTION LEVELS.

The minimum levels that need to be detectable by a screening test are as follows:

A. marijuana metabolites, 100 ng/ml;

B. cocaine metabolites, 300 ng/ml;

C. opiate metabolites, 300 ng/ml;

D. phencyclidine, 25 ng/ml; and

E. amphetamines, 1,000 ng/ml.

4740.1080 THRESHOLD DETECTION LEVELS.

Threshold detection levels for confirmatory tests of drugs and drug metabolites defined in Minnesota Statutes, section 152.02, and rules of the Board of Pharmacy are 1,000 ng/ml, except as listed in items A to K:

A. marijuana metabolite (delta-9 tetrahydrocannabinol-9-carboxylic acid), 15 ng/ml;

B. cocaine~~,~~ ~~150 ng/ml;~~

C~~.~~ metabolite (benzoylecgonine), 150 ng/ml;

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~~D.~~ C. opiates~~, 300 ng/ml~~:

(1) morphine, 300 ng/ml*; and

(2) codeine, 300 ng/ml*;

~~E.~~ D. phencyclidine, 25 ng/ml;

~~F.~~ E. amphetamines, 500 ng/ml;

~~G.~~ F. fentanyl, 5 ng/ml;

~~H.~~ G. lysergic acid diethylamide (LSD), 5 ng/ml;

~~I.~~ H. 3-4-methylenedioxy amphetamine (MDA), 300 ng/ml;

~~J.~~ I. alcohol (urine), .02 gram percent; and

~~K.~~ J. alcohol (blood), .02 gram percent.

* 300 ng/ml individually or in combination.

4740.1090 VARIANCE AND WAIVERS.

A laboratory may request that the department grant a variance or waiver from the provisions of parts 4740.1000 to 4740.1080. A request for a variance or waiver must be submitted to the department in writing. A request must contain the following information:

A. the specific rules for which the variance or waiver is requested;

B. the reasons for the request;

C. the alternative measures that will be taken if a variance or waiver is granted; and

D. the length of time for which the variance or waiver is sought.

The commissioner shall review information submitted with the request for waiver or variance. The commissioner shall provide the laboratory with a written decision that states the reasons for granting or denying the request for the variance.

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STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of Proposed Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing, Proposed Parts 4740.1010 to 4740.1090

SUPPLEMENTAL FINDINGS OF FACT, CONCLUSIONS AND ORDER ADOPTING RULE WITHOUT A PUBLIC HEARING

Upon review by the Attorney General of the rules identified as Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing Parts 4740.1010 to 4740.1090 adopted by Order of the Commissioner of Public Health dated April 19, 1989, (the "rule as adopted") the Attorney General has determined that the rules as adopted must be amended in one respect to remove excess discretion.

Said amendment may be made without substantial change from the rule as adopted and without raising significant new legal issues.

Accordingly:

Page 10, lines 26 through 29 of the rule as adopted are amended as follows:

> The commissioner shall review information submitted with the request for waiver or variance. If the laboratory proposes alternatives equivalent or superior to those prescribed in the rule and shows that strict enforcement of the rule would cause undue hardship, and the variance would not adversely affect public health or safety, the commissioner shall grant the variance, provided however such variance shall not conflict with statutory provisions. The commissioner shall provide the laboratory with a written decision that states the reasons for granting or denying the request for the variance.

Dated: May 9, 1989

Sr. Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE STATE

COMMISSIONER OF HEALTH

In the Matter of Rules
Relating to Licensure of
Laboratories for Drug and
Alcohol Testing in the Workplace

NOTICE OF SOLICITATION
OF OUTSIDE INFORMATION
OR OPINIONS

Notice is hereby given that the State Department of Health is seeking information or opinions from sources outside the agency in preparing to propose the adoption of a rule governing the licensure of laboratories for drug and alcohol testing in the workplace. The adoption of the rule is authorized by Act of June 3, 1987, chapter 388, section 4, Minnesota Session Law Service (West). Chapter 388, section 4 requires the agency to license laboratories which employers must use when requiring an employee to undergo drug or alcohol testing.

The State Department of Health requests information and opinions concerning the subject matter of the rule. Interested persons or groups may submit data or views on the subject matter of concern in writing or orally. Written statements should be addressed to John Ikeda, Laboratory Services Section, Minnesota Department of Health, 717 Delaware Street Southeast, Minneapolis, Minnesota 55440. Oral statements will be received during regular business hours over the telephone at (612) 623-5000 and in person at the above address.

All statements of information and opinions shall be accepted until 30 days from the date of this publication. Any written material received by the State Department of Health shall become part of the rulemaking record to be submitted to the attorney general or administrative law judge in the event that the rule is adopted.

Date: August 10, 1987

MINNESOTA DEPARTMENT OF HEALTH

Sister Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

minnesota department of health
717 s.e. delaware st. p.o. box 9441 minneapolis 55440
(612) 623-5000

October 14, 1988

The Honorable Glen Anderson
Chairman, House Appropriations Committee
State Office Building, Room 365
St. Paul, Minnesota 55155

Dear Representative Anderson:

Pursuant to Minnesota Statutes 16A.128, subdivision 2a. "A Notice of Intent to Adopt Rules without Public Hearing" and a copy of "Proposed Permanent Rules Relating to General Accreditation Requirements for Laboratories", parts 4740.0100 to 4740.0170, and "Proposed Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing", parts 4740.1010 to 4740.1080, are enclosed.

Sincerely yours,

Sister Mary Madonna Ashton
Commissioner of Health

SMMA/JI:DB

Enclosures

cc: Catherine Avina
Special Assistant
Attorney General's Office

an equal opportunity employer

minnesota department of health
717 s.e. delaware st. p.o. box 9441 minneapolis 55440
(612) 623-5000

October 14, 1988

The Honorable Gene Merriam
Chairman, Senate Finance Committee
Capital Building, Room 122
St. Paul, Minnesota 55155

Dear Senator Merriam:

Pursuant to Minnesota Statutes 16A.128, subdivision 2a. "A Notice of Intent to Adopt Rules without Public Hearing" and a copy of "Proposed Permanent Rules Relating to General Accreditation Requirements for Laboratories", parts 4740.0100 to 4740.0170, and "Proposed Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing", parts 4740.1010 to 4740.1080, are enclosed.

Sincerely yours,

Sr. Mary Madonna

Sister Mary Madonna Ashton
Commissioner of Health

SMMA/JI:DB

Enclosures

cc: Catherine Avina
Special Assistant
Attorney General's Office

an equal opportunity employer

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

IN THE MATTER OF PROPOSED PERMANENT RULES RELATING TO GENERAL ACCREDITATION REQUIREMENTS FOR LABORATORIES

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Commissioner of Health, (hereinafter "commissioner"), pursuant to Minnesota Statutes, sections 14.05 to 14.12 and 14.22 to 14.28, presents facts establishing the need for and the reasonableness of the above captioned proposed permanent rules.

This statement of need and reasonableness demonstrates that the commissioner:

- has statutory authority to adopt the rule,
- has taken necessary procedural actions,
- has determined that the rule is needed,
- has determined that the rule is reasonable, and
- has satisfied any other requirements imposed by law.

The commissioner will be granted increasing authority to certify and license laboratories. In anticipation of this trend, rules pertaining to licensure of laboratories performing drug and alcohol testing in the workplace will be in two sets. The first set will contain general administrative rules. The second set will consist of the technical standards which pertain specifically to drug and alcohol testing. As new accreditation programs are implemented, the standards which pertain to the specific type of laboratory test to be covered by licensure or certification may be added to Chapter 4740.

I. STATUTORY AUTHORITY

The statutory authority of the commissioner to adopt these rules is briefly noted below. The specific statutory authority for each rule is discussed in detail as part of the rule-by-rule justification.

Minnesota Statutes, section 181.953, subdivision 1, requires the commissioner to license laboratories which test samples from Minnesota employees for alcohol, drugs and drug metabolites. Authority is granted to the commissioner to:

- set standards for licensing, suspending and revoking a license,
- define appropriate component samples for testing,
- set threshold detection levels for drugs, drug metabolites and alcohol,
- list criteria for chain-of-custody procedures,
- set annual license fees, and
- grant licenses to laboratories licensed by a state or federal agency if that agencies standards meet or exceed those of the State of Minnesota.

II. COMPLIANCE WITH RULEMAKING PROCEDURAL REQUIREMENTS

Minnesota Statutes, sections 14.05 - 14.12 and 14.22 - 14.28, specify certain procedures which must be followed when an agency adopts or amends rules. Procedures applicable to all rules (Minnesota Statutes, sections 14.05 - 14.15) have been complied with by the commissioner. The commissioner has determined that the adoption of proposed parts 4740.0100 to 4740.0170 is non-controversial and has elected to follow procedures set forth in Minnesota Statutes, sections 14.22 - 14.28, which provide for an expedited process for the adoption of non-controversial administrative rules without holding a public hearing.

Minnesota Statutes, section 14.10, requires an agency that seeks information or opinions from persons outside the agency for adoption of rules to publish notice of such action in the State Register. This will serve to notify interested persons in the community of the opportunity to submit comments or data on the subject of the rules. A notice of solicitation of outside information or opinions appeared in the State Register, on August 17, 1987, at Volume 12, Number 7, page 294.

The adoption of these rules will not require expenditure of public money by local public bodies of greater than $100,000.00 in either of the two years following promulgation, nor do these rules have any impact on agricultural land. (Minnesota Statutes, section 14.11, 1986.)

Pursuant to Minnesota Statutes, section 14.23, the commissioner has prepared this statement of need and reasonableness which is available to the public.

The commissioner will publish a notice of intent to adopt the rules without public hearing in the State Register and mail copies of the notice and proposed rules to persons registered with the Minnesota Department of Health pursuant to Minnesota Statutes, section 14.14, subdivision 1(a). The notice will include the following statements:

a) that the public have 30 days in which to submit comments on the proposed rules;
b) that no public hearing will be held unless 25 or more persons make a written request for a hearing within the 30-day comment period;
c) giving information pertaining to the manner in which persons shall request a hearing; and
d) that the rule may be modified if modifications are supported by data and the views submitted.
e) other information required by Minnesota Statutes, section 14.22.

If 25 or more persons submit to the Minnesota Department of Health a written request for a hearing of the proposed rules, the agency shall proceed under the provisions of Minnesota Statutes, sections 14.131 - 14.20, and notice of hearing shall be published in the State Register.

If no hearing is required, the commissioner will submit the proposed rules and notice as published, the rules as proposed for adoption, any written comments which have been received, and this statement of need and reasonableness to the Attorney General for approval of the rules.

These rules shall become effective five working days after publication of a notice of adoption in the State Register.

III. SMALL BUSINESS CONSIDERATIONS

The impact of rules on small businesses was examined as required by Minnesota Statutes, chapter 14.115. The affect was considered by the following methods:

- at least one of the members of the technical advisory group owns and operates a small business,
- The Minnesota Association of Commerce and Industry reviewed preliminary drafts of the rules,
- over thirty laboratories which have applied for transitional laboratory approval to perform drug and alcohol testing will receive copies of the rules, as they appear in the State Register, for comment,
- and the administrative requirements for application and renewal of a license were established to simplify or consolidate application and reporting requirements.

Compliance with the "umbrella" standards for accreditation are necessary whether the laboratory is a small business or a large concern.

Impact of rules relating to technical standards and fee requirements are discussed in the statement of need and reasonableness specific to the particular laboratory test category.

IV. GENERAL STATEMENT OF REASONABLENESS

The Commissioner of Health is being granted increasing authority to regulate laboratories through licensure and certification. The purpose of this rule is to promote consistency in the accreditation of all laboratories performing tests or analyses for a purpose defined by rule or statute or pursuant to a Federal environmental regulatory program which requires certification by a state agency. Other rules will apply to laboratories according to the specific tests performed pursuant to the pertinent regulatory or federal program purposes.

The "umbrella" rule will help assure administrative consistency among various laboratory accredition programs and will promote simplicity and efficiency internally and for our clientele.

A technical advisory group consisting of seven prominent toxicologists and scientists reviewed the rules. Members of the group included:

- Fred Apple, Ph.D., Hennepin County Medical Center;
- Kingsley LaBrosse, Ph.D., Medtox, New Brighton;
- Thomas P. Moyer, Ph.D., Mayo Clinic;
- David Ehresman, MT(ASCP), St. Paul-Ramsey Medical Center;
- John H. Eckfeldt, M.D., University of Minnesota Hospitals;
- Larry Bowers, Ph.D., University of Minnesota Hospitals; and
- S. G. Jejurikar, Ph.D., Forensic Toxicology, Bureau of Criminal Apprehension, State of Minnesota.

Preliminary drafts of the rules were sent for comment to a group made up of the Minnesota State Bar Association, Minnesota Association of Commerce and Industry, Minnesota Department of Labor and Industry, Minnesota Department of Employee Relations, American Civil Liberties Union, Employers Association, the AFL-CIO and AFSME and the principal authors of the bill.

V. RULE-BY-RULE JUSTIFICATION

4740.0100 **Purpose and Scope**

The purpose is simply that Chapter 4740 contains accreditation and licensing standards for laboratories that perform tests or analyses covered by state law.

4740.0110 **Definitions**

Terms used for these rules are defined to make the provisions of the rules clear and understandable.

4740.1020 **Application Procedures**

Subpart 1. Standards This rule is based upon Minnesota Statutes, section 181.953, subdivision 1. The commissioner must adopt rules which address standards for licensure, suspension and revocation of a license.

Subpart 2. Contents The commissioner needs identifying information including name of the laboratory, address of the laboratory, and other items in order to carry out the provisions of Minnesota Statutes, section 181.953, subdivision 1. The application form will be consistent for all accredition programs covered in Chapter 4740.

Subpart 3. Documentation In order to confirm compliance with technical standards, the laboratory must have available for inspection the items covered in 4740.0120, Subpart 3. Certain items, such as proficiency testing results, may be required as part of the license or certificate application. The other items will be available for inspection by a person representing the commissioner.

Subpart 4. Fee The commissioner must set the fee at an amount so that total fees collected will recover the costs of administering the program, see Minnesota Statutes, section 181.95, subdivision 1(d).

Subpart 5. Inspection An on-site inspection of a laboratory is necessary to confirm statements and information received in the application process. Compliance with specific technical standards may be confirmed by examination of documents named in 4740.0120, Subpart 3.

4740.0130 **Provisional Accreditation**

Provisional certification is especially necessary in the early implementation of an accreditation program. Information submitted with the application for accreditation will indicate probable compliance. Compliance will be confirmed by on-site observations.

4740.0140 **Term of Accreditation**

The burden of application and renewal of a license or certificate is placed on the laboratory. This will clearly place the responsibility for renewal with the laboratory. We will be better able to direct our energies towards efforts directly related to inspections rather than spending disproportionate time in the renewal process.

4740.0150 **Compliance**

The laboratory is accredited based on information pertaining to test methodology, laboratory procedures and practices, instrumentation and laboratory management. Changes in these areas will require communications to determine if these changes affect laboratory data quality and accreditation status.

4740.0160 **Licensing and Certification; Renewal**

The accreditation program must be conducted using funds from license and certificate fees. A deadline for receipt of application for renewal, with fees, will help assure that adequate funds are available to administer the program at any given point in time. Automatic suspension of accreditation due to failure to submit a timely application for renewal will enable limited program resources to be channeled to the survey, compliance and review functions.

4740.0170 **Licensing and Certification; Suspension and Revocation**

Laboratories which will not or cannot comply with accredition standards may face suspension or revocation of the applicable accredition. The contested case procedures required by Minnesota Statutes, chapter 14, will be followed in such instances.

9-2-88

Date

Sister Mary Madonna Ashton
Commissioner of Health
Minnesota Department of Health

JAI:RS 5-24-88
Rev. 8/16/88:rs

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of Proposed Permanent Rules Relating to General Accreditation Requirements for Laboratories, Proposed Parts 4740.0100 to 4740.0170 and Proposed Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing, Proposed Parts 4740.1010 to 4740.1080

NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING

Notice is hereby given that the Minnesota Department of Health (hereinafter "Department") intends to adopt rules relating to general accreditation requirements for laboratories, proposed parts 4740.0100 to 4740.0170 and licensure of laboratories for drug and alcohol testing in the workplace, proposed parts 4740.1010 to 4740.1080. The Department intends to adopt the rules without a public hearing following the procedures set forth in the Administrative Procedure Act at Minn. Stat. §§ 14.22 to 14.28 (1986). The statutory authority to adopt the rules is Minn. Stat. §§ 144.07 (1986) and 181.953 (Supp. 1987).

All persons have 30 days in which to submit comment in support of or in opposition to the proposed rules or any part or subpart of the rules. Comment is encouraged. Each comment should identify the portion of the proposed rules addressed, the reason for the comment, and any change proposed.

Any person may make a written request for a public hearing on the rules within the 30-day comment period. If 25 or more persons submit a written request for a public hearing within the 30-day comment period, a public hearing will be held unless a sufficient number withdraw their request in writing. Any person requesting a public hearing should state his or her name and address and is encouraged to identify the portion of the proposed rules addressed, the reason for the request, and any change proposed. If a public hearing is required, the Department will proceed pursuant to Minn. Stat. §§ 14.131 to 14.20 (1986).

Comments or written requests for a public hearing must be submitted to:

Mr. John Ikeda
Laboratory Services Section
Division of Public Health Laboratories
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440
Telephone: (612) 623-5681

The proposed rules may be modified if the modifications are supported by data and views submitted to the Department and do not result in a substantial change in the proposed rules as noticed.

A copy of the proposed rules is attached to this notice.

Statements of Need and Reasonableness that describe the need for and reasonableness of each provision of the proposed rules and identify the data and information relied upon to support the proposed rules have been prepared and are available from John Ikeda upon request at the above address.

Pursuant to Minn. Stat. § 14.115, subd. 2, the impact on small businesses has been considered in the promulgation of the rules. Anyone wishing to present evidence or argument as to the rules' effect on small businesses may do so. The Department's position regarding the impact of the rules on small businesses is set forth in the Statements of Need and Reasonableness.

If no hearing is required, upon adoption of the rules, the rules and the required supporting documents will be submitted to the Attorney General for review as to legality and form to the extent the form relates to legality. Any person may request notification of the date of submission to the Attorney General. Persons who wish to be advised of the submission of this material to the Attorney General or who wish to receive a copy of the adopted rules must submit a written request to John Ikeda at the above address.

Date: 10/17, 1988

SISTER MARY MADONNA ASHTON
Commissioner

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of Proposed Permanent Rules Relating to General Accreditation Requirements for Laboratories, Proposed Parts 4740.0100 to 4740.0170 and Proposed Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing, Proposed Parts 4740.1010 to 4740.1080

AFFIDAVIT OF MAILING THE NOTICE OF INTENT TO ADOPT RULES WITHOUT A PUBLIC HEARING AND CERTIFICATE OF MAILING LIST

STATE OF MINNESOTA)
) ss.
COUNTY OF HENNEPIN)

John Ikeda, being duly sworn says:

I hereby certify that the attached list of persons and associations who have requested, pursuant to Minn. Stat. §§ 14.14, subd. 1a, and 14.22 or 14.30, that their names be placed on the Department of Health's rulemaking mailing list is accurate, complete, and current as of this 24 day of October, 1988.

That on the 24 day of October, 1988, at the City of Minneapolis, County of Hennepin, State of Minnesota, I mailed the attached Notice of Intent to Adopt Rules Without a Public Hearing by depositing in the State of Minnesota Central Mail System for United States mailing, a copy thereof, with postage prepaid, to all persons and associations on the aforementioned mailing list.

John Ikeda

JOHN IKEDA

Subscribed and sworn to before me

this 24 day of October, 1988.

Louise Kaniuk

LOUISE KANIUK
NOTARY PUBLIC-MINNESOTA
HENNEPIN COUNTY
MY COMMISSION EXPIRES FEBRUARY 22, 1991

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
September 21, 1988

APPROVED LABORATORIES

1. Compu Chem Laboratories
   P.O. Box 12652
   Research Triangle Park, North Carolina 27709

   Becky Harden

2. MetPath Inc.
   One Malcolm Avenue
   Teterboro, New Jersey 07608

   Patricia Maloney , Manager, Med Services

3. Smith-Kline Bioscience
   11636 Administration Drive
   St. Louis, Missouri 63146

   Walter Wright , Ph.D.

4. H.C.M.C.-Clinical Labs
   701 Park Avenue
   Minneapolis, Minnesota 55415

   Fred Apple , Ph.D.
   347-3018

5. Mayo Clinical Chemistry Lab
   400 Hilton Building
   Rochester, Minnesota 55905

   Thomas P. Moyer , Ph.D.
   507-284-7552

6. North Central Laboratories
   6975 Saukview Drive, PO Box 1417
   St. Cloud, Minnesota 56302

   Marion Siefert
   228-1255

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
September 21, 1988

7. Drug Scan Inc
1119 Mearns RoadPO Box 2969
Warmeister, Pennsylvania 18974

Richard Cohen
215-674-9310

8. Medtox
402 West County Road D
New Brighton, Minnesota 55112

Kingsley LaBrosse , Ph.D.
636-7466

9. PharmChem Laboratories Incorporated
3925 Bohannon Drive
Menlo Park, California 94025

Joyce Y. Chang , Ph.D.

10. St. Paul Ramsey Med Ctr Dept of Anat & Clin Path
640 Jackson Street
St. Paul, Minnesota 55101

David J. Ehresman , Clinical Chemist/Toxicologist
221-8825

11. American Institute for Drug Detection
9665 Allen Avenue
Rosemont, Illinios 60018

Don Shattuck

12. Smith-Kline Bio-Science Laboratories
506 East State Parkway
Schaumburg, Illinois 60173

Gary L. Smith , Ph.D.

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
September 21, 1988

13. MetPath Incorporated
1355 Mittel Boulevard
WoodDale, Illinois 60191

Lynn Bonse , MBA, MT(ASCP)

14. National Laboratory CenterMed Express
1211 Union Avenue, Suite 400
Memphis, Tennessee 38104-3513

Lisa J. Donnelly Marketing Technical Representative
901-726-8086

15. Laboratory Specialists Incorporated
113 Jarrell Drive P.O. Box 435
Belle Chase, Louisiana 70037

Pat Pizzo

16. Smith-Kline Bio-Science
7600 Tyrone Avenue
Van Nuys, California 91409-7666

Paul Dopp , Quality Assurance Manager
818-929-2520

17. Toxiscan Laboratories Inc.
2500 U. S. Highway 88, Suite 206
Minneapolis, MN 55418

Stephen Edmondson

18. Smith Kline Bio-Science
1777 Montreal Circle
Tucker, Georgia 30084

Jerry L. McHan , Ph.D.
404-934-9205

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
September 21, 1988

19. Psych. Diag. Lab. of America Inc.
100 Corporate Court
South Plainfield, New Jersey 07080

David M. Martin
800-237-PDLA

20. Schoenfeld Clinical Laboratory
8100 Constitution Place NE
Albuquerque, New Mexico 87110

R.G. Schoenfeld , Ph.D.

21. National Health Laboratories
51 East Bethpage Road
Plainview, New York 11803

Elias J. Khabbaza , Ph.D.
516-454-9090

22. Roche Biomedical Laboratories Inc.
PO Box 2289
Columbus, OH 43216

Donald W. Long , Director, Toxicology
614- 889-1061

23. International Clin. Lab-North Central Div.
2277 Charleston Drive
Lexington, KY 40505

Sam Morris
800-354-9355

24. Bioanalytical Technologies
2356 North Lincoln Avenue
Chicago, IL 60614

Poull L. Brien , President

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
September 21, 1988

25. Regina Medical Complex

Hastings, MN 55033

Maureen Kranz

26. Northwest Toxicology Inc.
1141 East 3900 South
Salt Lake City, UT 84124

Sheran D. Smith , Director, Client Relations

27. DataChem Incorporated
960 Levoy Drive
Salt Lake City, UT 84123

Kevin McCloskey , Ph.D., J.D.

28. Clinical Reference Laboratory
11846 West 85th Street
Lenexa, KA 66214

Timothy Sotos , Executive Vice President
(800) 445-6917

29. American Biotest Laboratory
3350 Scott Blvd., Building 15
Santa Clara, CA 95054

Laura Town
(408) 727-5525

30. Fargo Clinic - MeritCare
737 Broadway
Fargo, ND 58123

Jerry J. Baldwin, M.D.
(701) 234-2000

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
September 21, 1988

31. Keystone Laboratories
445 Biltmore Ave., Suite 104
Asheville, NC 28801

Peter G.M. Menedis
(704) 255-0307

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 20, 1988

Lab Drug Test List

1. Metropolitan Medical CenterToxicology Services
   900 South 8th Street
   Minneapolis, Minnesota 55404

   Matthew Schiller , M.D.
   347-4776

2. Metropolitan Medical CenterToxicology Services
   900 South 8th Street
   Minneapolis, Minnesota 55404

   Barbara Mayer
   347-4776

3. Chemical Dependency Consultant Lab
   5944 Concord Avenue South
   Minneapolis, Minnesota 55424

   Harold Lee
   929-9192

4. University of Minnesota Drug Analysis
   Box 198 Mayo Memorial BuildingUniversity of Minnesota Hospital
   Minneapolis, Minnesota 55455

   Kay Olson
   626-5456

5. University of Minnesota Drug Analysis
   Box 198 Mayo Memorial BuildingUniversity of Minnesota Hospital
   Minneapolis, Minnesota 55455

   Nancy B. Sproule
   626-5456

6. Midway Hospital
   1700 University Avenue
   St. Paul, Minnesota 55104

   Joseph P. Leverone , M.D.

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 20, 1988

7. Hill & Knowlton
400 Marquette, Suite 500
Minneapolis, Minnesota 55401

Ellen Waters

8. Lufkin Medical Labs(Div. of Smith-Kline Bioscience)
1103 2nd Avenue South, Box 629
Minneapolis, Minnesota 55440-0629

Peter B. Mockridge , M.D.
333-6521

9. Metpath
2700 University Avenue Southwest Suite 42
St. Paul, Minnesota 55114

Jessica Schoopman
647-0699

10. Laboratory of Clinical Medicine
Box 3288
Mankato, Minnesota 56001

Phyllis Fall
(507) 625-2646

11. Airport Medical Clinic
7501-26th Avenue South
Minneapolis, Minnesota 55450

Thomas Jetzer , M.D.

12. Airport Medical Clinic
7501-26th Avenue South
Minneapolis, Minnesota 55450

Barb Deede

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 20, 1988

13. O'Connor and Hannan
3800 IDS Center80 South 8th Street
Minneapolis, Minnesota 55402

J.R. Thoren

14. Analytitox
2177 West 7th Avenue
Denver, Colorado 80204

Jim Wright

15. Smith-Kline Bio-Science Laboratories
11636 Administration Drive
St. Louis, Missouri 63146

William Hauser

16. Smith-Kline Bioscience Labs
400 Egypt Road
Norriston, Pennsylvania 19403

Phillip R. Walsh

17. Farm Chem Labs
3925 Bohannon
Menlow Park, California 94025

Bob Fogerson

18. University of Minnesota Hospitals
Box 198 Mayo
Minneapolis, Minnesota 55455

John H. Eckfeldt , M.D.

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 20, 1988

19. Fridley Medical Center
7675 Madison Street
Fridley, Minnesota 55432

Kate Hunt
786-2700 x 161

20. LCM
1212 South Euclid Avenue
Sioux Falls, South Dakota 57105

Brad Randall , M.D.
(605) 339-1212

21. Continental Biochemical Labs
2740 28th Street
Grand Rapids, Michigan 49509

Mary Palbykin
(616) 538-6700

22. Roche Biomedical Laboratories
P.O Box 2230
Burlington, North Carolina 27216-2230

Karen Hawkins
(919) 584-5171

23. Maryland Medical Laboratory, Inc.
1901 Sulphur Spring Road
Baltimore, MD 21227

I.S. Dubey
301-247-9100

24. St. Elizabeth Community Health Center
555 South 70th Street
Lincoln, NE 68510

Dr. Post
402-486-7128

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
October 20, 1988

INTERESTED PARTY MAILING LIST

1. South-Western Publication, Pers. Terr. Level
   12800 Publication Drive
   St. Louis, MO 63131

   Barbara Diebold

2. NY State Dept. of Labor, Counselor's Off.
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   Brooklyn, NY 11201

   Andrew Jetter

3. Dept of Labor, 5th Floor Space Center
   444 Lafayette Road
   St. Paul, MN 55101

   Mike Ireland

4. Koenig, Robin, Johnson and Wood
   2305 Commerce
   Mound, MN 55364

   Clarkson Lindley

5. Mona, Meyer, McGrath
   8400 Normandale Lake Blvd.
   Bloomington, MN 55437

   Ronda Wilsher

6. Rider, Bennett, Egan and Arundel
   2500 1st Bank Pl.
   Minneapolis, MN 55402

   Anne Wight

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

7. Hill & Knowlton
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Ellen Waters

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Marilyn Freund

9.
1900 Jackson Street, N.E.
Minneapolis, MN 55418

Elsie Robertson

10.
2000 1st Bank Place West
Minneapolis, MN 55402

Chris Harristhal

11. Minnesota Department of Human Rights
5000 Bremmer To., 7th Pl. & MN St.
St. Paul, MN 55101

Deborah Coleman

12. ORC, 15th Floor
1211 Avenue of the America
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Denise Kaplan

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

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Robbinsdale, MN 55422

Meryl Syslo
571-9201 x2064

16. Yellow Freight Company
10990 Roe
Overland Park, KA 66207

Joe Carpenter

17. United Health Care
9900 Bren East
Minnetonka, MN 55343

Deanne Westerlund

18. CD Services, Human Resource Assoc.
Norwest Bank Building161 North Concord, Suite 321
South St. Paul, MN 55075

Jim Butcher , Director

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

19. Alderson, Odov, Leonard & Sween
P.O. Box 366
Austin, MN 55912

Sue Connor

20. Milavetz & Associates
Brooklyn Crossing Office3300 County Road 10, Suite 210
Brooklyn Center, MN 55123

Stacy Gallop , Personnel

21.
360 Sexton Building529 South 7th Street
Minneapolis, MN 55415

Vic Grossman
332-2339

22. Forensic Toxicologist Bureau of Criminal Apprehension
1246 University Avenue
St. Paul, MN 55104

S.G. Jejurikar , Ph.D.

23. Abbott Northwestern HospitalMedformation Office
800 East Street
Minneapolis, MN 55407

Joy Roeglin

24. Employers Association
9400 Golden Valley Road
Minneapolis, MN 55427

Kevin Wilkins
546-9100

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

25. Catholic Charities Job Services
1624 Chicago Avenue South
Minneapolis, MN 55403

Marian Mendel

26. Apache Control Incorporated
1805 West County Road C
Roseville, MN 55113

Marvis Sievert

27. Assistant City Attorney
A-1700 Government Center
Minneapolis, MN 55487

Steven R. Fredrickson

28. Now Foods Inc.
3857 Louisiana Avenue South
St. Louis Park, MN 55426

Phyllis Johnston

29.
Route 1, Box 241
Annandale, MN 55302

Roxy Granite

30. IBM
Highway 52 NorthDepartment 857, Building 002-1
Rochester, MN 55901

Mary Cummins

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

31. Labelco Inc.
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LouAnn Parnell
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32.
512 Nicolett Mall
Minneapolis, MN 55402

Dave Duddleston , Attorney at Law

33. Genova - Minnesota Inc.
500 Northwest 12th Street
Faribault, MN 55021

Personnel Department

34.
708 Second Street
Hudson, WI 54016

Mike Ward

35.
1765 Bluebill Circle
Eagan, MN 55112

Sharon Kastel
452-4450

36.
3907 West 54th Street
Edina, MN 55424

Joan Grebin
925-3867

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

37. State Government Affairs
Abbott Laboratories
Abbott Park, Illinois 60064

Charles Seeds Regional Manager

38. News, Tribune, and Harrold
424 West 1st Street
Duluth, MN 55802

Mary Ann Spurrier
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39.
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Forest Lake, MN 55025

Mrs. Christ

40. Merck & Company
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Rahway, NJ 07065

Peggie Spier
RY 60-31

41.
1811 Randolph Avenue
St. Paul, MN 55105-2157

Deborah Plumb
690-3062

42.
2922 14th St. N.
St. Cloud, Minnesota 56301

Tony Husting

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

43. Cimcorp/Par Systems
899 West Hwy 96
Shoreview, Minnesota 55126

Jack Kunik

44. Corporate Director, SafetyKraft Corporation
Kraft Court
Glenville, Illinios 60205

Jack Hansen

45.
3575 State Highway 13
Eagan, Minnesota 55122

Jim Hasselman

46.
2093 Fairways Lane
Roseville, Minnesota 55113

Lowell Hancuh

47. Labor Relations Inc.
7501 Golden Valley Road
Golden Valley, Minnesota 55427

Helen Campbell

48.
11940 Darrell Lane
Rogers, Minnesota 55374

William W. Peterson

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

49.
461 110th Avenue Northwest
Coon Rapids, Minnesota 55434

Emily Elmore

50. Swanson Tool and Die Incorporated
P.O. Box 166
Osseo, Minnesota 55369

Dennis Swanson

51. Brooklyn Park Police Department
5400 85th Avenue North
Brooklyn Park, Minnesota 55443

Officer R. Jackson

52. Northridge Care Center
5430 Boone Avenue North
New Hope, Minnesota 55428

Wade Reddy
536-7000

53. AFSME/AFC-CIO
265 Layfayette Road
St. Paul, Minnesota 55107

Rick Scott

54. AFSME/AFC-CIO
265 Layfayette Road
St. Paul, Minnesota 55107

Peter Benner

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

55. Consultation Services Center
633 North Snelling
St. Paul, Minnesota 55104

D. Rockers

56. Pharmchem Laboratories
3925 Bohannon
Menlow Park, California 94025

Charles Renfroe
(415) 328-6200

57. Eveleth Police Department
PO Box 401
Eveleth, Minnesota 55734

James Bozicevich , Chief of Police
(218) 744-4011

58. Division of Labor Standards
444 Lafayette Road
St. Paul, Minnesota 55101

Catherine Peterson , Labor Investigator, Sr.

59. Div of Labor Standards, Dept of Labor and Industry
444 Lafayette Road
St. Paul, Minnesota 55101

Donald Jackman , Director

60.
2200 1st National Bank Building
St. Paul, Minnesota 55101

Karin Wille
291-1215

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

61. Bloomington Police Department
2215 West Old Shakopee Road
Bloomington, Minnesota 55431

John Carlson

62.
3300 Piper Jaffrey Tower222 South 9th Street
Minneapolis, Minnesota 55402

Brian Ohm

63.
312 Central Avenue SoutheastRoom 438
Minneapolis, Minnesota 55414

Arnie Entzel

64.
4201 3rd Street NE, Apt. 2
Columbia Heights, Minnesota 55421

Shelly Stager

65. Colloton Law Offices
512 Nicollet Mall, Suite 340
Minneapolis, Minnesota 55402.

William Grimm

66. Association of General Contractors
111 East Kellogg Blvd, Suite 105
St. Paul, Minnesota 55101

Ron Rasley
291-1102

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

67.
617 5th Avenue South, Apt.#1
St. Cloud, Minnesota 56301

Tim Reckers

68. Civil Service Commission
Dakota County Government Center
Hastings, Minnesota 55333

Carroll

69.
4200 IDS Center
Minneapolis, Minnesota 55402

Elinor Rosenstein

70. Offenheimer Law Firm
1700 1st Bank Building
St. Paul, Minnesota 55101

Carol Ellingson

71.
1800 M Street NW
Washington, DC 20036

Raymond C. Kools
(202) 872-5000

72.
265 Prescott Street
St. Paul, Minnesota 55107

Ronald Ortlip
227-4936

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

73. Briggs and Morgan
2200 1st National Bank Building
St. Paul, Minnesota 55101

Elaina Ostby
291-1215

74. Lufkin Medical Labs Div. of Smith-Kline Biosci
1103 2nd Avenue South, Box 629
Minneapolis, Minnesota 55440-0629

Bob Cooper
333-6521

75.
Route 2, Box 636
Mora, Minnesota 55051

Jeff Richert

76.
550 South Snelling Avenue
St. Paul, Minnesota 55116

Jim Jorgensen
699-0090

77. Minnesota Teamsters Joint Council
3001 University Avenue SE
Minneapolis, Minnesota 55414

Dwayne Johnson
378-0445

78. Woodbury Police Department
2100 Radio Drive
Woodbury, Minnesota 55125

Greg Orth
739-4141

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

79. Labor Relations Association
7501 Golden Valley Road
Golden Valley, Minnesota 55427

Karen Olsen
546-1470

80.
1120 Payne Avenue
St. Paul, Minnesota 55101

Charlene Goldschmidt

81. Faegre and Benson
2300 Multifoods Tower33 South 6th Street
Minneapolis, Minnesota 55402

John W. Polley

82. Abbott Laboratories State Government Affairs
Department 383
Abbott Park, Illinois 60064

Chuck Seeds , Regional Manager
(312) 937-0369

83. High School State Legislature
817 Ivanhoe Drive
Northfield, Minnesota 55057

Sarah Lygre

84.
State and Center Streets
New Ulm, MN 56073

Mark Ullery

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

85. PharmChem Laboratories Incorporated
3925 Bohannon Drive
Menlo Park, CA 94025

Charles Renfroe

86. CF Industries
Salem Lake Drive
Long Grove, IL 60047

Barbara Bartlett , Corporate Nurse
(312) 438-9500 X 645

87.
1400 Norwest Center
St. Paul, MN 55101

Phyllis Karasov
(612) 227-7683

88. Dorsey and Whitney Law Firm
2200 1st Bank Place East
Minneapolis, MN 55402

Ann Carter
(612) 340-2692

89.
7111 Edgerton
Milwaukee, WI 53220

Mary Paluchniak

90.
33 Garden Drive
Silver Bay, MN 55614

Julie Quinn

LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
June 17, 1988

91. Roseville Police Department
2660 Civic Center Drive
Roseville, MN 55113

Tom Alleva
(612) 484-3371 x 626

92.
4200 IDS Building
Minneapolis, MN 55402

Eugene Keating

93. Maslow Law Firm
1800 Midwest Plaza
Minneapolis, Minnesota 55402

Howard Tarkow
339-8015

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LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
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June 17, 1988

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Division of Public Health Laboratories
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June 17, 1988

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Division of Public Health Laboratories
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Division of Public Health Laboratories
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Division of Public Health Laboratories
Minnesota Department of Health
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LABORATORIES PERFORMING DRUG/ALCOHOL TESTING ON EMPLOYEES

Division of Public Health Laboratories
Minnesota Department of Health
October 20, 1988

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7406.0100; .0300; .0500; .0700 (proposed) 977
7410.2500; .2600; .2610; .2800 (adopted) 980
7520.1000; .1100 (proposed) 1044

Public Utilities Commission
7840.1150 (proposed) 930

Reinvest in Minnesota (RIM) Reserve Program
8400.3000-.3930 (adopted) 1056

Unlicensed Mental Health Service Providers Board
9000.0050-.0200 (proposed emergency) 1102

Human Services Department
REVISOR INSTRUCTIONS 911
9500.1090; .1095; .1100; .1130 (proposed) 859
9500.1100 s .21a (proposed repealer) 859
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9505.5000; .5005; .5010; .5015; .5035; .5040; .5050; .5055; .5060; .5065; .5070; .5075; .5080; .5090; .5096; .5100; .5105 (proposed) 855
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9525.0215-.0355 (proposed) 836
9525.0210; .0220; .0230; .0240; .0250; .0260; .0270; .0280; .0290; .0300; .0310; .0320; .0330; .0340; .0350; .0360; .0370; .0380; .0390; .0400; .0410; .0420; .0430 (proposed repealer) 836
9525.2000-.2140 (proposed) 824
9575.0620 (adopted) 1057
9575.1500 (proposed) 1031

Workers' Compensation Court of Appeals
9800.0100; .0300; .0400; .0500; .0510; .0900; .1000; .1100; .1400; .1500; .1600; .1710; .1720; .1800 (adopted) 981
9800.0500 s.2; .0600; .0900 s.4; .1300 (repealed) 981

Proposed Rules

Pursuant to Minn. Stat. §§ 14.22, an agency may propose to adopt, amend, suspend or repeal rules without first holding a public hearing, as long as the agency determines that the rules will be noncontroversial in nature. The agency must first publish a notice of intent to adopt rules without a public hearing, together with the proposed rules, in the *State Register.* The notice must advise the public:

1. that they have 30 days in which to submit comment on the proposed rules;
2. that no public hearing will be held unless 25 or more persons make a written request for a hearing within the 30-day comment period;
3. of the manner in which persons shall request a hearing on the proposed rules; and
4. that the rule may be modified if the modifications are supported by the data and views submitted.

If, during the 30-day comment period, 25 or more persons submit to the agency a written request for a hearing of the proposed rules, the agency must proceed under the provisions of §§ 14.14-14.20, which state that if an agency decides to hold a public hearing, it must publish a notice of intent in the *State Register*.

Pursuant to Minn. Stat. §§ 14.29 and 14.30, agencies may propose emergency rules under certain circumstances. Proposed emergency rules are published in the *State Register* and, for at least 25 days thereafter, interested persons may submit data and views in writing to the proposing agency.

Department of Health

Proposed Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing; and

Proposed Permanent Rules Relating to General Accreditation Requirements for Laboratories

Notice of Intent to Adopt Rules Without a Public Hearing

NOTICE IS HEREBY GIVEN that the Minnesota Department of Health (hereinafter "Department") intends to adopt rules relating to general accreditation requirements for laboratories, proposed parts 4740.0100 to 4740.0170 and licensure for laboratories for drug and alcohol testing in the workplace, proposed parts 4740.1010 to 4740.1080. The Department intends to adopt the rules without a public hearing following the procedures set forth in the Administrative Procedure Act at *Minnesota Statutes* §§ 14.22 to 14.28 (1986). The statutory authority to adopt the rules is *Minnesota Statutes* §§ 144.07 (1986) and 181.953 (Supp. 1987).

KEY: PROPOSED RULES SECTION — Underlining indicates additions to existing rule language. ~~Strike outs~~ indicate deletions from existing rule language. If a proposed rule is totally new, it is designated "all new material." ADOPTED RULES SECTION — Underlining indicates additions to proposed rule language. ~~Strike outs~~ indicate deletions from proposed rule language.

All persons have 30 days in which to submit comment in support of or in opposition to the proposed rules or any part or subpart of the rules. Comment is encouraged. Each comment should identify the portion of the proposed rules addressed, the reason for the comment, and any change proposed.

Any person may make a written request for a public hearing on the rules within the 30-day comment period. If 25 or more persons submit a written request for a public hearing within the 30-day comment period, a public hearing will be held unless a sufficient number withdraw their request in writing. Any person requesting a public hearing should state his or her name and address and is encouraged to identify the portion of the proposed rules addressed, the reason for the request, and any change proposed. If a public hearing is required, the Department will proceed pursuant to *Minnesota Statutes* §§ 14.131 to 14.20 (1986).

Comments or written requests for a public hearing must be submitted to:

Mr. John Ikeda
Laboratory Services Section
Division of Public Health Laboratories
Minnesota Department of Health
717 Delaware Street Southeast
Minneapolis, Minnesota 55440
Telephone: (612) 623-5681

The proposed rules may be modified if the modifications are supported by data and views submitted to the Department and do not result in a substantial change in the proposed rules as noticed.

A copy of the proposed rules is attached to this notice.

Statements of Need and Reasonableness that describe the need for and reasonableness of each provision of the proposed rules and identify the data and information relied upon to support the proposed rules have been prepared and are available from John Ikeda upon request at the above address.

Pursuant to *Minnesota Statutes* § 14.115, subd. 2, the impact on small businesses has been considered in the promulgation of the rules. Anyone wishing to present evidence or argument as to the rules' effect on small businesses may do so. The Department's position regarding the impact of the rules on small businesses is set forth in the Statement of Need and Reasonableness.

If no hearing is required, upon adoption of the rules, the rules and the required supporting documents will be submitted to the Attorney General for review as to legality and form to the extent the form relates to legality. Any person may request notification of the date of submission to the Attorney General. Persons who wish to be advised of the submission of this material to the Attorney General or who wish to receive a copy of the adopted rules must submit a written request to John Ikeda at the above address.

Dated: 17 October 1988

Sister Mary Madonna Ashton
Commissioner

Rules as Proposed (all new material)

DRUG AND ALCOHOL TESTING OF EMPLOYEES

4740.1010 DEFINITIONS.

Subpart 1. **Scope, application.** The following terms used in parts 4740.1020 to 4740.1080 have the meanings given them in this part.

Subp. 2. **Alcohol.** "Alcohol" means ethyl alcohol.

Subp. 3. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 4. **Confirmatory test.** "Confirmatory test" means a drug or alcohol test, run on a sample that was positive on the initial screening test. Techniques for a confirmatory test are described in part 4740.1070, subparts 5 and 6.

Subp. 5. **Department.** "Department" means the Department of Health.

Subp. 6. **Drug.** "Drug" means a controlled substance as defined in *Minnesota Statutes*, section 152.02, and as updated yearly by rules of the Board of Pharmacy.

Subp. 7. **Employee.** "Employee" means a person, independent contractor, or person working for an independent contractor who performs services for compensation, in whatever form, for an employer.

Subp. 8. **Employer.** "Employer" means a person or entity located or doing business in this state and having one or more employees, and includes the state of Minnesota and all political or other governmental subdivisions of the state.

Subp. 9. **Initial screening test.** "Initial screening test" means a drug or alcohol test that can detect the presumptive presence of a drug, drug metabolite, or alcohol in a sample. Techniques for an initial screening test are described in part 4740.1070, subparts 5 and 6.

Subp. 10. **Job applicant.** "Job applicant" means a person, independent contractor, or person working for an independent contractor who applies to become an employee of an employer, and includes a person who has received a job offer that is contingent on the person passing drug or alcohol testing.

Subp. 11. **Laboratory.** "Laboratory" means a person, corporation, or other entity, including a governmental entity, that examines, analyzes, or tests samples.

Subp. 12. **NCCLS.** "NCCLS" means the National Committee for Clinical Laboratory Standards, Villanova, Pennsylvania.

Subp. 13. **NIDA.** "NIDA" means the National Institute for Drug Abuse, of the Alcohol, Drug Abuse, and Mental Health Administration, United States Health and Human Services Department.

Subp. 14. **Positive test result.** "Positive test result" means a finding of the presence of drugs, alcohol, or their metabolites in the sample tested by a confirmatory test in levels at or above the threshold detection levels set by the commissioner under part 4740.1080.

Subp. 15. **Presumptive presence.** "Presumptive presence" means some indication of the presence of a drug, drug metabolite, or alcohol that, in the judgment of the laboratory director or the laboratory director's designee, provides a reasonable basis for conducting a confirmatory test. The presumptive presence of a drug, drug metabolite, or alcohol is not a positive test result.

Subp. 16. **Sample.** "Sample" means a substance derived from a nonhuman source and collected for the purpose of analysis or a tissue, blood, excretion, or other bodily fluid specimen obtained from a human for the detection of a chemical, etiologic agent, or histologic abnormality.

Subp. 17. **Threshold detection level.** "Threshold detection level" means that level at which a drug, drug metabolite, or alcohol could reasonably be expected to be detected in a sample by a confirmatory test.

4740.1020 LICENSE REQUIRED FOR LABORATORIES PERFORMING DRUG AND ALCOHOL TESTING FOR EMPLOYERS.

A laboratory that performs drug and alcohol laboratory tests of employees and job applicants for Minnesota employers must possess a valid license to do so. A laboratory must obtain a license according to the procedures in parts 4740.0100 to 4740.0170, as proposed at .. *State Register* .... and as subsequently adopted. In addition to the information required on an application for a license, a laboratory that performs only initial drug and alcohol screening tests must disclose on its application the name of the licensed laboratory that performs its confirmatory tests.

4740.1025 EXCEPTION.

A medical clinic, hospital, or other medical facility need not be licensed under parts 4740.1010 to 4740.1080 to perform a breath test as an initial screening test for alcohol if:

A. the medical clinic, hospital, or other medical facility is not owned or operated by the employer; and

B. the results of the breath test are confirmed by a blood test performed by a laboratory licensed under parts 4740.1010 to 4740.1080.

4740.1040 RECIPROCITY.

A license shall be granted to a laboratory located in another state, if the requirements of *Minnesota Statutes*, section 181.953, subdivision 1, paragraph (c), are met.

4740.1050 TERM OF LICENSE.

Laboratories shall be licensed for a term of one year beginning on July 1 and ending June 30. Unless a laboratory submits a timely application for license renewal, the license expires without further notice at the end of the term.

4740.1060 FEES.

Subpart 1. **Annual license fee required.** The laboratory must pay an annual license fee with the initial application for license and with each renewal application. The amount of the fee is determined under subpart 3. It is based upon the number of samples taken from Minnesota employees, that the laboratory tests.

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Subp. 2. **Information required to determine fee.** The laboratory must submit an estimate of the number of annual Minnesota employee samples to be tested for drugs and alcohol with the application for a license or license renewal. The laboratory must submit to the department quarterly reports of the volume of actual employee drug and alcohol testing samples and the results of proficiency testing results for the past quarter. The statistics from these reports are used to adjust the license fee collected from the laboratory on its next license renewal application to reflect actual sample volume.

Subp. 3. **License fee schedule.** Annual license fees are determined according to the following schedule:

$$\text{License fee} = \text{(a)}\ \$1{,}200 + \text{(b)}\left[\frac{\text{Total annual alcohol samples taken from Minnesota employees} + \text{Total annual drug samples taken from Minnesota employees}}{2}\right] \times \$3/\text{sample}$$

A sample obtained for both alcohol and drug testing is considered as one alcohol sample and one drug sample for fee purposes. The $1,200 in part (a) of the schedule is nonrefundable.

Laboratories located outside Minnesota are assessed actual cost of additional labor, travel, and lodging expenses the department incurs in the laboratory inspection.

4740.1065 ANNUAL INSPECTION.

The commissioner shall conduct periodic inspections of laboratories licensed for drug and alcohol testing of employees. Inspections shall be unannounced and occur at least annually.

4740.1070 PERFORMANCE METHODS REQUIRED FOR ISSUANCE OF A LICENSE.

Subpart 1. **Standards required.** To qualify for a license to conduct drug and alcohol testing for Minnesota employees and job applicants, the officers or the owner of a laboratory must use the performance methods described in subparts 2 to 8.

Subp. 2. **Test samples.** The usual sample for drug testing is freshly voided urine. A breath, urine, or blood sample may be used for initial screening tests. When the breath test is used as the initial screening test for alcohol, a blood sample shall be obtained for the confirmatory test. The blood sample shall be collected immediately after the breath test. When an initial positive urine test indicates the presence of drugs, a blood test may be used for the confirmatory test.

The sample volume must be adequate to allow for the initial screening test, a confirmatory test, and a confirmatory retest.

Subp. 3. **Collection of urine samples; procedures.** The laboratory must have written procedures for collecting urine samples. The collection procedures must contain paragraphs 6 and 11 to 16 of the specimen collection procedures in Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies, NIDA, as provided by the *Federal Register*, volume 52, pages 30639 and 30640, Friday, August 14, 1987. Paragraphs 1 to 5 and 7 to 10 of these procedures are optional. The site where the sample is collected must have a stall or partitioned area that allows the individual being tested to provide the individual's urine specimen in privacy. The collection site person must sign and date either the tape sealing the sample container or the sample container label.

Subp. 4. **Collection of blood samples; procedures.** The laboratory must have written procedures for collection of blood samples. The procedure must address identification of the employee or job applicant, necessary collection supplies, seating or positioning of the employee or job applicant during sample collection, cleansing of the skin at the venipuncture site, and verification that the sample and paperwork are from the individual from which the sample was collected. NCCLS Guidelines H3-A2, Procedures for Collection of Diagnostic Blood Specimens by Venipuncture, 2nd Edition, Approved Standard, 1984, is an acceptable guide for the collection of blood samples. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford Building, 117 University Avenue, Saint Paul, Minnesota 55155.

The collection site person must sign either the tape sealing the sample container or the sample container label.

Subp. 5. **Techniques for drug testing.** For an initial screening test for drugs or drug metabolites, the laboratory must use a chromatographic technique or an immunoassay method. Samples that show the presumptive presence of a drug or drug metabolite must be confirmed by the gas chromatography/mass spectrometry (GC/MS) technique.

Subp. 6. **Techniques for alcohol testing.** A breath test, alcohol dehydrogenase reaction, microdiffusion, or oxidation of distillate with potassium dichromate may be used as a method to initially test for the presence of alcohol. The presumptive presence of alcohol must be confirmed using gas chromatography.

Subp. 7. **Confirmatory tests required.** A laboratory that performs only initial testing must obtain confirmatory results from a licensed laboratory that performs confirmatory tests.

Subp. 8. **Chain-of-custody procedures for handling samples.** The laboratory must follow written chain-of-custody procedures that, at a minimum, meet the requirements of items A to C.

A. Possession of a sample must be traceable to the employee from whom the sample is collected, from the time the sample is collected through the time the sample is tested, the test result reported, the sample retested, and the sample stored.

B. At all times, the sample must be in the possession of, in view of, or placed in a secured area by a person authorized to handle the sample.

C. A sample must be accompanied by a written chain-of-custody record. Individuals relinquishing or accepting possession of the sample must record the time the possession of the sample was transferred and must sign and date the chain-of-custody record at the time of transfer.

Subp. 9. **Storage of positive samples.** All confirmed positive samples shall be stored frozen for at least six months. The sample container must be sealed and labeled. The freezer must be locked or be located in a secure area.

Subp. 10. **Requirements for directors.** The director of the laboratory must be a full-time employee of the laboratory, must possess a doctoral or a master's degree in a biological or medical science, and must have at least three years' experience in an analytical toxicology laboratory.

Subp. 11. **Proficiency testing required.** Satisfactory participation in a proficiency testing program is required of a laboratory applying for or renewing a license. The Forensic Urine Drug Testing surveys conducted by the College of American Pathologists and the American Association for Clinical Chemistry and the NIDA Performance Test Program are acceptable proficiency testing programs. The laboratory must participate at the appropriate screening and confirmatory test levels for which an application for license is submitted.

Subp. 12. **Procedures for proficiency testing.** Before applying for or renewing a license, a laboratory must participate in and report the results of three cycles of proficiency testing. The laboratory must mail proficiency testing results to the commissioner.

The procedures for handling and testing proficiency test samples after receipt by the laboratory must be identical to the procedures for normal laboratory samples.

Laboratory personnel shall not be informed that these samples are part of a performance test to the extent possible.

A licensed laboratory may also be subjected to blind proficiency testing. Performance on blind testing samples is required at the same level as for the open proficiency testing.

A false-positive result from a confirmatory test sample is unsatisfactory performance. Two false-positive results from a screening test sample during a one-year period constitute unsatisfactory performance. The laboratory must inform the commissioner, in writing, of any false-positive test result on a proficiency testing sample, with a plan of corrective action. The commissioner will be informed within 14 days of receipt of the proficiency testing report.

Subp. 13. **Laboratory procedure manual.** The laboratory must possess and follow a laboratory procedure manual. The laboratory manual must describe the individual test procedures performed by the laboratory. The manual must have a table of contents and numbered pages. The manual must be reviewed annually. The description of the test procedures must include sections addressing the sample used for the test, reagents, supplies and materials, equipment calibration, quality control, the step-by-step procedure, calculations, reporting results, special notes, safety precautions, limitations of the procedure, references, and flow diagrams. Changes in a procedure must be reviewed and dated. Clinical Laboratory Procedure Manuals; Approved Guidelines, GP2-A, National Committee for Clinical Laboratory Standards, 1984, is an acceptable guide to writing a laboratory manual. This document is not subject to frequent change, is incorporated by reference, and is available at the State Law Library, Ford Building, 117 University Avenue, Saint Paul, Minnesota 55155.

4740.1080 THRESHOLD DETECTION LEVELS.

Threshold detection levels for confirmatory tests of drugs and drug metabolites defined in *Minnesota Statutes*, section 152.02, and rules of the Board of Pharmacy are 1,000 ng/ml, except as listed in items A to K:

A. marijuana metabolite (delta-9 tetrahydrocannabinol-9-carboxylic acid), 15 ng/ml;

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B. cocaine, 150 ng/ml;

C. benzoylecgonine, 150 ng/ml;

D. opiates, 300 ng/ml;

E. phencyclidine, 25 ng/ml;

F. amphetamines, 500 ng/ml;

G. fentanyl, 5 ng/ml;

H. lysergic acid diethylamide (LSD), 5 ng/ml;

I. 3-4-methylenedioxy amphetamine (MDA), 300 ng/ml;

J. alcohol (urine), .02 gram percent; and

K. alcohol (blood), .02 gram percent.

4740.1090 VARIANCE AND WAIVERS.

A laboratory may request that the department grant a variance or waiver from the provisions of parts 4740.1000 to 4740.1080. A request for a variance or waiver must be submitted to the department in writing. A request must contain the following information:

A. the specific rules for which the variance or waiver is requested;

B. the reasons for the request;

C. the alternative measures that will be taken if a variance or waiver is granted; and

D. the length of time for which the variance or waiver is sought.

The commissioner shall review information submitted with the request for waiver or variance. The commissioner shall provide the laboratory with a written decision that states the reasons for granting or denying the request for the variance.

Rules as Proposed (all new material)

CHAPTER 4740
DEPARTMENT OF HEALTH
LABORATORIES; ACCREDITATION REQUIREMENTS

4740.0100 PURPOSE AND SCOPE.

The rules in chapter 4740 contain accreditation procedures and standards for laboratories that perform tests or analyses as required by state or federal law.

4740.0110 DEFINITIONS.

Subpart 1. **Scope.** The terms used in parts 4740.0100 to 4740.0170 have the meanings given them in this part.

Subp. 2. **Accreditation.** "Accreditation" means licensure or certification of a laboratory to perform specific tests.

Subp. 3. **Certification.** "Certification" means written acknowledgment of the laboratory's demonstrated capability to perform tests for a specific purpose.

Subp. 4. **Commissioner.** "Commissioner" means the commissioner of the Minnesota Department of Health.

Subp. 5. **Laboratory.** "Laboratory" means a person, corporation, or other entity, including a governmental entity, which examines, analyzes, or tests samples.

Subp. 6. **Licensure.** "Licensure" means authorization to perform laboratory tests for a purpose defined by statute.

Subp. 7. **Out-of-control quality control result.** "Out-of-control quality control result" means a result from an internal quality control sample that does not fall within a statistically acceptable range.

Subp. 8. **Sample.** "Sample" means a substance derived from a nonhuman source and collected for the purpose of analysis or a tissue, blood, excretion, or other bodily fluid specimen obtained from a human for the detection of a chemical, etiologic agent, or histologic abnormality.

4740.0120 APPLICATION PROCEDURES.

Subpart 1. **Standards.** To obtain accreditation, the laboratory must comply with subparts 2 to 5 and with the technical standards that apply to the specific laboratory test for which accreditation is sought, as specified in rule.

Subp. 2. **Contents.** The application shall include:

A. the address of the principal place of business or headquarters;

B. the address and phone number of the laboratory that seeks accreditation, if different than in item A;

C. the names of officers and the laboratory director;

D. written assurance that the laboratory meets the standards of parts 4740.0100 to 4740.0170 and the standards that apply to the specific test for which laboratory accreditation is sought, as specified in rule;

E. the signatures of two officers or managing agents of the laboratory and proof of the signatories' authority to bind the laboratory; and

F. other reasonable information necessary to determine compliance with accreditation requirements.

Subp. 3. **Documentation.** At the time of application, the laboratory shall submit or have available for inspection the following documents:

A. a current laboratory manual;

B. criteria for accepting and rejecting samples for testing;

C. proficiency testing results;

D. internal quality assurance records;

E. corrective action for out-of-control quality control results;

F. sample receipt and storage records;

G. equipment calibration and standardization records;

H. equipment repair and preventive maintenance records;

I. personnel education and training requirements;

J. laboratory safety policies; and

K. written chain-of-custody procedures.

Subp. 4. **Fee.** The laboratory shall submit with its application a nonrefundable fee, in the amount established by the specific rule for the purpose or type of test for which accreditation is sought.

Subp. 5. **Inspection.** The laboratory must demonstrate compliance with accreditation requirements through an inspection conducted by persons designated by the commissioner. Inspections shall be unannounced and at a frequency established by the rule specific to the purpose or type of test for which accreditation is sought.

4740.0130 PROVISIONAL ACCREDITATION.

A laboratory that meets accreditation application requirements shall receive provisional accreditation until an on-site inspection is completed. Upon demonstration, through inspections, of compliance with standards specific to the purpose or type of testing for which accreditation is sought, full accreditation shall be granted.

4740.0140 TERM OF ACCREDITATION.

Laboratories shall be accredited for a term of one year, which shall include any period of provisional accreditation. Unless a laboratory submits a timely application for renewal of the accreditation, the accreditation expires without notice at the end of the term.

4740.0150 COMPLIANCE.

All accredited laboratories shall immediately inform the commissioner of any changes to the information required by part 4740.0120 and the rules specific to the laboratory test for which accreditation is sought. The laboratory director must inform the commissioner in writing of any changes in test methodology, instrumentation, key personnel, or laboratory ownership and submit revisions to the documents listed in part 4740.0120, subpart 3, within 14 calendar days of the change.

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4740.0160 ACCREDITATION RENEWAL.

A laboratory shall submit an application for renewal of accreditation with the applicable renewal fee, no later than 30 days before the expiration date of the current accreditation. The renewal application shall contain the same information required for an initial application in part 4740.0120, subpart 2. At the time of application for a renewal of its accreditation, the laboratory shall also submit or have available for inspection the documents listed in part 4740.0120, subpart 3. Unless a laboratory submits a timely application for accreditation renewal, the accreditation expires without further notice at the end of the term.

4740.0170 ACCREDITATION; SUSPENSION AND REVOCATION.

The commissioner may, pursuant to *Minnesota Statutes*, chapter 14, suspend, revoke, refuse to renew, condition, or limit the accreditation of a laboratory upon finding that the laboratory has repeatedly violated provisions of parts 4740.0100 to 4740.0160 or has repeatedly failed to meet standards defined under the rule applicable to the specific laboratory test for which the laboratory is accredited.

Pollution Control Agency

Proposed Permanent Rules Relating to Air Quality and Air Quality Permitting

Notice of Intent to Adopt Rule Amendments Without a Public Hearing

NOTICE IS HEREBY GIVEN that the Minnesota Pollution Control Agency (Agency) intends to adopt the above-entitled rule amendments without a public hearing following the procedures set forth in the Administrative Procedure Act for adopting rule amendments without a public hearing in *Minnesota Statutes* section 14.22 to 14.28 (1986). The Agency's authority to adopt the rule amendments is set forth in *Minnesota Statutes* section 116.07, subd. 4 (1986).

All persons have until 4:30 p.m. on November 30, 1988, to submit comments in support of or in opposition to the proposed rule amendments or any part or subpart of the rule amendments. Comment is encouraged. Each comment should identify the portion of the proposed rule amendments addressed, the reason for the comment, and any change proposed.

Any person may make a written request for a public hearing on the rule amendments within the comment period. If 25 or more persons submit a written request for a public hearing within the comment period, a public hearing will be held unless a sufficient number withdraw their requests in writing. Any person requesting a public hearing should state his or her name and address, and is encouraged to identify the portion of the proposed rule amendments addressed, the reason for the request, and any change proposed. If a public hearing is required, the Agency will proceed pursuant to *Minnesota Statutes* section 14.131 to 14.20 (1986).

Comments or written requests for a public hearing must be submitted to:

Ms. Elizabeth Henderson
Staff Engineer
Minnesota Pollution Control
Division of Air Quality
520 Lafayette Road North
St. Paul, Minnesota 55155
(612) 296-7554

The proposed rule amendments may be modified if the modifications are supported by data and views submitted to the Agency and do not result in a substantial change in the proposed rule amendments as noticed.

The proposed rule amendments, if adopted, will bring air quality rule terminology into agreement with proposed amendments to *Minnesota Rules* ch. 7005.0100 in conjunction with proposed amendments to the Offset Rules, *Minnesota Rules* Parts 7005.3010 to 7005.3060, which are being promulgated in a separate rulemaking proceeding. The rule amendments will also change *Minnesota Rules* Part 7005.0520, Table 2 to reference "dry" standard cubic feet per minute in reference to exhaust gases from industrial equipment; and will delete *Minnesota Rules* Part 7001.1210, Subpart 2, Item E. which exempts facilities using less than 10,000 gallons of solvent borne coating per year from air emission facility permitting requirements. The proposed rule amendments are published below. One free copy of the rule amendments is available upon request from Ms. Henderson at the address and telephone number stated above.

A Statement of Need and Reasonableness that describes the need for and reasonableness of each provision of the proposed rule amendments and identifies the data and information relied upon to support the proposed rule amendments has been prepared and is available from Ms. Henderson upon request.

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of Proposed Permanent Rules Relating to General Accreditation Requirements for Laboratories, Proposed Parts 4740.0100 to 4740.0170 and Proposed Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing, Proposed Parts 4740.1010 to 4740.1090

FINDINGS OF FACT, CONCLUSIONS AND ORDER ADOPTING RULES WITHOUT A PUBLIC HEARING

Notice of the intent of the Department of Health (hereinafter "Department") to adopt the above-captioned rules was published in the State Register on October 31, 1988, and was sent by United States mail to all persons on the list maintained by the Department pursuant to Minn. Stat. §§ 14.14, subd. 1a and 14.22 on October 24, 1988. Statements of need and reasonableness were prepared before the notice of intent to adopt rules without a public hearing was mailed to all persons on the rulemaking mailing list and published in the State Register and were available to the public.

All persons were given the opportunity to submit written comment on the rules for 30 days after notice of proposed rulemaking. The Department received 45 requests for a public hearing; 31 of the requests were subsequently withdrawn. Therefore, the Department did not receive requests for a public hearing from 25 or more persons which were not withdrawn. The Department received 38 comments on the rules. No requests for notice of submission to the Attorney General were received by the Department.

Based on the comments and evidence in the record before the Department, the Department makes the following

FINDINGS OF FACT

1. Part 4740.0100 has been modified to add subparts 4a and 4b because defining the terms "etiologic agent" and "histologic" will aid in understanding their use in these rules;

2. Part 4740.0120, subpart 5, has been modified to allow the Department to announce some inspections so that key laboratory personnel may be present;

3. Part 4740.0130 has been modified so that laboratories will have certain knowledge of the fact of provisional accreditation and its term by written notification;

4. Part 4740.0170 has been modified so that the Department can take action to protect the public health when warranted before repeated patterns are apparent;

5. Part 4740.1010, subpart 8, has been modified to add the words "independent contractor," since an independent contractor may be an employer;

6. Part 4740.1010, subpart 9, has been modified to clarify the definition of "initial screening test";

7. Part 4740.1010, subpart 10, was added to define "initial screening test minimum detection level" in order to clarify the requirements of part 4740.1075;

8. Part 4740.1010, subpart 14, was modified to correct the name of the National Institute on Drug Abuse (hereinafter "NIDA");

9. Part 4740.1010, subpart 18, was modified to clarify the conclusions to be drawn by the presence of a drug, drug metabolite, or alcohol at the threshold detection level;

10. Part 4740.1050 was modified to eliminate the need to establish a pro-rated fee schedule for a laboratory submitting a license application in the middle of a set term;

11. Part 4740.1060, subpart 1, was modified to clarify that all licensure fees and costs must be paid before a license will be issued.

12. Part 4740.1060, subparts 2 and 3, were modified to respond to the considerable public comment on the fee structure as proposed and still meet the statutory directive in Minnesota Statutes, section 181.953, subdivision 1(e) (1988), that the licensure fees entirely support the regulatory costs. An Addendum to the Statement of Need and Reasonableness, dated January 18, 1989, together with the approval of the Commissioner of Finance is incorporated here as the findings of fact supporting the modifications to the fee schedule;

13. Part 4740.1065 has been modified to permit the Department to announce some inspections so that key laboratory personnel may be present;

14. Part 4740.1070, subpart 2, has been modified to clarify that either a blood or urine sample may be used for a confirmatory test when a urine sample was used in the screening test;

15. Part 4740.1070, subpart 10, has been modified to allow medical doctors to be the director of a laboratory;

16. Part 4740.1075 was added to establish minimum detection levels for initial screening tests. The standards are the same as the NIDA standards for initial screening tests;

17. Part 4740.1080 was modified to delete free cocaine from the list and add its metabolite, benzoylecgonine, since cocaine is quickly metabolized. The change is consistent with NIDA standards; and

18. The Statements of Need and Reasonableness for parts 4740.0100 to 4740.0170 and for parts 4740.1010 to 4740.1090 are hereby incorporated as the findings of fact except where inconsistent with the above.

Based on the above findings of fact, the Department makes the following

CONCLUSIONS

1. Parts 4740.0100 to 4740.0170 and 4740.1010 to 4740.1090, as modified, are needed and reasonable.

2. The modifications are not substantial changes because the modifications do not affect classes of people who could not reasonably have been expected to comment on the proposed rule as originally noticed, do not add significant new subject matter which a reasonable person, on the basis of the proposed rule as originally noticed, would not have anticipated would occur during the rulemaking proceeding, and make no major substantive change the possibility of which was not raised by the proposed rule as originally noticed.

NOW, THEREFORE, IT IS HEREBY ORDERED that the rules identified as Permanent Rules Relating to General Accreditation Requirements for Laboratories and Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing are adopted this 19 day of April, 1989, pursuant to authority vested in the Department by Minn. Stat. §§ 144.07 (1986) and 181.953 (1988).

M.C. J. Mary Madonna Ashton

SISTER MARY MADONNA ASHTON
Commissioner of Health

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

DEPARTMENT OF HEALTH

In the Matter of Proposed Permanent Rules Relating to General Accreditation Requirements for Laboratories, Proposed Parts 4740.0100 to 4740.0170 and Proposed Permanent Rules Relating to Drug and Alcohol Testing Laboratories; Licensing, Proposed Parts 4740.1010 to 4740.1090

DECLARATION OF COUNSEL

I, Paul G. Zerby, Special Assistant Attorney General, do hereby declare that I have examined the above-captioned rules and the supporting rulemaking record and that, based on my examination, the Administrative Procedure Act and Minn. Rules ch. 2010 have been followed. Any exceptions are listed below. For Attorney General billing purposes, the four-digit docket client code is 1430.

Dated: April 26, 1989

PAUL G. ZERBY
Special Assistant
Attorney General

SF-00006-05 (4/86)

STATE OF MINNESOTA

Office Memorandum

DEPARTMENT : ATTORNEY GENERAL - Health

DATE : April 26, 1989

TO : Jackie Albright
Special Assistant
Attorney General
Public Finance Division

FROM : Paul G. Zerby
Special Assistant
Attorney General

Read 4/26/89

PHONE : 341-7272

SUBJECT : In the Matter of Rules Relating to Licensure of Laboratories for Drug and Alcohol Testing in the Workplace and Rules Relating to Accreditation of Laboratories

Enclosed for your review, pursuant to Minn. Stat. § 14.26 (1986) and Minn. Rules pt. 2010.0300 (1987), are the following documents to support the above-referenced rules:

1. Notice of Solicitation of Outside Information;
2. Rule as proposed with a certificate of approval as to form by the Revisor of Statutes attached;
3. Notice of Intent to Adopt Rules Without a Public Hearing (as mailed);
4. Statement of Need and Reasonableness;
5. Notes to House and Senate;
6. Affidavit of Mailing the Notice of Intent to Adopt Rules Without a Public Hearing;
7. Notice of Intent to Adopt Rules Without a Public Hearing (as published in the State Register);
8. Rules as adopted (original and three copies);
9. Findings of Fact, Conclusions, and Order Adopting Rules Without a Public Hearing;
10. Statement of Need and Reasonableness re fee structure modification;
11. Declaration of Counsel;
12. Comment (38 submissions);
13. Requests for Hearing (46 submissions); and
14. Withdrawals of Request for Hearing (31 submissions).

CEA:cs

Enclosures

STATE OF MINNESOTA

COUNTY OF HENNEPIN

BEFORE THE MINNESOTA

COMMISSIONER OF HEALTH

IN THE MATTER OF PROPOSED PERMANENT RULES RELATING TO DRUG AND ALCOHOL TESTING LABORATORIES; LICENSING

STATEMENT OF NEED AND REASONABLENESS

The Minnesota Commissioner of Health, (hereinafter "commissioner"), pursuant to Minnesota Statutes, sections 14.05 to 14.12 and 14.22 to 14.28, presents facts establishing the need for and the reasonableness of the above captioned proposed permanent rules.

In order to adopt the proposed rules, the Commissioner must demonstrate that she has complied with all the procedural and substantive requirements of rulemaking. Those requirements are that: 1) there is statutory authority to adopt the rule, 2) all necessary procedural steps have been taken, 3) the rules are needed, 4) the rules are reasonable, and 5) any additional requirements imposed by law have been satisfied. This statement demonstrates that the Commissioner has met these requirements.

I. STATUTORY AUTHORITY

The statutory authority of the Commissioner of Health to adopt the rules pertaining to licensure of laboratories performing drug and alcohol tests from Minnesota employees is outlined below. Specific statutory authority for each rule is discussed in detail as part of the rule-by-rule justification.

- Minnesota Statutes, section 181.953, requires the commissioner to adopt rules for the licensure of laboratories performing drug and alcohol tests on employee urine and blood samples.

- The commissioner may adopt reasonable rules pursuant to Minnesota Statutes, section 144.12, for the preservation of the public health.

II. COMPLIANCE WITH RULEMAKING PROCEDURAL REQUIREMENTS

Minnesota Statutes, sections 14.05 - 14.12 and 14.22 - 14.28, specify certain procedures which must be followed when an agency adopts or amends rules. Procedures applicable to all rules (Minnesota Statutes, sections 14.05 - 14.15) have been complied with by the commissioner. The commissioner has determined that the adoption of proposed parts 4740.1000 to 4740.1080 is non-controversial and has elected to follow procedures set forth in Minnesota Statutes, sections 14.22 - 14.28, which provide for an expedited process for the adoption of non-controversial administrative rules without holding a public hearing.

Minnesota Statutes, section 14.10, requires an agency that seeks information or opinions from persons outside the agency for adoption of rules to publish notice of such action in the State Register. This will serve to notify interested persons in the community of the opportunity to submit comments or data on the subject of the rules. A

notice of solicitation of outside information or opinions appeared in the State Register, on August 17, 1987, at Volume 12, Number 7, page 294.

The adoption of these rules will not require expenditure of public money by local public bodies of greater than $100,000.00 in either of the two years following promulgation, nor do these rules have any impact on agricultural land. (Minnesota Statutes, section 14.11, 1986.)

Pursuant to Minnesota Statutes, section 14.23, the commissioner has prepared this statement of need and reasonableness which is available to the public.

The commissioner will publish a notice of intent to adopt the rules without public hearing in the State Register and mail copies of the notice and proposed rules to persons registered with the Minnesota Department of Health pursuant to Minnesota Statutes, section 14.14, subdivision 1(a). The notice will include the following statements:

a) that the public have 30 days in which to submit comments on the proposed rules;
b) that no public hearing will be held unless 25 or more persons make a written request for a hearing within the 30-day comment period;
c) giving information pertaining to the manner in which persons shall request a hearing; and

d) that the rule may be modified if modifications are supported by data and the views submitted.

e) other information required by Minnesota Statutes, section 14.22.

If 25 or more persons submit to the Minnesota Department of Health a written request for a hearing of the proposed rules, the agency shall proceed under the provisions of Minnesota Statutes, sections 14.131 - 14.20, and notice of hearing shall be published in the State Register.

If no hearing is required, the commissioner will submit the proposed rules and notice as published, the rules as proposed for adoption, any written comments which have been received, and this statement of need and reasonableness to the Attorney General for approval of the rules.

These rules shall become effective five working days after publication of a notice of adoption in the State Register.

Non-Mandatory Actions by the Commissioner

The commissioner of health, pursuant to the authority granted under Minnesota Statutes, section 15.059, established in September, 1987, a "Technical Advisory Group". This group of toxicologists and laboratory professionals reviewed drafts of proposed rules. Review included assessment of standards, Threshold Detection Levels (Confirmatory Test Levels) and license fees. In December, 1987, the Commissioner established a second "Advisory Group"

which consisted of Representatives of Employers, Unions, government Human Rights Advocate Groups and principal authors of the bill.

The "Technical Advisory Group" and the "Advisory Group" provided direct advice on Laboratory Standards, Chain-of-Custody and Confirmatory Test Levels.

The technical advisory group, consisting of seven prominent toxicologists and scientists, reviewed the proposed rules. Members of the group included:

- Fred Apple, Ph.D., Hennepin County Medical Center;
- Kingsley LaBrosse, Ph.D., Medtox, New Brighton;
- Thomas P. Moyer, Ph.D., Mayo Clinic;
- David Ehresman, MT(ASCP), St. Paul-Ramsey Medical Center;
- John H. Eckfeldt, M.D., University of Minnesota Hospitals;
- Larry Bowers, Ph.D., University of Minnesota Hospitals; and
- S. G. Jejurikar, Ph.D., Forensic Toxicology, Bureau of Criminal Apprehension, State of Minnesota.

The Commissioner will send copies of proposed rules, as they appear in the State Register, to over 170 individuals, groups, laboratories, and government agencies registered as interested parties.

III. SMALL BUSINESS CONSIDERATIONS

The impact of rules on small businesses was examined as required by Minnesota Statutes, chapter 14.115. The affect was considered by the following methods:

- at least one of the members of the technical advisory group owns and operates a small business,

- The Minnesota Association of Commerce and Industry reviewed preliminary drafts of the rules,

- over thirty laboratories which have applied for transitional laboratory approval to perform drug and alcohol testing will receive copies of the rules, as they appear in the State Register, for comment,

- and the administrative requirements for application and renewal of a license were established to simplify or consolidate application and reporting requirements.

Impact of Standards

The standards proposed by rule have the potential of raising costs for all laboratories performing drug and alcohol tests in the workplace. A key area of contention involved the National Institute for Drug Abuse (NIDA) requirement that initial screening tests and confirmatory tests be conducted by the same laboratory.

The cost of equipment necessary for confirmatory tests is in the hundreds of thousands of dollars. To assure that a smaller laboratory may compete with larger laboratories, the rules allow a laboratory to perform only initial screening tests. The laboratory must forward samples positive on the initial screening test to a laboratory licensed by the commissioner to perform confirmatory tests. In addition, a copy of the chain-of-custody procedures used between laboratories must be submitted to the commissioner for review.

Other standards outlined by rule are either required by Minnesota Statutes, section 181.953 or are considered to be good laboratory practice among members of the laboratory community. These practices include participation in a proficiency testing program, conduct and documentation of internal quality assurance, adherence to sound chain-of-custody procedures, and the use of proper confirmatory test methods.

NIDA Standards and National Committee for Clinical Laboratory Standards (NCCLS) were consulted during advisory group discussions. NIDA is a division of the United States Department of Health and Human Services. NIDA is in the process of developing standards for employee drug testing for federal agencies. Unions, employers, and other governmental units are looking to NIDA as a model program for drug testing in the workplace. The NCCLS is an organization dedicated to the standardization of laboratory practices. Members include persons in public health, medicine, the laboratory diagnostics industry, and the academic setting.

Impact of License Fees

The legislature requires that the commissioner recover the costs of administering the laboratory licensure program through fees. The costs of conducting the program, combined with the relatively small number of laboratories offering specialized toxicology testing, will have an impact on small laboratories. However, testing job applicant and employee samples for drugs and alcohol is but one specific segment of the toxicology testing market. Laboratories may choose to enter, or not enter, the target market. Laboratories performing significant numbers of tests for employers will not be forced out of the market place. It is logical to assume that the added cost of licensure will be passed on to the user of such services.

The approval from the Department of Finance for licensure fees is attached as Appendix A.

Rules are written in two parts. The first, part 4740.0100 to 4740.0170, addresses general administrative issues. Parts 4740.1000 to 4740.1080, address the technical standards specific to alcohol and drug testing.

IV. RULE-BY-RULE JUSTIFICATION

4740.1000 **Purpose and Scope**

Minnesota Statutes, section 181.953 requires that the Commissioner of Health assure that laboratories meet defined standards when testing Minnesota employees for drugs or alcohol. Licensure of these laboratories is the method to be used for assessment of compliance.

4740.1010 **Definitions**

Terms used in the rule are defined to promote a better understanding of the rule.

4740.1020 **License Required**

The paragraph states that a laboratory must possess a valid license to test employee/job applicant samples for drugs and alcohol testing from Minnesota employees. This is consistent with Minnesota Statutes, section 181.953, subdivision 1(a) which states that an employer who requests

or requires an employee or job applicant to undergo drug or alcohol testing shall use the services of a testing laboratory licensed by the commissioner.

National Institute for Drug Abuse (NIDA) requires that a laboratory performing drug and alcohol testing perform both the initial screening test and the confirmatory test. This practice would be in contradiction with Minnesota Statutes, section 14.115, which deals with the affect of rules on small business. It is reasonable to require laboratories which do only the initial screening test to send samples with presumptive presence of a drug or alcohol to a laboratory licensed by the commissioner, using strict written chain-of-custody procedures.

4740.1025 **Exception**

The legislature's intent is that a medical clinic, hospital, or other medical facility employs personnel competent to perform the breath test as an initial screening test for alcohol. Therefore, a medical clinic, hospital or other medical facility need not be licensed to perform a breath test as an initial screening test for alcohol. The exception conforms with Minnesota Statutes, section 181.951, as amended April 14, 1988, Chapter 536, Minnesota Sessions Law Services (West).

4740.1040 **Reciprocity**

The commissioner must grant reciprocity to laboratories licensed by another federal or state agency, under Minnesota Statutes, section 181.953, subdivision 1(c).

4740.1050 **Term of License**

A one year term of license allows more effective program planning and budgeting. The burden of renewal of a license rests with the applicant to control administrative costs.

4740.1060 **Annual License Fee Required**

The Department of Finance approved proposed fees for the Licensure of Laboratories Performing Drug and Alcohol Testing in Workplace, see attached memo dated December 3, 1987, to Dave Hovet. The commissioner of health is required to recover laboratory licensure costs and equipment costs through license fees. The fee schedule reflects the need to recover the costs of an actual on-site inspection through the fixed $1,200.00 base fee, yet recognize that other costs should be covered by the per sample fee.

4740.1065 **Annual Inspection**

Annual inspections will be used to assess compliance with standards. Advisory group members agreed with our contention that annual inspections are necessary for a laboratory licensed for drug and alcohol testing in the

workplace. Non-compliance with rule needs to be detected early to help minimize the risk of errors in testing or reporting of results.

4740.1070 **Performance Standards Required for Issuance of a License**

Subpart 1. Standards Required This simply states that to qualify for issuance of a license, the officers or owner must comply with Subparts 2 to 13.

Subpart 2. Test Samples The type of samples acceptable for drug and alcohol testing are indicated in accordance with Minnesota Statutes, section 181.953, subdivision 1(b)(2). Urine is the usual sample of choice for employee drug and alcohol testing. Blood and breath samples may be used.

Subpart 3. Collection of Urine Samples; Procedures Minnesota Statutes, section 181.953, subdivision 1(b)(3) requires the commissioner to define procedures for sample collection which assure privacy to the employee and job applicant, while minimizing the risk of sample tampering during the sample collection process. Sample collection usually takes place in clinic or other medical facility which is designed, equipped, and staffed for that purpose.

However, the commissioner of health recognizes that samples may be collected in a facility other than a clinic or hospital. The commissioner of health recognizes that not all aspects of items 1 through 10, Specimen Collection, Federal Register, Volume 52, Number 157, Friday, August 14, 1987, page 30639 can be adhered to in a non-clinic setting. However, the commissioner expects that strict sample identification will be maintained through the collection process, consistent with individual privacy issues. National Institute for Drug Abuse (NIDA) guidelines are attached as Appendix B. NIDA, a division of the United States Health and Human Services Department, exists to study issues involving drug abuse.

Subpart 4. Collection of Blood Samples; Procedures

Minnesota Statutes, section 181.953, subdivision 1(b)(3) requires the commissioner to define procedures for sample collection which assure privacy to the employee and job applicant, while minimizing the risk of sample tampering during the sample collection process. Collection of blood is an invasive procedure which could affect the health of an individual. Therefore, the laboratory will have a written procedure for the collection of blood samples. The commissioner recommends the NCCLS Standard (Appendix C) as an acceptable guide for writing the sample collection procedure. The NCCLS is a nationally recognized organization dedicated to the improvement of clinical laboratory testing. NCCLS guidelines are written by experts in the clinical laboratory testing

profession and are reviewed by peers. Comments are sought from all clinical laboratory professionals before guidelines and standards are approved.

Subpart 5. Techniques for Drug Testing The commissioner must determine the tests acceptable for initial testing and confirmatory testing. Any drug test may be used for the initial test if it meets FDA requirements for in Vitro diagnostic products under 21 CFR, Chapter 1, Part 809. The confirmatory test must be done by the gas chromatographic/mass spectrometer (GC/MS). GC/MS is currently recognized as the most specific method for the detection of drugs and drug metabolites. Confirmation of presumptively positive samples by GC/MS will minimize the risk of a false-positive result for an employee or job applicant. Right to a retest of positive confirmed samples essentially eliminates the possibility of a false-positive result. Acceptable testing methods will be reviewed as technology changes and upon formal request for variance.

Subpart 6. Techniques for Alcohol Testing Tests for alcohol are specified to, as much as possible, conform with existing rules. Minnesota Rules, 7502.0700.

Subpart 7. Confirmatory Tests Required Samples tested for drugs, drug metabolites and alcohol must be tested by a licensed laboratory. Therefore, a laboratory which is licensed to perform only initial screening tests must confirm the presumptive presence of a drug, drug

metabolite or alcohol through a laboratory licensed to perform confirmatory tests.

Subpart 8. Chain-of-Custody Procedures for Handling Samples The commissioner recognizes that specifics of chain-of-custody procedures will vary from lab to lab. However, possession must be traceable back to the employee from whom the sample was collected. Several sources of information were reviewed concerning chain-of-custody procedures. The Handbook for Sampling and Sample Preservation of Water and Wastewater, Environmental Monitoring and Laboratory, Office of Research and Development, US Environmental Protection Agency, Cincinnati, Ohio, EPA-600/4-82-029, Sept., 1982, pages 348 and 349 outlines criteria for chain-of-custody procedures. The criteria are incorporated into Items A through C, Subpart 8. USEPA samples are collected during enforcement investigations, the evidentiary nature of which requires strong chain-of-custody procedures.

Subpart 9. Storage of Positive Samples Confirmed positive samples will be properly stored to assure that an employee may request a retest. The freezer used to store confirmed positive samples will be locked or located in a secured area to prevent tampering, unauthorized removal or the possible unauthorized disclosure of names of persons with positive results. Minnesota Statutes, section 181.953, subdivision 1(b)(7) and subdivision 3.

Subpart 10. Requirements for Directors The laboratory scientific director shall be fully capable of managing the technical aspects of the laboratory. Language is derived directly from Minnesota Statutes, section 181.953, subdivision 2(1)).

Subpart 11. Proficiency Testing Required Proficiency testing is used as a tool for evaluating laboratory performance by such certification and licensing bodies as MEDICARE/HCFA, The College of American Pathologists and The Joint Commission for Accreditation of Hospitals. Proficiency testing standards are stated in the transitional laboratory requirements, Minnesota Statutes, section 181.953, subdivision 2(2) and proficiency testing is necessary and reasonable as a requirement for licensure. Proficiency testing results will be used as an indicator of laboratory performance between laboratory inspections.

Subpart 12. Procedures for Proficiency Testing The frequency and numbers of samples to be tested are outlined. The College of American Pathologists and American Association of Clinical Chemists provide programs which are widely recognized as acceptable programs. "Blind" proficiency testing, which simulates a real sample, arrives at the laboratory as a routine sample test. Results are considered a better indication of true laboratory performance. A false-positive confirmatory test result for an employee may have serious impact on the employee or job applicant. Therefore, a

false-positive test result for a proficiency testing confirmatory test sample is not satisfactory. The commissioner understands that statistically random errors occur in laboratory testing. Therefore, the laboratory will explain corrective actions implemented to help assure that false-positive results will be resolved prior to issuance of a laboratory report.

Subpart 13. Laboratory Procedure Manual The laboratory procedure manual is a key component of reliable laboratory test results. Clinical-type laboratories should use a format similar to those outlined in **Clinical Laboratory Procedure Manuals**, National Committee for Clinical Laboratory Standards (NCCLS), 1984. Written laboratory procedures are reasonable business and scientific practices. NCCLS guidelines are attached as Appendix D.

4740.1080 **Threshold Detection Levels**

Threshold detection levels or, perhaps more appropriately, confirmatory test levels for the more common drugs of abuse are defined. A group of seven prominent toxicologists reviewed the values (Appendix E). Decisions concerning threshold detection levels for cocaine, benzoylecgonine, opiates, phencyclidine, amphetamines, fentanyl, lysergic acid diethylamide, 3-4-methylenedioxy amphetamine, and alcohol centered on the analytical capabilities of the population of laboratories performing the confirmatory test.

Physiologic effects of possible passive inhalation of marijuana smoke were discussed at length. Although delta-9 tetrahydrocannabinol-9-carboxylic acid may be detected at levels less than 15 ng/ml, members of the advisory group felt that 15 ng/ml is the limit of Δ-9-THC levels in passive inhalation. The Employers Association recommended a 15 ng/ml level for Δ-9-THC.

Threshold detection levels for the remaining hundreds of substances defined under section 152.01, subdivision 1, schedules I through V were set at 1000 ng/ml. Threshold detection levels for the substances not listed are not generally known or documented (Minnesota Statutes, section 181.953, subdivision 1(b)(5)).

4740.1090 **Variance and Waivers**

Variance and Waiver gives a laboratory the opportunity to apply for an exception or alternative to a specific portion of the rule.

9-2-88

Date

Sister Mary Madonna Ashton
Commissioner of Health
Minnesota Department of Health

JAI 1-5-88
Rev. 8/16/88:rs

APPENDIX A: Statement of Need and Reasonableness for License Fees

DEPARTMENT : HEALTH

STATE OF MINNESOTA

Office Memorandum

DATE : December 3, 1987

TO : Dave Hovet, Chief
Financial Management

FROM : Robert Lindner, Ph.D., M.D., Director
Division of Public Health Laboratories

PHONE : 623-5640

SUBJECT : Laboratory License Fees: Drug and Alcohol Testing in the Workplace

The Statement of Need and Reasonableness for license fees to be collected pursuant to Minnesota Law, 1987, Chapter 388 is attached. Copies of the proposed administrative rules and proposed technical rules are also attached.

RL/JI:sb

Attachments

DEPARTMENT : HEALTH

STATE OF MINNESOTA

Office Memorandum

DATE : December 30, 1987

TO : Bruce Reddemann, Director
Budget Operations and Support
Department of Finance

FROM : David Hovet, Director
Financial Management

PHONE : 623-5072

SUBJECT : Establish Fees

Please find attached, a request to establish fees relating to the licensure of laboratories performing drug and alcohol tests of employees in Minnesota. If you should have any questions, please contact me.

DH:kw
Enclosure

Department of Finance Approval for Establishing Fees for Licensure of Laboratories Performing Drug and Alcohol Tests of Employees in Minnesota

Minnesota Laws, 1987, Chapter 388, Section 4, Subdivision 1 authorizes the Department of Health to establish fees to recover costs for the licensure of laboratories performing drug and alcohol tests of employees in Minnesota. The Department of Health will establish an annual license fee. License fees collected from the laboratories will be used to cover expenses for conduct of the licensure program.

The proposed fees will recover the $47,000 one-time appropriation for FY88 and the costs of administering Section 4, Subdivision 1 of Chapter 388, Minnesota Laws, 1987.

Upon review of the attached supporting information justifying the need and the amount of the proposed fees, and pursuant to the authority vested in the Department of Finance under Minnesota Statute 16A.128 (1984), the license fees set forth in the proposal of the Department of Health are hereby approved.

JAN. 7, 1988
Date

Operating Budget Director

Statement of Need and Reasonableness

Minnesota Law, 1987, Chapter 388, Section 4, Subdivision 1 requires the Commissioner of Health to establish fees to approximately equal the costs of conducting a licensure program for laboratories performing drug and alcohol tests of employees in the state. Paragraph 7(d) reads as follows:

The commissioner shall charge laboratories an annual license fee. The fee may vary depending on the number of Minnesota employee samples tested annually at a laboratory. Fee receipts must be deposited in the state treasury and credited to a special account and are appropriated to the commissioner to administer this subdivision, and to purchase or lease laboratory equipment as accumulated fee receipts make equipment purchases or leases possible. Notwithstanding section 144.122, the commissioner shall set the license fee at an amount so that the total fees collected will recover the costs of administering this subdivision and allow an additional amount to be credited to the special account each year sufficient to allow the commissioner to obtain appropriate laboratory equipment for use in administering this subdivision by July 1, 1994.

Under the proposed rule, the laboratory will submit an initial payment of $1,200.00 for the annual license fee with the application for license. The initial payment is not refundable. Following the review of the application, a final payment on the annual license fee shall be due. This final payment shall be based on the formula,

$$\left[\frac{\text{Minnesota Alcohol Samples}}{2} + \text{Minnesota Drug Samples}\right] \times \$3.00/\text{sample}.$$

A sample obtained for both alcohol and drug testing shall be considered one (1) alcohol sample and one (1) drug sample for fee purposes. If the laboratory satisfies application criteria and pays the entire license fee, the laboratory will receive a provisional license. Full licensure may be granted after an on-site inspection to include, but not be limited to, assessment of external and internal quality control, examination of written laboratory procedures, review of records of sample receipt and storage, and an audit of records to ascertain the validity of statistics submitted to the Minnesota Department of Health. Demonstrated compliance with licensure standards will be required to qualify for a license.

Drug and alcohol tests used by laboratories are sophisticated and varied. Initial tests use a variety of chromatographic or immuno-chemical technologies. The confirmatory test method, Gas Chromatography/Mass Spectrometry (GC/MS) demands a high level of training and skill. Therefore, a toxicologist consultant will be hired to perform on-site inspection. A professional-level employee (0.5 FTE) will manage the program and will work with the toxicologist on initial laboratory inspections. A clerk-typist (0.5 FTE) will provide office support.

The fees collected will be used to support the licensure program. We estimate that approximately ten laboratories performing approximately 22,000 drug and alcohol tests of Minnesota employees per year will apply for a license

Estimated Expenses

Estimated expenses in FY88 are expected to be higher than FY89 due to the costs associated with the rule-making process. Table I shows estimated costs for FY88 and 89, which are $77,400 and $53,000 respectively. The $47,000 appropriation will be returned to the general fund on June 30, 1989.

Estimated Revenue

The license fee consists of a fixed $1,200.00 component to assure that direct inspection costs are recovered. The variable $3.00 per sample tested fee is to cover other program expenses. Fees collected from alcohol samples are 50% of the drug sample fee to reflect relative costs of the test to the employer. A laboratory will establish the license fee by the formula:

$1,200.00 + [(Alcohol samples)(0.5) + Drug Samples] x $3.00 (see Table II).

Estimated revenue for FY88 is:

10 labs x $1,200 fixed license fee	12,000.00
+ [(8,800)(0.5) + 12,800] x $3.00	51,600.00
	63,600.00

	INCOME (FEES)	EXPENSES	EXTRAORDINARY EXPENSES	CASH FLOW	SPECIAL ACCT BAL
7-1-88	$0	$0	$0	$0	$47,000
FY88	$63,600	$77,400	$0	-$13,800	$33,200
FY89	$66,780	$53,000	$47,000	-$33,220	-$20

The license fee is necessary to carry out the tasks required by the law. The fees are reasonable and they meet the statutory criteria for covering estimated license program costs.

12-24-87
Date

Robert Lindner
Robert Lindner, Ph.D., M.D.
Director, Public Health Laboratories

TABLE I

ESTIMATED EXPENSES FY 88 AND FY89
DRUG AND ALCOHOL TESTING IN THE WORKPLACE
LABORATORY LICENSURE PROGRAM

	Costs	
FY88 EXPENSES		
Rule-Making Process		
Attorney, 100 hours @ $50/hr	$5,000	
Public Hearing Examiner, 100 hours @ $60/hr	$6,000	
Professional Staff	$18,000	
Clerical, .25 FTE	$4,300	
Office Supplies, Duplicating	$1,500	
Communications	$500	
State Register	$1,000	
Licensure Implementation		
Attorney 20 hours @ $50/hr	$1,000	
Inspections, 1/yr x 10 labs (6 mos.)	$6,500	
(Toxicologist Consultant and Travel)		
Professional Staff	$18,000	
Clerical, .25 FTE	$4,300	
Office Supplies, Duplicating	$1,600	
Equipment	$0	
Communications	$400	
Total Direct Costs	$68,100	
Indirect Costs (13.6%)	$9,300	
Total Costs		$77,400
FY89 EXPENSES		
Inspections, 1/yr x 10 labs	$13,650	
(Toxicologist Consultant and Travel)		
Professional Staff, 0.5 FTE	$18,700	
Clerical, 0.5 FTE	$10,500	
Office Supplies	$3,500	
Equipment	$0	
Communications	$250	
Total Direct Costs	$46,600	
Indirect Costs	$6,400	
Total Costs		$53,000

JAI 10-30-87

Revised 06-JAN-1988

TABLE II

Drug and Alcohol Testing in the Workplace
Number of Samples Tested in the Last Year
(Information from Transitional Approval Applications)

Laboratory	Alcohol	Drug
1	1000	1000
2	1000	1000
3	1000	3000
4	100	1000
5	100	100
6	1000	3000
7	4000	4000
8	100	100
9	100	100
10	100	100
11	0	100
12	100	100
13	100	100
14	100	100
TOTAL	8800	13800

TOTAL FOR LICENSE FEES 17200
Alcohol Samples x 0.5 + Drug Samples

JAI 10-13-87

Revised 24-NOV-1987

APPENDIX B: Federal Register, Friday August 14, 1987 Alcohol, Drug Abuse and Mental Health Administration, Department of Health And Human Services, "Scientific and Technical Guidelines for Federal Drug Testing Programs; Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies; Notice of Proposed Guidelines".

federal register

Friday
August 14, 1987

Part XII

Department of Health and Human Services

Alcohol, Drug Abuse, and Mental Health Administration

Scientific and Technical Guidelines for Federal Drug Testing Programs; Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies; Notice of Proposed Guidelines

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

Scientific and Technical Guidelines for Federal Drug Testing Programs; Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

AGENCY: Alcohol, Drug Abuse, and Mental Health Administration, HHS.

ACTION: Notice of proposed guidelines.

SUMMARY: The Department of Health and Human Services invites comments on proposed Scientific and Technical Guidelines for Federal Drug Testing Programs and Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies.

DATES: Interested persons are invited to submit comments on or before October 13, 1987.

ADDRESSES: Written comments should be addressed to the Office of Workplace Initiatives, National Institute on Drug Abuse, 5600 Fishers Lane, Room 10A-53, Rockville, Maryland 20857.

FOR FURTHER INFORMATION CONTACT: Nancy Rittman (301) 443-6780.

SUPPLEMENTARY INFORMATION: This document sets forth the Department of Health and Human Services (DHHS) proposed "Scientific and Technical Guidelines for Drug Testing Programs" and "Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies" as directed in the President's Executive Order No. 12564 dated September 15, 1986, and section 503 of Pub. L. 100-71, the "Supplemental Appropriations Act for 1987," dated July 11, 1987.

Public Law 100-71 requires DHHS to publish these proposed guidelines and standards in the **Federal Register** and allow interested persons not less than 60 days to submit written comments on them. Following review and consideration of written comments DHHS will publish the final guidelines and standards in the **Federal Register** and they shall become effective upon publication.

Public Law 100-71 requires that DHHS publish guidance in the **Federal Register** to accomplish the following: (1) Establish comprehensive standards for all aspects of laboratory drug testing and laboratory procedures to be applied in carrying out Executive Order 12564, including standards which require the use of the best available technology for ensuring the full reliability and accuracy of drug tests and strict procedures governing the chain of custody of specimens collected for drug testing; (2) specify the drugs for which Federal employees may be tested; and (3) establish appropriate standards and procedures for periodic review of laboratories and criteria for certification and revocation of certification of laboratories to perform drug testing in carrying out Executive Order 12564.

The scientific and technical guidelines which follow satisfy the first two of these requirements of Pub. L. 100-71 by establishing comprehensive standards for all aspects of laboratory drug testing and specifying the drugs for which Federal employees may be tested. The third requirement of Pub. L. 100-71 is met by the Secretary's proposed "Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies" which immediately follow the guidelines.

These guidelines are essentially the same as the guidelines dated February 13, 1987 and issued by the Secretary on February 19, 1987, under Executive Order 12564, with minor changes to be consistent with the certification standards which follow and to prepare the guidelines for publication in the **Federal Register**. **Part II of the February 13, 1987 guidelines which sets forth model language for agency contracts to obtain laboratory urinalysis services has been deleted in its entirety.** Since this part of the guidelines did not reflect mandatory standards to be imposed on agencies, DHHS decided to delete it as it is redundant and possibly confusing.

Once the guidelines and certification standards are finalized and published in the **Federal Register**, following consideration of public comment made in response to this notice, the Secretary may make additional changes to the guidelines and standards to reflect improvement in the available science and technology without further opportunity for notice and comment. These changes will be published as a notice in the **Federal Register**.

While the certification system proposed by this notice is in development, Federal agencies may use agency or contract laboratories that have been certified for urinalysis testing by the Department of Defense (DOD). The DOD certification process is extremely strict and sophisticated and, during the interim period while the DHHS certification process becomes operational, DHHS believes that DOD certification will be more than adequate to ensure the full reliability and accuracy of drug tests and the reporting of test results. This is consistent with the provisions in the Scientific and Technical Guidelines for Drug Testing Programs dated February 13, 1987, and given statutory recognition by Pub. L. 100-71, that allows use of the DOD laboratories "prior to the existence of ADAMHA/NIDA-recognized accreditation and proficiency testing programs."

Information Collection and Recordkeeping Requirements

The proposed certification standards include a number of information collection and recordkeeping requirements which would be imposed on laboratories wishing to become certified to perform drug testing on Federal employees. These include the documentation requirements of section V and the information required to be submitted by the laboratory during its inspection under Appendix B. As required by section 3504(h) of the Paperwork Reduction Act of 1980, we have submitted a copy of this notice to the Office of Management and Budget (OMB) for its review of these information collection and recordkeeping requirements. Other organizations and individuals desiring to submit comments on these requirements should submit them to the DHHS office designated for this purpose whose name appears in the preamble and to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, Room 3208, Washingotn, DC 20503, Attention: Desk Officer for HHS.

Dated: August 4, 1987.

Robert E. Windom,

Assistant Secretary for Health.

Approved: August 10, 1987.

Otis R. Bowen,

Secretary.

Scientific and Technical Guidelines for Drug Testing Programs

August 3, 1987.

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Scientific and Technical Requirements

The Drugs

The President's Executive Order defines "illegal drugs" as those included in Schedule I or II of the Controlled Substances Act (CSA), unless the use is authorized by a legal prescription or other exemption as permitted under appropriate laws. These schedules cover hundreds of drugs, but it is obviously not practical to test for all of them.

Agency preemployment and random drug testing programs shall at a minimum test for *marijuana* and *cocaine*, and in addition agencies may test for opiates, amphetamines, and phencyclidine (PCP). When conducting reasonable suspicion testing, an agency may test for any drug identified in Schedule I or II of the Controlled Substances Act. The above provisions are not intended to limit agencies specifically authorized by law to include additional categories of drugs in the drug testing of their own employees or employees in their regulated industries.

This document presents specific information on the drugs most likely to be included in agency drug testing programs (i.e., marijuana, cocaine, opiates, amphetamines, and PCP). Agencies shall petition the Secretary of Health and Human Services or his designee (hereinafter referred to as "the Secretary") for approval to include any additional drugs (or classes of drugs) in its testing protocols.

Specimen Collection Procedures

Collection Site

A designated collection site is a place where individuals present themselves for the purpose of providing urine specimens to be analyzed for drugs of abuse. The site shall possess all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and transportation (shipping) of urine specimens to a drug testing laboratory.

Collection Procedures

Procedures shall provide for the collection site to be secure. A collection site facility dedicated solely to urine collection shall be secure at all times. In cases where a facility cannot be dedicated solely for the purpose of drug testing, the portion of the facility being used for testing shall be secured during drug testing operations. Chain of custody forms shall be properly executed by authorized collection site personnel upon receipt of specimens. The handling and transportation of urine specimens from one authorized individual or place to another shall always be accomplished through the use of chain of custody procedures. No unauthorized personnel shall be permitted in any part of the collection site when urine specimens are collected or stored.

Procedures for providing urine specimens shall comply with the provisions of these guidelines which allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided. Agencies shall take precautions to ensure that a urine specimen has not been authorized or diluted during the collection procedure and that all information on the urine bottle and in the record book can be identified as belonging to a given individual

To ensure that unadulterated specimens are obtained, the following procedures specify the minimum precautions that shall be taken during the collection of urine specimens:

1. To deter the dilution of specimens at the collection site, toilet bluing agents shall be placed in the toilet tanks, wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall not be any other source of water (e.g., shower, sink, etc.) in the enclosure where urination occurs.

2. Upon arrival at the collection site, the collection site person shall request the individual to present some type of photo identification. If the individual does not have proper identification, this shall be noted on the chain of custody form. If the individual fails to appear at the assigned time, collection site personnel shall contact appropriate authority to obtain guidance on action to be taken.

3. The collection site person shall ask the individual to remove any unnecessary outer garments (e.g., coat, jacket) that might conceal items or substances that could be used to tamper with or adulterate his/her urine specimen. Also, all personal belongings (e.g. purse, briefcase) shall remain with the outer garments; the individual may, however, retain his/her wallet. The collection site person shall note any unusual behavior or appearance.

4. The individual shall be instructed to wash and dry his/her hands prior to urination.

5. After washing hands, the individual shall remain in the presence of the collection site person and not have access to water fountains, faucets, soap dispensers, or cleaning agents or any other materials which could be used to adulterate the specimen.

6. The individuual may provide his/her specimen in the privacy of a stall, or otherwise partitioned area that allows for individual privacy. The collection site person shall note any unusual behavior by the individual.

7. In the exceptional event where an agency designated collection site is not accessible and there is a requirement for immediate specimen collection (e.g., accident investigation), a public restroom may be used according to the following procedures:

A same-sex collection site person shall accompany the individual into the public restroom which shall be made secure during the collection procedure. Toilet bluing shall be placed into the bowl. The collection site person shall remain in the restroom, but outside the stall, until the specimen is collected. In order to deter specimen dilution, the individual shall be asked not to flush the toilet until the specimen has been handed over to the collection site person. The individual shall be allowed to flush the toilet and shall then participate with the collection site person in completing the chain of custody procedures.

8. Upon receiving the specimen from the individual, the collection site person will determine that it contains at least 60 milliliters of urine. If there is not sufficient urine in the container, additional urine shall be collected. The individual may be given reasonable amounts of liquid (e.g., a glass of water). If an individual fails, for any reason, to provide the necessary specimen, collection site personnel shall contact appropriate authority to obtain guidance on action to be taken.

9. After the specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his/her hands.

10 *Immediately* after collection, collection site personnel shall measure the temperature of the specimen and conduct an inspection to determine the specimen's color, and signs of contaminants. Any unusual findings resulting from the inspection shall be included on the chain of custody form. The time from urination to delivery of the sample for temperature measurement is critical and in no case shall exceed four (4) minutes. If the temperature of the specimen is outside the range of 32.5–37.7°C/90.5–99.8°F this

's rise to reasonable suspicion of teration/substitution, and another specimen shall be collected under direct observation and both specimens forwarded to the laboratory. Any specimen suspected to be adulterated shall always be forwarded for testing. When reasonable suspicion is established, the second specimen shall be obtained under direct observation.

11. Both the individual being tested and the collection site person shall keep the specimen in view at all times prior to its being sealed and labeled. If the specimen is transferred to a second container, the collection site person shall request the individual to observe the transfer of the specimen and the placement of the tamperproof seal over the bottle cap and down the sides of the bottle. The collection site person will place the identification label securely on the bottle.

12. **The identification label shall contain the date, individual's specimen number, and any other identifying information provided/required by the** Agency. The individual shall initial the label on the specimen bottle.

13. The collection site person will enter the identifying information in a dger. Both the collection site person the individual shall sign the ledger to the identifying information.

14. The individual shall be asked to read and sign a certification statement regarding his/her urine specimen.

15. The collection site person shall complete the appropriate chain of custody form.

16. The urine specimen and chain of custody form are now ready for shipment. If the specimen is not immediately prepared for shipment, it shall be appropriately secured during temporary storage.

Note: While any part of the chain of custody procedures is being performed, it is essential that the urine specimen and custody documents be under the control of the involved collection site person. If the involved collection site person shall leave his/her work station momentarily, the specimen and custody form shall be taken with him/her or shall be secured. After the collection site person returns to the work station the custody process will continue. If the site person is leaving for an extended period of time, the specimen shall be packaged for mailing before he/she leaves the site.

Collection Control

Collection site personnel shall always tempt to have the container or cimen bottle within sight before and r the individual has urinated. The containers shall be tightly capped, properly sealed, and labeled. A chain of custody form approved by the agency shall be utilized for maintaining control and accountability from point of collection to final disposition of specimens. With each transfer of possession, the chain of custody form shall be dated, signed by the individual releasing the specimen, signed by the individual accepting the specimen, and the purpose for transferring possession noted. Every effort shall be made to minimize the number of persons handling specimens.

Transportation To Laboratory

After collection of urine specimens, collection site personnel shall arrange to ship the specimens to the drug testing laboratory. The specimens shall be placed in appropriate containers (specimen boxes or padded mailers) that are securely sealed to eliminate the possibility of tampering. Collection site personnel shall sign and date across the tape sealing the container and ensure that the chain of custody documentation is attached to each sealed container. An outer mailing wrapper is placed around each sealed container. Specimens may be delivered to the drug testing laboratory using either the United States Postal Service, commercial air freight, air express, or may be hand carried. It is not necessary to send specimens by registered mail.

Laboratory Analysis Procedures

Definitions

Intralaboratory Chain of Custody

Procedures used by the laboratory to maintain control and accountability from the receipt of urine specimens until testing is completed, results are reported, and while specimens are in storage.

Initial Test

A sensitive, rapid, and inexpensive immunoassay screen to eliminate "true negative" specimens from further consideration.

Confirmatory Test

A second analytical procedure used to identify the presence of a specific drug or metabolite in a urine specimen. The confirmatory test shall be different in technique and chemical principle from that of the initial test procedure to ensure reliability and accuracy. (At this time gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine (PCP)).

Aliquot

A portion of a specimen used for testing. An appropriate amount is transferred into a labeled test tube.

Receiving/Preparation

The laboratory shall be secure at all times; no unauthorized personnel shall be permitted. Upon receipt of specimens, accession personnel shall inspect packages for evidence of possible tampering and compare information on specimen bottles with that on chain of custody forms. Any discrepancies shall be properly noted and described. Any direct evidence of tampering shall be reported immediately to the agency, and shall also be noted on the chain of custody form which shall accompany all specimens during laboratory possession.

Specimen bottles and original chain of custody forms will normally be retained within the accession area until all analyses have been completed. Aliquots and intralaboratory chain of custody forms shall be used by laboratory personnel for conducting the initial and confirmatory tests.

Short-Term Refrigerated Storage

Specimens that do not receive an initial testing within two (2) days of arrival at the laboratory shall be placed in secure, temporary refrigeration units. Temperatures shall not exceed six (6) degrees centigrade. Emergency power equipment shall be available in case of prolonged power failure.

Specimen Processing

Drug testing laboratories will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory testing, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both internal and external blind proficiency test samples shall appear as ordinary samples to laboratory personnel.

Initial Test

The initial testing shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative or positive for these five drugs or classes of drugs:

	Initial test level (ng/ml)
Marijuana metabolites	100
Cocaine metabolites	300
Opiates	300
Phencyclidine	25
Ampretamines	1000

These test levels are subject to change by HHS as advances in technology or other considerations warrant identification of these substances at other concentrations. *Alternate initial test methods and testing levels shall be submitted for written approval to the Secretary.*

Confirmatory Test

All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques. Quantitative GC/MC confirmation procedures at the following cutoff values shall be used for the following drugs:

	Confirmatory test level (ng/ml)
Marijuana metabolites [1]	20
Cocaine metabolites [2]	150
Opiates	300
Phencyclidine	25
Amphetamines	300

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid.
[2] Benzoylecgonine.

These test levels are subject to change by HHS as advances in technology or other considerations warrant identification of these substances at other concentrations.

Confirmation methods and levels for other drugs tested shall be submitted by the agency to the Secretary.

Chain of Custody

Proper chain of custody controls shall always be enforced during all testing and specimen handling. Only authorized personnel may handle specimens to be tested and they shall sign chain of custody forms to document when specimens are in their possession. Authorized technicians shall sign the chain of custody forms and be responsible for each urine specimen to be tested. The laboratory shall include sufficient safeguards to ensure that unauthorized personnel are prevented from gaining access to the laboratory.

Reporting Results

Test results shall be reported to the agency's designated Medical Review Officer within an average of five (5) working days of receipt of the specimen. The report shall contain the specimen number assigned by the submitting agency, the drug testing laboratory specimen identification number, and results of the drug tests. All specimens negative on the initial test or negative on the confirmatory test *shall be reported as negative.* Only specimens confirmed positive shall be reported positive for a specific drug. Results may be transmitted to the Medical Review Officer (see pg. xx) by various electronic means (e.g., teleprinters, facsimile, or computer) in a manner consistent with the Privacy Act. It is not permitted to provide results verbally by telephone. A certified copy of the original chain of custody form, signed by the laboratory director of laboratory certifying official, shall only be sent to the Medical Review Officer. Copies of all analytical results shall be available from the laboratory when requested by appropriate authority.

In addition, the laboratory shall provide the Medical Review Officer with a monthly statistical summary of urinalysis testing of Federal employees without any personal identifying information. Screening and confirmation data shall be included from results reported within that period. This summary normally shall be forwarded by registered mail within two (2) weeks (14 calendar days) after the end of the month, covered by the summary and shall contain the following information:

Initial Testing

(a) Number of specimens received.
(b) Number reported out.
(c) Number of specimens screened positive for:

Marijuana metabolites
Opiates (morphine/codeine)
Amphetamines
Any other drugs requested
Cocaine metabolites
Phencyclidine

Confirmation Testing

(a) Number of specimens received.
(b) Number of specimens confirmed positive for:

Marijuana metabolite
Morphine and/or codeine
Amphetamine
Any other drugs requested
Cocaine metabolites
Phencyclidine
Methamphetamine

All records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of two (2) years.

Long-Term Storage

Specimens confirmed positive shall be retained and placed in properly secured long-term frozen storage for at least 365 days. Within this 365-day period an agency may request the laboratory to retain the specimen for an additional period of time. This ensures that the urine specimen will be available for a possible retest during any administrative or disciplinary proceeding. If the laboratory does not received a request to retain the specimen during the initial 365-day period, the specimen may be discarded.

Retesting Specimens

Should specimen reanalysis be required, the quantitation of a drug or metabolite in a specimen is not required to be subject to the same testing level criteria that were used during the original analysis. Some analytes deteriorate or are lost during freezing and/or storage.

Security

The laboratory facilities shall use appropriate security measures to ensure limited and/or controlled access.

Subcontracting

The drug testing laboratory shall perform all work with its own personnel and equipment, unless otherwise authorized by the agency.

Laboratory Facilities

Laboratories shall comply with applicable provisions of any State licensure requirements. Certified laboratories shall have the facility and capability, at the same laboratory, of performing screening and confirmation tests for each drug or metabolite for which service is offered.

Laboratory Personnel

The scientific director of the drug testing laboratory shall be qualified to assume professional, organizational, educational, and administrative responsibility for the laboratory and shall be involved in the day-to-day management of the laboratory. The scientific director shall meet three criteria. He or she shall: (1) Be (a) certified as a Laboratory Director by the State in forensic or clinical laboratory toxicology, or (b) hold a Ph.D. in one of the natural sciences, or (c) have training and experience equivalent to the Ph.D., such as a scientific degree followed by extensive research experience in biology, chemistry and pharmacology or toxicology; (2) have extensive experience in analytical toxicology (the analysis of biological materials for drugs

of abuse)—at least two years postdoctoral experience or at least six years experience beyond any other degree and (3) appropriate training and/or experience in forensic applications of analytical toxicology (court testimony, research and publications in analytic toxicology of drugs of abuse, etc.). The director is responsible for ensuring that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the urine drug testing laboratory.

A key individual in the laboratory is the certifying scientist; (who may be the laboratory scientific director); this individual reviews the standards, control specimens, and quality control data together with the screening and confirmation test results. After having assured that all results are acceptable, this individual certifies the test result. The certifying scientist shall have training in the sciences, specific training in the theory and practice of the procedures used, including the recognition of aberrant results and quality control procedures.

Supervisors of analysts shall possess a B.S. degree in chemistry or at least the education and experience comparable to a Medical Technologist certified by the American Society of Clinical Pathologists, MT(ASCP), or its equivalent. These individuals also shall have training in the theory and practice of the procedures used, and understanding of quality control concepts. Periodic verification of their skills shall be documented. Other technicians or nontechnical staff shall possess the necessary training and skills for the task assigned. Inservice continuing education programs to meet the needs of all laboratory personnel is required. Personnel files shall include: Resume of training and experience; certification or license, if any; references; job descriptions; health records; records of performance evaluation and advancement; incident reports; and results of tests for color blindness.

Quality Assurance and Quality Control

Urine drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process:

Specimen acquisition, chain of custody, security, and reporting of results, in addition to the screening and confirmation of analytical procedures. Quality control procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process.

a. Requirement of Internal Laboratory Quality Control

Each analytical run of specimens to be screened shall include: control urine specimens containing no drug; specimens fortified with known standards; and positive controls with the drug or metabolite at or near the threshold (cutoff). Implementation of procedures shall be documented to ensure that carryover does not contaminate the testing of a subject's specimen. A minimum of 10 percent of all test samples shall be quality control (QC) specimens. The known standards shall be the first specimens processed in each run. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Internal proficiency test samples, prepared from spiked urine samples of determined concentration shall be included in the run and should appear as normal samples to laboratory personnel. Each run shall include at least two (2) blind control samples (one positive and one negative) per 200 specimens. Equivalent standards, positive and negative controls shall be analyzed in parallel with confirmation tests.

b. Agency External Laboratory Quality Control Procedures

Participation in other proficiency testing surveys, by which the laboratory's performance is compared with peers and reference laboratories, is encouraged. *Participation in a ADAMHA/National Institute on Drug Abuse (NIDA)-recognized certification program for laboratories engaged in urine drug testing is mandatory.*

During the initial 90-day period of any new drug testing program a minimum of 1000 samples of which at least 800 are blank (i.e., certified to contain no drug) shall be submitted to the contract laboratory as external blind proficiency test specimens. Subsequent to the initial 90-day period, a minimum of 250 specimens per quarter shall be submitted to the contract laboratory as external blind proficiency test specimens. Any unsatisfactory proficiency testing result shall be investigated by the agency and corrective actions shall be taken. A report of the investigative findings, together with subsequent corrective actions, should be recorded, dated, signed by the responsible supervisor and laboratory director, and sent to the agency contracting officer. Should a false-positive error occur on a blind proficiency test specimen and the error is determined to be:

(1) An administrative error (clerical, sample mix-up, etc.), the reviewing official has the option of recommending corrective action to minimize the occurrence of the particular error in the future and reviewing a reanalysis of previously run specimens if there is reason to believe that the error could have been systematic.

(2) A technical or methodological error, the laboratory shall submit all QC data from the batch of specimens which included the test specimen with the erroneous analysis. In addition, the laboratory shall retest all specimens analyzed positive by the laboratory from the time of final resolution of the error back to the time of the preceding cycle of (correctly run) Proficiency Test samples (this retesting to be documented by a signed statement by the Laboratory Director). The reviewing official has the option to recommend (1) no further action other than the above (in case of less serious error with associated corrective action which reasonably assures the unlikelihood of reoccurrence) or (2) suspension of the contract.

c. Interim External Laboratory Quality Control Procedures

Prior to the existence of the ADAMHA/NIDA-recognized certification program, agencies shall ensure laboratory proficiency by one of the following methods:

1. Agencies may use agency or contract laboratories that have been certified for urinalysis testing by the Department of Defense.

2. Agencies may develop interim self-certification procedures by establishing preaward inspections and proficiency testing plans approved by HHS.

Documentation

Documentation of all aspects of the testing process shall be available. This documentation will be maintained for at least two (2) years and will include: personnel files on analysts, supervisors, directors, and all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; all test data; reports; performance records on proficiency testing; performance on certification inspections; and hard copies of computer-generated data.

Reports

All test results, including screening, confirmation, and quality control data, shall be reviewed by the certifying scientist or laboratory director before a test result is certified as accurate. The report shall identify the drugs/

metabolites tested for, whether positive or negative, and the threshold concentration for each.

Inspections

The agency shall reserve the right to inspect the laboratory at any time. Contracts with laboratories, as well as for collection site services, shall permit unannounced inspections. Preaward inspections and evaluation of the procedural aspects of the program shall be accomplished prior to the award of any contract.

Judicial Proceedings

The laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against a Federal employee that is based on positive urinalysis result reported by its laboratory.

Reporting and Review of Results

As essential part of the drug testing program is the final review of results. A positive test result does not automatically identify an employee/applicant as an illegal drug user. An individual with a detailed knowledge of possible alternate medical explanations *shall* be involved in the review process. This review will be performed by the Medical Review Officer (MRO) prior to the transmission of results to agency administrative officials.

The MRO may be an agency or contract employee who is a licensed physician with knowledge of substance abuse disorders. The role of the MRO is to review and interpret positive test results obtained through the agency's testing program. In the conduct of this responsibility, the MRO should undertake the examination of alternate medical explanations for a positive test result. This action could include conducting employee medical interviews, review of employee medical history, or the review of any other relevant biomedical factors. The MRO is required to review all medical records made available by the tested employee when a confirmed positive test could have resulted from legally prescribed medication. After the MRO has reviewed the pertinent information and the laboratory assessment is verified, the case will be referred to the agency Employee Assistance Program Administrator and to the management official empowered to recommend or take administrative action. Should any question arise as to the veracity of a positive test result, the MRO is authorized to order a reanalysis of the original sample. If the MRO determines there is a legitimate medical explanation for the positive test result, the MRO may deem that the result is consistent with legal drug use, and take no further action. Additionally, the MRO, based on review of inspection reports, QC data, multiple samples, and other pertinent results, may deem the result scientifically insufficient for further action and declare the individual as negative. The contract laboratory shall be able to provide information to assist in this review process by employing or having available a forensic toxicologist or someone with equivalent forensic experience in urine drug testing who can be called on when specific consultation is required by the agency.

(**Note.**—Before the MRO certifies a confirmed positive result for *opiates*, he/she shall verify that there is clinical evidence (in addition to the urine test) of illegal use of any opium, opiate, or opium derivative listed in Schedule I or II. This requirement does not apply if the agency's GC/MS confirmation testing for opiates verifies the presence of 6-O-monoacetylmorphine.)

Protection of Employee Records

Any laboratory contract shall provide that the contractor's records are subject to the Privacy Act, 5 U.S.C. 552a and the patient access and confidentiality provisions of section 503 of Pub. L. 100-71. The agency shall establish a Privacy Act System of Records (or modify an existing system), or use any applicable Government-wide system of records, to cover both the agency's and the contractor's records of employee urinalysis results. The contract and the Privacy Act System shall have specific provisions requiring that employee records are maintained and used with the highest regard for employee privacy.

Future Revisions

In order to ensure the full reliability and accuracy of drug tests and the accurate reporting of test results, the Secretary may make changes to these guidelines to reflect improvements in the available science and technology. These changes will be published in final as a notice in the Federal Register.

Standards for Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

Introduction

Urine drug testing is a critical component of efforts to combat drug abuse in our society. Many laboratories are familiar with good laboratory practices but may be unfamiliar with the varied forums in which their results can be used. Accordingly, these standards establish minimum standards to certify laboratories engaged in urine drug testing for legal, regulatory, safety, employment and other, non-medical purposes. Certification, even at the highest level, does not guarantee unequivocal accuracy of each result reported by a certified laboratory. Therefore, results from certified laboratories must be interpreted with a complete understanding of the total collection, analysis and reporting process before a final conclusion is made.

I. Goals and Objectives of Certification

Urine drug testing is an important tool to identify drug users in a variety of settings. In the proper context, urine drug testing can be used to deter drug abuse in general. To be a useful tool, the testing procedure must be capable of detecting drugs or their metabolites at concentrations sufficiently low to include occasional, recent users as well as addicts using drugs on a chronic basis.

Urine is the body fluid most often tested because it can be readily obtained by relatively non-invasive means. However, the presence of a drug in a urine specimen is normally used to simply indicate the subject's prior use of the drug, and provides little insight as to whether the subject was under the influence of the drug at a specific time. Even so, the consequence of a positive urine test for an illegal drug can carry severe penalties. Even when punitive actions do not take place, the suggestion that drug abuse has occurred can be devastating to the life of the subject. For these reasons, urine drug test results must be as error-free as possible and defensible in the event that they are challenged during a civil or criminal proceeding.

Reliable discrimination between the presence, or absence, of specific drugs or their metabolites is critical, not only to achieve the goals of the testing program but to protect the rights of the subjects being tested. Thus, it is in the public interest to set standards which urine drug testing laboratories must meet in order to achieve maximum acceptability of test results. Evaluation of these laboratories will be done by an organization recognized by the National Institute on Drug Abuse. In part, this evaluation will include periodic, on-site inspections. The possible impact of a positive test result on an individual's livelihood, freedom or rights, together with the possibility of a legal challenge of the result, sets this type of test apart from most clinical laboratory testing. In fact, urine drug testing should be considered a special application of analytical forensic toxicology. That is, in addition to the application of appropriate analytical methodology, the

specimen must be treated as evidence and all aspects of the testing procedure must be documented and preserved for possible court testimony. Laboratories engaged in urine drug testing should acquire the services or advice of a qualified forensic toxicologist, or individual with equivalent qualifications (of experience, training, etc.) to address the specific needs of the laboratory including the demands of chain of custody of specimens, security, proper documentation of all records, storage of positive specimens for later or independent testing, presentation of evidence in court and expert witness testimony.

II. Laboratory Facilities

In general, laboratories shall conform to the requirements concerning environment, space, utilities, safety, and storage outlined in Appendix B.

Certified laboratories must have the capability, at the same laboratory site, of performing screening and confirmation tests for each drug or metabolite for which service is offered. Screening tests are presumptive tests of acceptable sensitivity, designed to eliminate negative specimens from further consideration. Confirmatory tests are procedures conducted independently of the screening test that utilize appropriate methodology based on different chemical and physical principles from those used in screening procedures. It is essential to confirm all positive screening test results prior to reporting them.

The laboratory must be secure not only in the traditional sense of resisting breaking and entering, but also in the sense of limiting access to areas where specimens are being processed and records are stored. Access to these secure areas in limited to specifically authorized individuals whose authorization is documented. Visitors, maintenance and service personnel must be escorted at all times. Documentation of individuals accessing these areas, dates and time of entry and purpose of entry, must be maintained.

Receipts are given when specimens are delivered by courier. This is the beginning of internal chain of custody document(s) which permit the time, date and purpose to be documented each time the specimen is handled or transferred and identify every individual in the chain. Finally, all positive specimens are retained in original containers in secure storage at freezing temperatures (−20° C or less) for at least twelve months. The laboratory must be prepared to maintain storage on any specimen under legal challenge for an indefinite period.

III. Personnel

The scientific director of the drug testing laboratory will be qualified to assume professional, organizational, educational and administrative responsibility for the laboratory and is involved in the day to day management of the laboratory.

This director is an individual with documented scientific qualifications in analytical forensic toxicology. Acceptable qualifications include certification as a Laboratory Director by the State in forensic or clinical laboratory toxicology or a Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology. This certification or academic training must be followed by extensive experience in analytical forensic toxicology (the analysis of biological material for drugs of abuse) and appropriate training and/or experience in forensic applications of analytical toxicology (court testimony, research and publications in analytical toxicology of drugs of abuse, etc.).[1]

The doctoral degree requirement may be waived provided that the individual holds the position of laboratory scientific director at the time of publication of these standards and possesses a graduate degree in the natural sciences or other closely related discipline followed by extensive experience (6 yrs. postgraduate) in analytical forensic toxicology.

The director is responsible for ensuring that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the urine drug testing laboratory.

A key individual in the laboratory is the certifying scientist (who may be the Laboratory Scientific Director). This individual reviews the standards, blanks and quality control data together with the screening and confirmation test results. After having assured that all results are acceptable, this individual certifies the test result. This individual must have sound training in the sciences, specific training in the theory and practice of the procedures used including the recognition of aberrant results, and familiarity with quality control procedures.

Supervisors of analysts must possess at least a B.S. degree in chemistry or education and experience comparable to a medical technologist certified by the American Society of Clinical Pathologists, MT(ASCP), or its equivalent. These, too, must have training in the theory and practice of the procedures used, and understanding of quality control concepts. Periodic verification of their skills must be documented. Other technicians or non-technical staff must possess the necessary training and skills for the task assigned. In-service continuing education programs to meet the needs of all laboratory personnel are desirable. Personnel files must include: resume of training and experience, certification or license if any, references, job descriptions, health records, records of performance evaluation and incident reports, as well as results of tests for color blindness where appropriate.

IV. Quality Assurance and Quality Control

Urine drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process: specimen acquisition, chain of custody, security, and reporting of results, in addition to validation of analytical procedures. Quality control procedures must be designed, implemented and reviewed to monitor the conduct of each step of the process. Application and documentation of the process shall be conducted as described in Appendix B.

Each analytical run of specimens to be screened must include: control urine specimens containing no drug; specimens fortified with known standards; and positive controls with the drug or metabolite at or near the threshold (cutoff). In addition, internal proficiency test specimens, blind to the analyst, shall be tested periodically. Similar controls must be analyzed in parallel with confirmation tests. Implementation of procedures to ensure that carry-over does not contaminate the testing of a subject's specimen must be documented.

Participation in proficiency testing surveys by which the laboratory performance is compared with peers and reference laboratories is encouraged. Participation in a NIDA-operated or recognized proficiency testing program is one of the requirements of continued certification (See Appendix A). Acceptable performance in two cycles of this proficiency test program is one of the criteria which must be met before a laboratory becomes eligible for certification.

If any proficiency test results are unsatisfactory according to pre-established criteria, the cause of the unsatisfactory result must be

[1] This training and experience is comparable to that of a person certified by the American Board of Forensic Toxicology or the American Board of Clinical Chemistry in Toxicological Chemistry.

investigated and corrected. A report of the investigation fingings, together with subsequent corrective actions, will be recorded, dated and signed by the responsible supervisor and laboratory director. Unsatisfactory performance on NIDA recognized proficiency test samples may be sufficient cause to lead to loss of certification by the laboratory.

Many laboratories have applied computer control to various aspects of laboratory operations. In addition, robotics and automation are leading to less human intervention into testing processes. These applications present new variables to monitor in order to detect errors, loss of data and maintenance of documentation. All laboratory systems including data processing and automation systems must be validated and tested periodically to provide documented evidence of proper function. Specific requirements will be developed to deal with these issues as they arise.

V. Documentation

Documentation of all aspects of the testing must be available. This documentation will be maintained for at least two years, and will include: personnel files on analysts, supervisors, directors and all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on proficiency testing; performance on certification inspections and hard copies of computer-generated data. The laboratory must be prepared to maintain documents for any specimen under legal challenge for an indefinite period.

VI. Reports

All test results, including screening, confirmation and quality control data must be reviewed by a qualified, responsible scientist before being certified as accurate. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the threshold (or cut-off) concentration for each.

VII. Certification

The Secretary or his or her designee (hereinafter referred to as "the Secretary") may certify any laboratory that meets these standards to conduct urinalysis for drugs of abuse. In addition, the Secretary may consider any laboratory that is certified by a DHHS-recognized certification program which is established in compliance with these standards to be certified to conduct urinalysis for drugs of abuse. In determining whether to certify a laboratory or to accept the certification of a DHHS-recognized certification program, the Secretary shall consider the following criteria:

(1) The adequacy of the laboratory facilities;

(2) The expertise and experience of the laboratory personnel;

(3) The excellence of the laboratory's quality control program;

(4) The performance of the laboratory on any proficiency tests;

(5) The performance of the laboratory on any laboratory inspections; and

(6) Any other factor affecting the reliability and accuracy of drug tests and reporting done by the laboratory.

VIII. Revocation

The Secretary shall revoke certification of any laboratory certified under these provisions or accept the revocation of a recognized certification program, if the Secretary determines that revocation is necessary to ensure the full reliability and accuracy of drug tests and the accurate reporting of test results. The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests (for example, a single false positive error in reporting the results of an employee's drug test);

(2) Unsatisfactory participation in proficiency evaluations or laboratory inspections;

(3) A material violation of a certification standard or contract term or other condition imposed on the laboratory by a Federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the laboratory; or

(5) Any other cause which materially affects the ability of the laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results.

The period and terms of revocation shall be determined by the Secretary, and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing of Federal employees.

IX. Suspension

Whenever the Secretary has reason to believe that revocation may be required and that in order to protect the interests of the United States and its employees immediate action is necessary, the Secretary may suspend a laboratory's certification to conduct urinalysis for drugs of abuse for Federal agencies. The suspension of certification by a DHHS-recognized certification program may also be accepted by the Secretary. The period and terms of suspension shall be determined by the Secretary and shall depend upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing of Federal employees.

X. Notice; Opportunity for Review

(a) *Written Notice.* When a laboratory is suspended or the Secretary seeks to revoke certification, the Secretary shall immediately serve the laboratory with written notice of the suspension or proposed revocation by personal service or registered or certified mail, return receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and,

(3) The period of suspension or proposed revocation.

(b) *Opportunity for Review.* The written notice shall also state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date of mailing or service of the notice. The review shall be by a person or persons designated by the Secretary and shall be based on written submissions by the laboratory and DHHS and, at the Secretary's discretion, may include an opportunity for an oral presentation. Formal rules of evidence and procedures applicable to proceedings in a court of law will not be applied. The decision of the reviewing official shall be final.

(c) *Effective Date.* A suspension shall be effective immediately. A proposed revocation shall be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension shall terminate immediately and any proposed revocation shall not take effect.

XI. Recertification

Following the termination or expiration of any suspension or revocation, a laboratory may apply for recertification. Upon the submission of evidence satisfactory to the Secretary that the laboratory is in compliance with these standards or any DHHS-recognized certification program and any other conditions imposed as part of the suspension or revocation, the Secretary may re-certify the laboratory

or accept the recertification of the laboratory by the recognized certification program.

XII. Future Revisions

In order to ensure the full reliability and accuracy of drug tests and the accurate reporting of test results, the Secretary may make changes in these standards to reflect improvements in the available science and technology. These changes will be published in final as a notice in the Federal Register.

Appendix A—Proficiency Test Program

The proficiency testing (PT) program is a part (in conjunction with laboratory inspection) of the initial evaluation of a laboratory seeking certification and of the continuing assessment of laboratory performance necessary to maintain this certification.

Initial participation in 3 cycles of testing will be required as part of certification process. These initial 3 cycles (and those required for recertification) can be compressed into a 3-month period (one per month).

After certification, laboratories will be challenged bimonthly with one set of 10 specimens—a total of 6 cycles per year.

All procedures associated with the handling and testing of the proficiency test specimens after receipt by the laboratory must be carried out in a manner identical to that applied to normal laboratory specimens. Laboratory personnel should not be aware that these specimens are part of a performance test to the extent possible.

Any certified laboratory may also be subjected to blind proficiency testing. Performance on blind testing specimens at the same level as for the open (non-blind) PT will be required.

Laboratories will be required to report as follows:

(Drug or metabolite) None detected at a concentration of ____ng/mL.

Or:

(Drug or metabolite) greater than ____ng/mL Positive.

Confirmed by (method) at ____ng/mL.

Test Specimen Composition

The following are examples of drugs and metabolites and threshold concentration levels (lowest possible level of spiked specimen) which would be appropriate for PT specimens. These concentration ranges have been chosen to allow detection of the analyte by commonly used immunoassay screening techniques. These levels are generally in the range of concentrations which might be expected in the urine of casual drug users. For some drug analytes, the specimen composition will consist of the parent drug as well as major metabolites as noted in the second column below. In some cases, more than one drug class may be included in one specimen container but generally no more than two drugs will be present in any one specimen to more reasonably represent the type of specimen which a laboratory normally encounters. Within a particular PT cycle, the actual composition of kits going to different laboratories will vary but within any annual period, all labs participating will have analyzed the same total set of specimens.

It is presumed that these concentrations and drug types will be changed periodically due to factors such as changes in detection technology and patterns of drug abuse.

Drug class and specimen composition	Concentration (ng/mL)
Marijuana: THC metabolite (delta-9-THC-9-carboxylic acid)	125–150.
Cocaine:	
Cocaine	300–450.
Benzoylecgonine	300–450.
Ecgonine methyl ester	150–200.
Opiates:	
Morphine	300–1200.
Morphine-3-glucuronide	300–1200.
Codeine	300–1200.
Amphetamines:	
Amphetamine	1250–1400.
Methamphetamine	1500–1700.
Phencyclidine: Phencyclidine	100–125.
Blank	Less than 2 ng/mL of any of the target drugs.

Evaluation-pt

1. For all drugs for which the laboratory offers service, no false drug identifications are acceptable. A false positive result under some circumstances may result in suspension or revocation of certification.

The most serious false positives are those by drug class such as THC in a blank or cocaine in a specimen known to contain only opiates. While clearly false positives also, misidentifications within a class are less serious errors but still ones which are unacceptable in a appropriately controlled laboratory.

Procedure for dealing with a false positive report from a laboratory:

A. Immediate notice to laboratory and to NIDA.

B. Allow the laboratory 5 working days to respond to the error. This response should include the submission of all QC data from the batch of specimens in which the error occurred, unless the error is to be explained as an administrative error. In this case the QC data need not be provided.

C. Allow 5 working days for review of the response. The response will be reviewed by a Reviewing Official which will have the authority to decide whether the laboratory explanation can be accepted as an error which was beyond its control (such as a clerical error on the part of the inspection organization where the laboratory can document that the analysis which it submitted was not the one attributed to it). If the error is determined to be attributable to the laboratory and that it is:

(1) An administrative error (clerical, sample mix-up, etc.), the Reviewing Official will have the option of recommending corrective action to minimize the occurrence of the particular error in the future and if necessary to review and reanalyze previously run specimens if there is reason to believe that the error could have been systematic.

(2) A technical or methodological error, the laboratory must submit all QC data from the batch of specimens which included the test specimen with the erroneous analysis. In addition, the laboratory will be required to retest specimens analyzed positive by the laboratory from the time of final resolution of the error back to the time of the last satisfactory Proficiency Test cycle (this retest to be documented by a signed statement by the Laboratory Director). Depending on the type of error which caused the false positive, this retesting may be limited to one analyte or may include all drugs for which service is offered.

If any result on a retest sample must be corrected because the criteria for a positive is not satisfied, immediate notification of the client who sent the specimen for testing is required. The Reviewing Official will have the option to recommend (1) no further action other than the above (in the case of less serious error with associated corrective action which reasonably assures the unlikelihood of reoccurrence) or (2) suspension or revocation and recertification for all drugs or for only the drug or drug class in which the error occurred.

D. During the time required to resolve the error, the laboratory would remain on the NIDA registry but with a designation that a false positive result is pending resolution. If the Reviewing Official recommends that the laboratory's certification be suspended or revoked, this will then become the official status of the laboratory until the suspension or recertification process is complete.

2. At least 90% of all drugs for which service is claimed must be detected.

3. Participant performance will be evaluated for all samples for which drugs were spiked at concentrations above the level for reporting unless the overall participant response indicates

that less than 80% of the participants were able to detect a drug.

4. A laboratory must participate satisfactorily in 3 monthly cycles of open surveys before they can be considered for certification.

5. Failure to participate in a survey (except in instances where testing of client specimens was suspended) or to participate satisfactorily may result in suspension or revocation of certification.

6. Failure to participate satisfactorily during a blind proficiency testing survey may result in suspension or revocation of certification.

7. Quantitative results reported on confirmation tests must fall within two standard deviations or 20% of the calculated group mean (whichever is larger) resulting from all participating laboratories testing a given kit.

8. Inadequate performance, as determined by the Secretary, on the criteria in items 2, 6, and 7 and the laboratory inspection may result in the failure of the laboratory to achieve certification, or lead to the suspension or revocation of a certification which has already been granted.

Appendix B—Laboratory Inspection

The following list includes certain items of inspection preceded by an asterisk(*). These are considered critical and compliance with these items must generally be documented prior to the physical inspection. Inspection teams will consist of three qualified individuals, at least two of whom have participated in a NIDA recognized training course for laboratory inspectors. Inspections will document the overall quality of the laboratory setting for the purposes of certification. In addition, the inspection reports will provide recommendations to the laboratory to correct deficiencies noted during the inspection.

1.0 *Extent of Service*

*1.1 Does laboratory perform screening and confirmatory testing on all samples reported positive?.					N/A	YES	NO
*1.2 Does laboratory perform screening and confirmation tests that are based on different scientific principles?.					N/A	YES	NO
1.3 Does the laboratory test for the following drugs and what methods are used? (circle drugs and screening and confirmation methods)							
Amphetamines	Immunoassay	TLC	GC	LC	GC/MS	Other.*	
Barbiturates	Immunoassay	TLC	GC	LC	GC/MS	Other.*	
Cocaine	Immunoassay	TLC	GC	LC	GC/MS	Other.*	
Opiates	Immunoassay	TLC	GC	LC	GC/MS	Other.*	
Phencyclidine	Immunoassay	TLC	GC	LC	GC/MS	Other.*	
THC	Immunoassay	TLC	GC	LC	GC/MS	Other.*	
1.4 Does the laboratory confirm all drugs by an appropriate mass spectrometric method?					N/A	Yes	No
1.5 If not, does the laboratory test for the appropriate parent drug or metabolite?					N/A	Yes	No
Amphetamine					N/A	Yes	No
Barbiturate					N/A	Yes	No
Cocaine					N/A	Yes	No
Opiates					N/A	Yes	No
PCP					N/A	Yes	No
THC					N/A	Yes	No
1.6 Does the laboratory use quantitative cutoff values on the confirmation test for each drug tested?					N/A	Yes	No

2.0 *Proficiency Testing*

The laboratory must participate in a NIDA recognized proficiency testing (PT) and interlaboratory comparison program. The size of the laboratory operation does not effect the need to participate in such a program.

*2.1 Is the laboratory enrolled in a NIDA recognized PT survey (interlaboratory comparison) program?	N/A	Yes	No

Note.—It is strongly recommended that the current Survey Manual be readily available to the bench technologists in the section.

2.2 Is there evidence of active review by the Scientific Director of the survey (interlaboratory comparison) results?	N/A	Yes	No
2.3 Is there evidence of evaluation and, if indicated, corrective action in response to "unacceptable" results on the survey?	N/A	Yes	No

3.0 *Quality Control*

Supervision of Quality Control: The Quality Control Program must be under the direct surveillance of the Quality Control Supervisor or their designated assistants and reviewed weekly by the Scientific Director.

3.1 Is there evidence of active review of records of controls, instrument function and maintenance of each routine procedure on all shifts?	N/A	Yes	No
* 3.2 Is there documentation of corrective action taken when controls, etc. exceed defined tolerance limits?	N/A	Yes	No
3.3 Is there a written system documented and operating to routinely detect clerical errors and analytical errors prior to results being reported?	N/A	Yes	No
* 3.4 Are all results of samples reviewed by a Certifying Scientist prior to release of the results?	N/A	Yes	No

APPENDIX C: Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture - Second Edition

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Procedures for the Collection of Diagnostic Blood Specimens by Venipuncture—Second Edition

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We invite comments from all of our readers—those not active, as well as those active, in NCCLS.

We always seek improvement and welcome suggestions that will help us make our publications more useful. Our National Office will record your comments and forward them to the appropriate chairholder.

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FOREWORD

The errors that can occur during the collection and handling of blood specimens are potentially numerous, e.g., inaccurate identification of specimens, the use of incorrect anticoagulants, the formation of hematomas, hemoconcentration, etc. National standards for venipuncture can reduce or alleviate many of these errors in much the same way that quality control standards have reduced errors within the laboratory.

Reducing errors during blood collecting will result in biologically representative specimens that are comparable from one institute to another. A well-planned, attractive environment in which to perform venipunctures will reduce patient anxiety and increase the efficiency and accuracy of the venipuncturist. Venipuncturists need a complete assortment of equipment at their fingertips so they can judiciously select the most appropriate materials for each patient. Standards governing the processing of paperwork will reduce errors and wasted time. Without question, a comprehensive training program is needed to produce efficient, well-trained venipuncturists. Finally, standards for the actual venipuncture procedure are needed to help eliminate the many errors that can occur during blood collection. Biologically representative specimens for laboratory testing will be obtained if national venipuncture standards are used.

The various comments about the first edition received by the subcommittee have been reviewed and incorporated where appropriate. However, not all points of view could be accommodated; comments not leading to changes, and the working group's responses to these comments, are summarized in Appendix B.

KEY WORDS

Accession, blood specimen, sample, venipuncture.

PROCEDURES FOR THE COLLECTION OF DIAGNOSTIC BLOOD SPECIMENS BY VENIPUNCTURE

1.0 INTRODUCTION

Although the need for accurate and precise methodology in the laboratory is emphasized, little attention has been devoted to establishing quality control procedures for collecting and handling a blood specimen. Our highly sophisticated and well-controlled laboratory technology is useless if the specimens presented for analysis are already riddled with error because of faulty identification or poor collection techniques. Proper specimen collection and specimen handling are of the utmost importance, for today, errors are more likely to occur in these areas than during the laboratory procedure itself.

Collection errors encompass incorrect identification of the patient specimen, hemolyzed blood specimens, and use of an incorrect anticoagulant during specimen collection. Studies show that 8% of errors in patient name, age, sex, and identification numbers are undetected despite extensive manual checking procedures (1). Clerical errors are difficult to detect and control systematically. National standards for proper specimen collection would alleviate many of these problems.

2.0 SCOPE

These standard procedures establish criteria for the proper collection of blood specimens by venipuncture. Depending on individual needs and circumstances, the procedures are a suitable model for adaptation by institutions. Considerations when devising a training program for performing venipunctures are included. Factors to consider when devising sufficiently informative forms to accompany the collected blood specimens are also given.

3.0 DEFINITIONS

In the context of this publication, the terms listed below are defined as follows:

3.1 (To) Accession All steps needed to ensure that a specific blood specimen and the accompanying forms are unmistakably identified as referring to a specific person.

3.2 (Patient) Specimen A volume of blood appropriately collected to perform one or more laboratory tests.

3.3 (Patient) Sample An aliquot of a blood specimen that has been appropriately collected, transported, and processed in the laboratory to provide material for a specific laboratory test. The sample will usually consist of an aliquot of anticoagulated whole blood, of plasma, or of serum.

3.4 Venipuncture All steps involved in obtaining an appropriately identified blood specimen from a vein of a person.

4.0 FACILITIES

Because venipuncture facilities can influence the blood collecting process, the following should be available.

4.1 Outpatient area Factors to consider when planning venipuncture facilities include: accessibility by ambulatory patients, by patients confined to wheelchairs, and by the medical laboratories, size, lighting, public address system, and patient registration desk. An outpatient area may include the following:

4.1.1 *Large waiting room*, with a relaxing, restful environment for the patient and adequate, comfortable seating.

4.1.2 ***Subwaiting rooms,*** facilitating the continuous flow of traffic in and out of the venipuncture areas. Within these rooms, patients can remove their coats, roll up their sleeves in preparation for the blood drawing, and relax for a few minutes before having their blood drawn. Restrooms should be available.

4.1.3 ***Venipuncture rooms,*** equipped adequately and with facilities to allow the venipuncturist to wash his/her hands before moving to the next patient. The rooms should afford privacy during the blood collecting procedure. Reasonably sound-proof rooms for pediatric patients should be considered.

4.1.4 ***Recovery room*** for patients who feel faint and for other emergency situations. This room should be equipped with a bed, blankets, pillows, chair, cabinet with supplies, blood pressure cuff, stethoscope, small oxygen tank, and a supply of emergency drugs. The drugs and oxygen tank should be checked periodically.

4.2 **Hospital area** A central venipuncture area should be designed to include the following features:

4.2.1 ***Central desk,*** with a telephone system for emergency request calls, facilities for processing daily and future requests, and a paging system for contacting the venipuncturist who is out of the central area, collecting specimens.

4.2.2 ***Cart area*** constructed to allow easy access to the supplies.

4.2.3 ***Storage area*** large enough to accommodate the necessary supplies.

4.2.4 ***Counter space,*** adequate for efficient sorting and dispatching of specimens.

4.2.5 ***Time stamper.***

5.0 SUPPLIES

The following checklist describes the supplies that should be available at any location where venipunctures are performed routinely. The supplies are listed in order of use.

5.1 ***Utility carts,*** designed to roll smoothly and silently over all types of surfaces, and featuring the following: stainless steel construction for easy cleaning, special casters 4 to 5 inches in diameter to facilitate movement in and out of the elevators, and three shelves, each with guardrails, for adequate storage of supplies. The venipuncturist may also find it very useful to have a specially designed rack on the top shelf for storing supplies.

5.2 ***Blood collecting trays*** may be used by personnel who perform a limited number of venipunctures. The trays should be lightweight and easy to handle with enough space and compartments for the various supplies that are needed.

5.3 ***Venipuncture chairs*** should be designed for the maximum comfort and safety of the patient, plus easy accessibility for the venipuncturist. Both armrests of the chair should be adjustable so that the best venipuncture position for each patient can be achieved. The armrests provide support while preventing backbending of the elbow and subsequent flattening of the vein. The chair should have a safety device to prevent patients who faint from falling.

5.4 ***Beds*** or other reclining surfaces.

5.5 ***Needles*** are packaged in individual color-coded containers according to their respective gauge sizes. The gauge number indicates the size of the needle; a large gauge number indicates a small needle, while a small guage number indicates a large needle. The most commonly used sizes are 19 through 23. Needles should always be sterile.

5.6 ***Sterile syringes,*** plastic or glass, of proper size to draw blood.

5.7 ***Holders used for evacuated tubes and needles*** Use holders to match tube diameters. Refer to NCCLS standard H1-A2 (2).

5.8 ***Evacuated tubes*** are manufactured to withdraw a predetermined volume of blood. At present, evacuated tubes used in venipuncture are designated either as non-sterile or sterile. Non-sterile tubes may be a source of infection to the patient should reflux occur during the venipuncture procedure despite proper precautions. Tubes selected for general use should be displayed on a wall chart in one or more locations in the venipuncture areas to assure proper information for various types of collection. Consult instructions furnished in the package by the manufacturer of tubes and needles. Refer to NCCLS standard H1-A2 (2).

5.9 ***Tourniquets,*** such as the following types:

(1) pre-cut tourniquet, a soft, pliable rubber bandage that is 3 inches wide and 15 inches long, (7.5 cm x 37.5 cm). It is cut 1-1/2 (3.8 cm) or 1 inch (2.5 cm) wide and 15 inches long (3.8 cm x 37.5 cm)

(2) rubber tubing (usually uncomfortable to the patient)

(3) blood pressure cuff (guidelines are needed for inflation)

(4) velcro type tourniquet, quick and easy to apply. It is also easy to adjust the venous pressure when this type of tourniquet is used. This tourniquet is available in adult and pediatric sizes.

5.10 ***Antiseptics*** for skin preparation and equipment.

(1) 70% isopropyl alcohol dispenser

(2) 70% isopropyl alcohol preps

(3) povidone-iodine swab sticks for blood cultures only

(4) 0.5% chlorhexidine gluconate in 70% isopropyl alcohol

(5) Because tourniquets are potential germ carriers, they should be wiped with alcohol or replaced frequently.

5.11 ***Sterile gauze pads,*** small, i.e., 2 inches x 2 inches or 3 inches x 3 inches (5.0 x 5.0 cm or 7.5 x 7.5 cm) packages; cotton or rayon balls may be used.

5.12 ***Gauze,*** 2-inch (5.0 cm) rolls

5.13 ***Needle destroyer and disposal boxes***

5.14 ***Ice or refrigerant***

5.15 ***Adhesive bandage and/or gauze***

5.16 ***Equipment for heating*** the puncture site for the purpose of dilating the blood vessels.

5.17 ***A file of tests*** indicating which tube is to be used, including minimum volume requirements, special handling, and precautions to be taken.

6.0 VENIPUNCTURE PROCEDURE

The venipuncture procedure is complex and requires both knowledge and skill. The trained venipuncturist must execute the following basic steps when drawing a blood specimen:

Step Number and Title

(1) Prepare accession order

(2) Identify patient

(3) Verify patient diet restrictions

(4) Assemble supplies

(5) Reassure the patient

(6) Position the patient

(7) Verify paperwork and tubes

(8) Close patient's hand
(9) Select vein site
(10) Cleanse venipuncture site
(11) Apply tourniquet
(12) Inspect needle and syringe
(13) Grasp patient's arm
(14) Perform venipuncture
(15) Release tourniquet
(16) Open patient's hand
(17) Place gauze
(18) Remove needle
(19) Bandage patient's arm
(20) Fill the tubes (if syringe and needle are used)
(21) Dispose puncturing unit
(22) Chill specimen
(23) Eliminate diet restrictions
(24) Time stamp paperwork
(25) Send tubes to proper laboratories

6.1 Step 1: Prepare Accession Order

Each request for a blood specimen must be accessioned to identify all paperwork and supplies associated with each patient. An organized system will ensure prompt and accurate processing of the various forms required when performing a venipuncture and analyzing the results. (3).

6.1.1 ***Procedure for Accessioning in Out-Patient Area*** Record the information given on the blood request form on the labels.

6.1.1.1 Essential items are:

(1) patient's name and age from ID plate or wristband
(2) identification number
(3) date and time the specimen is obtained

6.1.1.2 Optional items include:

(1) accessioning number (see 6.1.2 to 6.1.4)
(2) doctor's name
(3) department or unit for which the work is being done
(4) other information as needed, e.g., special comments: intravenous (I.v.), unusual sampling site if other than arm, name or initials of person who obtains specimen

6.1.1.3 Select the correct types and sizes of evacuated tubes. Apply a label to each of the necessary tubes and all test references for the patient before drawing the blood specimen.

6.1.2 ***Procedure for Accessioning in Hospital*** This procedure may differ from the out-patient procedure in one respect only: In the hospital, the tubes should be labeled immediately after the blood specimen has been drawn. (Prior to drawing the specimen, keep the labels in a master envelope containing the blood request form and test results forms.) This procedure eliminates the possibility of mixing up the blood specimens.

6.1.3 ***Accessioning in the Emergency Room*** For a person who cannot be identified immediately:

6.1.3.1 Assign a master identification number (temporary) to the patient. When assigning a master number, use a three-part identification tag with the same master number on all three parts.

(1) Attach the first part to the patient's arm.
(2) Attach the second part to the specimen test tube.
(3) Attach the third part to the blood transfusion bag if a transfusion is necessary.

6.1.3.2 Select the appropriate test forms and write the identification number on them.

6.1.3.3 Complete the necessary labels either by hand or by computer and apply the labels to the test forms and specimen tubes.

6.1.4 ***Accessioning Blood Bank Specimens (4).*** Blood bank specimens must be labeled according to the standards set by the American Association of Blood Banks. For the recipient of a transfusion it is required that: "The intended recipient and the blood sample shall be positively identified at the time of collection. Blood samples shall be obtained in stoppered tubes identified with a firmly attached label bearing at least the recipient's first and last names, identification number, and the date. The completed label shall be attached to the tube before leaving the side of the recipient, and there must be a mechanism to identify the person who drew the blood."

All tubes should be labeled in ink or indelible pencil. Other information such as doctor, hospital, and room number may be added. If imprinted labels are used, the information on the labels should match the wristband exactly (4).

6.2 Step 2: Identify Patient

Identification of the patient is crucial. The venipuncturist must ensure that the blood specimen is being drawn from the individual designated on the request form. The following steps are a suggested sequence for ensuring patient identification, regardless of the clinical setting.

6.2.1 ***Patient who is conscious*** Ask the patient to give full name, address, identification number, and/or birth date. Compare this information with the information on the request form, the patient's identification bracelet, and the information on the identification card posted outside each room. Report any discrepancy, however minor, to the appropriate person and have them identify the patient by name and identification number before drawing any specimen. Notify proper personnel of any discrepancy so that it may be corrected.

6.2.2 ***Patient who is unconscious, too young, mentally incompetent, or does not speak the language of the venipuncturist*** Ask the nurse, a relative, or a friend to identify the patient by name, address, and identification number and/or birth date. Compare these data with the information on the request form.

6.2.3 ***Procedure for Identifying Unidentified Emergency Patients*** Identification standards established by the American Association of Blood Banks (4) provide clear guidelines for unidentified emergency patients:

"The patient must be positively identified when the blood specimen is collected. The unidentified emergency patient should be given some temporary but clear designation until positive identification can be made.

In all cases, the name and hospital number of the emergency identification should be attached to the patient's body either by wristband or some similar device. Except in the case of isolated patients, bed labels should not be used in place of wristbands."

6.3 Step 3: Verify Patient Diet Restrictions

Some tests require the patient to fast and/or eliminate certain foods from the diet prior to the blood drawing. Time and diet restrictions vary according to the test. Such restrictions are necessary to ensure accurate test results.

6.4 Step 4: Assemble Supplies

6.4.1 Assemble the following supplies:

(1) collection tubes

(2) tourniquet

(3) alcohol and gauze pads, alcohol prep pads or 0.5% chlorhexidine gluconate in 70% alcohol and gauze pads

(4) povidone-iodine swab sticks if blood culture is to be drawn

(5) gauze pads and gauze (cotton balls should be used on patients with dermatitis)

6.4.2 Select the appropriate type of needle based on the patient's physical characteristics and the amount of blood to be drawn.

6.4.3 Select the system for drawing the blood specimen.

6.4.3.1 *Evacuated Systems* The evacuated system is the most commonly used means of collecting specimens today. It is generally preferable to the needle and syringe because it allows the blood to pass directly from the vein into the evacuated tube. The system is composed of three basic elements: a sterile blood collection needle, a holder that is used to secure both the needle and the evacuated tube, and an evacuated tube containing a premeasured vacuum and premeasured additive. For greater detail, refer to NCCLS standard H1-A2 (2).

6.4.3.2 *Plastic or Glass Syringe* In general, use a syringe when drawing a specimen from individuals with fragile, thready, or "rolly" vein walls.

6.5 Step 5: Reassure the Patient

The venipuncturist must gain the patient's confidence and assure the patient that, although the venipuncture will be slightly painful, it will be of short duration. It is wise to tell the patient when the needle enters the skin so the patient is not frightened. Never tell a patient, "This won't hurt."

6.6 Step 6: Position Patient

6.6.1 *Procedure for Seating Patient* Ask the patient to be seated comfortably in a chair. Have the patient position his or her arm on the slanting armrest and extend the arm to form a straight line from the shoulder to the wrist. The arm should be supported firmly by the armrest and should not be bent at the elbow.

6.6.2 *Procedure for Having Patient Lie Down* Ask the patient to lie on his/her back in a comfortable position. Place a pillow (if additional support is needed) under the arm from which the specimen is being drawn. Have the patient extend his/her arm to form a straight line from the shoulder to the wrist.

6.6.3 Avoid startling the patient unnecessarily, such as awakening suddenly, to prevent changes in test results.

6.6.4 No food, chewing gum, or thermometer should be in the patient's mouth.

6.7 Step 7: Verify Paperwork and Tubes

This verification must be done to ensure that no mistakes were made during the preparation of the paperwork and selection of the tubes.

6.7.1 *Procedure for Checking Paperwork and Tubes*

6.7.1.1 Compare the identification number on the accessioning label with the identification number on the blood request form and/or computer-generated label. If the two numbers do not match, check further to determine which one is incorrect and make the necessary correction.

6.7.1.2 Check the tubes to be sure the appropriate kinds and sizes were selected. (The color-coded stoppers and labels make it easy to perform this step.)

6.8 Step 8: Close Patient's Hand

The veins become more prominent and easier to enter when the patient forms a fist. Avoid vigorous hand exercise ("pumping").

6.9 Step 9: Select Vein Site

Refer to Figure 1 for a description of the superficial veins of the anterior surface of the upper extremity.

6.9.1 **CAUTION** A patient's life may depend on vein patency. It is important to select the vein site carefully because the veins provide an avenue of entry for transfusion, infusion, and therapeutic agents.

6.9.2 *Preferred Veins* Although the larger and fuller median cubital and cephalic veins (Fig. 1) are used most frequently, wrist and hand veins are also acceptable for venipuncture. In many hospitals, special identification bands are used to indicate restricted use of certain veins for expected i.v. therapy, or insertion of a cannula.

6.9.3 *Factors to Consider in Site Selection*

6.9.3.1 *Extensive Scarring* Avoid healed burn areas.

6.9.3.2 *Mastectomy* Because of lymphostasis, specimens taken from the side on which a mastectomy was performed may not be truly representative specimens.

6.9.3.3 *Hematoma* Specimens collected from a hematoma area may cause erroneous test results. If another vein site is not available, collect the specimen distal to the hematoma.

6.9.3.4 *Intravenous Therapy* Optimally specimens should be collected from the opposite arm. If this should prove impossible, consult the attending physician.

6.9.3.5 *Cannula, Fistula, Vascular Graft* Use a cannulated arm only after consulting the attending physician.

6.9.4 *Procedure for Vein Selection*

6.9.4.1 Palpate and trace the path of veins several times with the index finger. Unlike veins, arteries pulsate, are more elastic, and have a thick wall. Thrombosed veins lack resilience, feel cord-like, and roll easily.

6.9.4.2 If superficial veins are not readily apparent, you can force blood into the vein by massaging the arm from wrist to elbow. Tapping sharply at the vein site with index and second finger a few times will cause the vein to dilate. Applying a warm, damp washcloth (about 40°C) to the proposed site for 5 min may have the same result. Lowering the extremity over the bedside will allow the veins to fill to capacity.

6.9.4.3 Many times, veins in the opposite arm will prove suitable for venipuncture.

6.10 Step 10: Cleanse Venipuncture Site

Cleanse the vein site to prevent chemical or microbiological contamination of either the patient or the specimen.

6.10.1 ***Cleansing Method for Venipuncture***

6.10.1.1 Soak a gauze pad with 70% isopropyl alcohol solution, or with chlorohexidine, 0.5%, in alcohol, or remove a commercially prepared alcohol pad from its sterile package.

6.10.1.2 Cleanse the vein site with a circular motion from the center to the periphery.

6.10.1.3 Allow the area to dry to prevent hemolysis of the specimen and to prevent the patient from having a burning sensation when the venipuncture is performed.

6.10.2 ***Touching the Vein Site after Cleansing***

If the venipuncture proves difficult and you must touch the vein again to draw blood, cleanse the site again.

6.11 Step 11: Apply Tourniquet

Use a tourniquet to increase venous filling, which makes the veins more prominent and easier to enter.

6.11.1 ***Precautions when Using a Tourniquet*** Never leave the tourniquet on for longer than 1 min. Localized stasis may occur with a tourniquet, together with the formation of a partial filtrate of blood and hemoconcentration. This may result in erroneously high values for all protein-based analytes, packed cell volume, and other cellular elements (5,6). If you must apply a tourniquet for the preliminary vein selection, release it and reapply after waiting 2 min. If the patient has a skin problem, put the tourniquet over the patient's gown or use a piece of gauze or paper tissue so the skin is not pinched.

6.11.2 ***Suggested Procedure for Applying Tourniquet.*** Wrap the tourniquet around the arm 3 to 4 inches (7.5 to 10.0 cm) above the venipuncture site. Tuck the end under the last round. If a velcro tourniquet is used, adhere the tabs to each other.

6.12 Step 12: Inspect Needle and Syringe

6.12.1 ***Needles*** Inspect the tip of the needle visually to determine that it is free of hooks at the end of the point, and that its opening is clear of any small particles that would obstruct the flow of blood.

6.12.2 ***Syringes*** Move the plunger within the barrel of the syringe to show syringe and needle patency and freedom of plunger movement.

6.13 Step 13: Grasp the Patient's Arm

Hold the patient's arm to facilitate the venipuncture procedure.

6.13.1 ***Procedure for Grasping Arm*** Grasp the patient's arm firmly, using your thumb to draw the skin taut. This anchors the vein. Your thumb should be 1 or 2 inches (2.5 cm or 5.0 cm) below the venipuncture site.

6.14 Step 14: Perform Venipuncture

6.14.1 ***Venipuncture Procedure when Evacuated Tubes Are Used***

6.14.1.1 Thread the appropriate needle into the holder until it is secure, using the needle sheath as a wrench.

6.14.1.2 Before using, tap all tubes that contain additives to ensure that all the additive is dislodged from the stopper and the wall of the tube. Use a sterile blood collection tube. When drawing blood for cultures, wipe the stopper with a suitable antiseptic solution. Check the stopper to make certain it is dry before performing the venipuncture.

6.14.1.3 Insert the blood collection tube into the holder and onto the needle up to the recessed guideline on the needle holder. Do not push the tube beyond the guideline, because a premature loss of vacuum may result. The tube will retract slightly. Leave it in this position.

6.14.1.4 Make sure the patient's arm or other venipuncture site is in a downward position to prevent reflux.

6.14.1.5 With the bevel up, line up needle with the vein. Grasp the flange of the needle holder and push the tube forward until the butt end of the needle punctures the stopper. Maintain the tube below the site when needle is in the vein.

6.14.1.6 Remove the tourniquet as soon as blood flow is established. Once the draw has started, do not change the position of the tube until it is withdrawn from the needle. During the procedure, do not allow the contents of the tube to contact the stopper. Movement of the fluid back and forth in the tube can cause backflow of blood into the venous system and possible adverse patient reaction.

6.14.1.7 Keep constant, slight forward pressure (in the direction of the needle) on the end of the tube. This prevents release of the shut-off valve and stopping of blood. Do not vary pressure or reintroduce pressure after completing the draw.

6.14.1.8 Fill the tube until the vacuum is exhausted and blood flow ceases. This will ensure that there is a correct ratio of anticoagulant to blood. It is normal for the tube not to be completely filled.

6.14.1.9 When the blood flow ceases, remove the tube from the holder. The shut-off valve re-covers the point, stopping blood flow until the next tube is inserted.

6.14.1.10 Mix immediately after drawing each tube that contains an additive by gently inverting the tube 5 to 10 times. To avoid hemolysis, do not mix vigorously.

6.14.1.11 To obtain additional specimens, insert next tube into holder and repeat procedure from step 6.14.1.7.

6.14.2 ***Venipuncture Procedure Using Needle and Syringe***

6.14.2.1 Insert the appropriate needle onto the syringe.

6.14.2.2 Place the patient's arm in a downward position if possible.

6.14.2.3 Line up the needle and syringe with the vein from which the blood will be drawn.

6.14.2.4 Turn the needle so that the bevel side is in an upward position.

6.14.2.5 Push the needle into the vein. You will feel a sensation of resistance, followed by easy penetration as the vein is entered.

6.14.2.6 Withdraw the desired amount of blood.

6.14.2.7 Replace the first syringe with another if additional blood is needed. The needle should remain in the vein when this is being done. Slip a clean dry gauze under the needle to catch the blood while making the change.

6.14.2.8 Pierce stopper with the needle; the evacuated tube will fill to the correct ratio of blood and anticoagulant, if present (see 6.20).

6.14.3 ***Multiple Specimen Collection***

6.14.3.1 We recommend the following "order of draw" when drawing several specimens during a single venipuncture (7).

First—blood culture tube
Second—non-additive tube (e.g., red stopper)
Third—coagulation tube (e.g., blue stopper)
Last—additive tube (e.g., green stopper)

6.14.3.2 Non-additive tubes are drawn before additive tubes to avoid additive contamination of the non-additive tube. Cross contamination between different additive tubes can also occur, (6) making test results erroneous.

6.14.3.3 We recommend the following "order of draw" for additive-containing tubes:

(1) citrate-containing tube (blue stopper)
(2) heparin-containing tube (green stopper)
(3) EDTA-K_2-containing tube (lavender stopper)
(4) oxalate/fluoride-containing tube (gray stopper)

6.14.3.4 If the blue-stoppered tube intended for coagulation testing is to be drawn, never draw first because thromboplastin from the site of the venipuncture can invalidate coagulation assay results. If a blue-stoppered tube is the only tube to be drawn, a 5 mL discard tube should be filled first.

6.14.4 ***If a blood sample cannot be obtained:***

6.14.4.1 *Change the position of the needle.* If the needle has penetrated too far into the vein, pull it back a bit. If it has not penetrated far enough, advance it farther into the vein. Rotate the needle half a turn.

6.14.4.2 *Try another tube.* The tube being used may not have had sufficient vacuum.

6.14.4.3 *Loosen the tourniquet.* The tourniquet may have been applied too tightly, thereby stopping the blood flow. Reapply the tourniquet loosely. If the tourniquet is a velcro type, quickly release and press back together.

6.14.4.4 *Probing is not recommended.* Probing is painful to the patient. In most cases, we advise another puncture in a site below the first site, or use of another vein on the other arm.

6.14.4.5 *It is advisable not to attempt a venipuncture more than twice.* Have another person attempt to draw the specimen or notify the physician.

6.15 Step 15: Release the Tourniquet

Remove the tourniquet when blood begins to flow to allow blood circulation to return to normal. Removing the tourniquet also reduces bleeding at the venipuncture site after the specimen is obtained.

6.16 Step 16: Open Patient's Hand

This reduces the amount of venous pressure as muscles relax. Do not allow the patient to pump the hand.

6.17 Step 17: Place the Gauze

Lightly place the gauze pad over the venipuncture site.

6.18 Step 18: Remove the Needle

Apply slight pressure to the pad. Remove the needle slowly while keeping the bevel in an upward position. Exercise care not to scratch the patient's arm.

6.19 Step 19: Bandage the Arm

6.19.1 ***Under normal conditions:***

6.19.1.1 Slip the gauze pad over the site, continuing mild pressure.

6.19.1.2 Apply an adhesive or gauze bandage over the venipuncture site after making sure that stasis is complete.

6.19.1.3 Tell patient to leave on the bandage for at least 15 min.

6.19.2 ***When the patient continues to bleed:***

6.19.2.1 Apply pressure to the site with a gauze pad until the bleeding stops.

6.19.2.2 Wrap a gauze bandage tightly around the arm over a pad.

6.19.2.3 Tell the patient to leave on the bandage for 15 min.

6.19.3 You should be alert to excess bleeding. If bleeding persists longer than 5 min, alert a nurse so that the attending physician can be notified of the problem. Continue pressure on the site as long as necessary to stop the bleeding.

6.20 Step 20: Fill the Tubes If Syringe and Needle Are Used

If you use evacuated tubes, do not remove stoppers. Puncture the diaphragm of the rubber stopper on the appropriate tube, and allow the correct amount of blood to *flow slowly* into the tube along the wall. Never force blood into a tube. This technique is extremely important.

If plain test tubes are used, remove needle from syringe and gently expel blood into tube, allowing it to run along the side of the tube.

6.21 Step 21: Dispose Puncturing Unit

Dispose of needles promptly to prevent their reuse or accidental injury. Use a needle cutter to cut off the tip, or insert the needle back into its shield and discard it in an appropriately labeled box designated for this purpose.

6.22 Step 22: Chill the Specimen (This is done only for certain specimens.)

Some tests require that the blood specimens be cooled immediately following the venipuncture to slow down metabolic processes which may alter some chemical values.

6.22.1 Examples of common tests requiring chilling the specimen:

(1) serum gastrin
(2) ketones
(3) lactic acids
(4) pressor amines
(5) renin activity
(6) vitamin C

6.23 Step 23: Eliminate Diet Restrictions

This is done only in the hospital. Once you have drawn the blood, mark off the patient's name from the "hold breakfast" list so that hospital personnel will know the patient may be served breakfast. If the list is not available, advise the floor nurse. An out-patient should be told that he/she may now have food.

6.24 Step 24: Time Stamp Paperwork

Once the specimen has been drawn, you should record the time. The time stamp machine should stamp the month, day, year, and time on each form. If a computer is used, enter the same information for the patient. A permanent record is needed by the physician who must know exactly when each specimen was drawn to correlate the results with any change in the patient's condition. The laboratory also must know the time when the specimen was collected. If unable to obtain specimens, a record of the reasons and initials of venipuncturist are necessary.

6.25 Step 25: Send Tubes to Proper Laboratories

Send tubes to appropriate laboratories designated to perform the required testing procedures.

7.0 VENIPUNCTURE IN CHILDREN

If a venipuncture is done on a child under two years of age, the site should be limited to superficial veins (i.e., the femoral vein is not recommended). For skin puncture blood collection, refer to NCCLS publication H4-A (8).

7.1 Procedure for Pediatric Venipuncture

Take special care to secure the arm to prevent injury caused by unexpected movement when the needle enters the skin. List the *amount* of blood withdrawn. Venipuncture should not be performed in veins usually used for I.v. infusions. The skin over the chosen vein should be cleansed with 70% alcohol and air dried. (When specimens are obtained for blood culture, cleanse the culture bottle stopper and the skin with Betadine (povidone-iodine.)

Apply a tourniquet proximal to the venipuncture site and remove it as soon as blood begins to flow into the collection container.

7.2 Venipunctures should be performed with either:

7.2.1 a tuberculin or 3 mL syringe with a 21 to 23 gauge needle or a 20 to 23 gauge winged infusion set with attached tubing (Winged infusion sets with attached tubing are used for intravenous infusions in children.)

7.2.2 winged infusion set and tubing attached to vacuum tube holder

8.0 ADDITIONAL CONSIDERATIONS

8.1 Patient Inquiry If possible, do not inform the patient of the tests being done. The physician can better inform the patient.

8.2 Patient Who Objects to Tests Do not argue with the patient. Report the patient's objections to the physician. The physician can explain better to the patient why the tests are needed.

8.3 Physician Relationship The doctor has priority with the patient. The venipuncturist should not enter the room while the doctor is visiting with the patient. You should come back at another time. However, if you have a stat order, politely ask if the physician would like the sample drawn now or at another time.

8.4 Keep track of number of venipunctures and amount of blood withdrawn each time so that the patient is not exsanguinated.

8.5 To prevent a hematoma when performing a venipuncture:

8.5.1 Puncture only the uppermost wall of the vein.

8.5.2 Remove the tourniquet before removing the needle.

8.5.3 Use the major superficial veins.

8.5.4 Make sure the needle fully penetrates the uppermost wall of the vein. Partial penetration may allow blood to leak into the soft tissue surrounding the vein by way of the needle bevel.

8.5.5 Apply a small amount of pressure to the area with the gauze pad when bandaging the arm.

8.6 To prevent hemolysis when performing a venipuncture:

8.6.1 Mix anticoagulated specimens gently but thoroughly by inverting tube gently 5 to 10 times.

8.6.2 Avoid drawing blood from a hematoma.

8.6.3 Avoid drawing the plunger back too forcefully when using a needle and syringe.

8.6.4 Avoid using a needle that is too small.

8.6.5 Make sure the needle is fitted securely on a syringe to avoid frothing.

8.2.6 Without touching, ascertain that the venipuncture site is dry.

8.2.7 If you use a sterile glass syringe, it must be dry.

8.7 Physician on Call A physician should be on call to handle emergency situations within the outpatient area in which venipunctures are made. In addition, one or two of the venipuncture personnel should have extensive first aid training, including special training in cardiopulmonary resuscitation, so that medical attention can be given to a needy patient while the physician on call is enroute.

8.8 Semi-Conscious or Comatose Patients Take special care when drawing blood from these patients to anticipate any unexpected movements or jerks either while introducing the needle, or while it is in place in the arm. Gauze should be readily available and the tourniquet quickly released in the event the needle is violently removed or repositioned. If the needle accidently goes much deeper into the arm, inform the doctor who will examine the area for possible damage.

8.9 Do not use gel separator tubes for blood bank specimens.

9.0 SPECIAL SITUATIONS

9.1 Time Intervals Some specimens must be taken at timed intervals because of medications and/or biological variations (circadian rhythms). It is important that collection of specimens for timed tests be obtained at the precisely specified interval. Directions should be given to the venipuncture team to obtain these specimens accurately.

9.1.1 ***Examples of tests requiring timed specimens***

9.1.1.1 tests where there is a diurnal effect, such as glucose, corticosteroids and other hormones, and serum iron

9.1.1.2 therapy monitoring such as prothrombin time, APTT, salicylic acid, digoxin, and other drugs

9.1.2 In many of these cases, the dose of the medication and the time of the last dose given, as well as the time of the specimen collection, should be recorded accurately on the request slip.

9.2 Specific Collection Techniques

9.2.1 ***Alcohol*** Use something other than alcohol to cleanse the venipuncture site, e.g., soap.

9.2.2 ***Heavy Metals*** Use special, metal free collection containers (10).

9.2.3 ***Legal Specimens*** Use lock box precautions.

9.3 Indwelling Lines or Catheters

9.3.1 Obtaining blood samples from indwelling lines or catheters may be a problem and a potential source of test error.

9.3.2 A line is a piece of tubing inserted into a patient's vein or artery for administering fluids and medications, monitoring pressures, and obtaining blood samples for diagnostic tests.

9.3.3 Locations of lines used for obtaining blood samples are internal jugular, arterial, umbilical, and occasionally the atrial and central venous pressure system.

9.3.4 Because it is normal practice to flush lines with a solution of heparin to reduce the risk of thrombosis, lines must be cleared of this fluid before blood specimens can be drawn for diagnostic testing. An adequate amount of blood must be withdrawn from the line and discarded prior to drawing a specimen to ensure the actual specimen is not diluted with the flush solution.

9.3.5 We recommend that a sample at least three times the volume of the line be removed and discarded before a specimen is obtained for analysis (9).

9.4 Heparin Locks

9.4.1 An indwelling winged infusion set can be successfully left in a vein from 36 to 48 h for i.v. administration of medication or as a vein source to obtain a blood sample. This procedure, known as a "heparin lock," has become more common in hospitals to "save" veins for therapeutic use and also to cause less trauma to the patient. With this system, a continuous intravenous infusion is not necessary to keep the vein open, thus giving the patient more comfort and mobility.

9.4.2 ***We do not recommend that the venipuncturist draw blood from indwelling cardiovascular (arterial, central venous) or umbilical lines. Cutdowns should not be used unless specially instructed and supervised by a physician.***

9.5 Blood Specimens from the Cannula

9.5.1 A cannula is used as an access for dialyzing and for blood drawing in kidney patients. For convenience in obtaining blood specimens from patients who have cannulas, a "T" connector is used. In the middle of the "T" tube connector there is a small tube about 6 inches (15 cm) long with a rubber diaphragm cap. Drawing blood from the cannula with a "T" tube on kidney transplant or dialysis patients should be done only by specially trained personnel, or the transplant or dialysis teams.

9.5.2 It is necessary to maintain a sterile technique when drawing blood specimens from the "T" tube, and it is also necessary to draw a discard tube to avoid heparin dilution effect.

9.6 Fistula

Routinely, the fistula arms should not be used for blood drawing. When possible, draw specimens from the opposite arm. Care must be taken of the fistula, as it is permanent.

In this case, a surgical procedure is used to fuse the vein and artery together and must develop for four to six weeks before it can be used for dialysis.

9.7 Intravenous Fluids

9.7.1 When a patient is being administered an i.v. infusion in an arm, do not draw blood from that site. It has been shown that blood drawn above the i.v. site would be diluted with the fluid being administered. Test results from this blood will be erroneous and thus misleading to the physician.

You should look for a blood-drawing site in the opposite arm. Occasionally, an i.v. will be running in both arms and no site can be found except in the area of the i.v. administration.

9.7.2 Satisfactory samples may be drawn below the i.v. by following these procedures:

9.7.2.1 Turn off the i.v. for at least 2 min before venipuncture.

9.7.2.2 Apply tourniquet below the i.v. site. Select a vein other than the one with the i.v.

9.7.2.3 Perform venipuncture. Draw 5 mL of blood and discard before drawing test specimens.

9.8 The Patient in Isolation

9.8.1 Patients are isolated for two reasons:

9.8.1.1 to prevent the disease from spreading to other patients, visitors, and employees

9.8.1.2 to protect the patient from outside contamination. The patient's normal protective mechanism may be reduced to such a point that infection could be serious or fatal.

9.8.2 ***The Isolation System*** A color-coded card is put on the door or window of the patient's room. The card describes what type of isolation the patient is in and what precautions must be taken by those entering the room.

9.8.2.1 There are five types of isolation:

(1) strict
(2) respiratory
(3) wound and skin
(4) protective
(5) enteric

9.8.2.2 Gowns, gloves, masks, etc., are kept in a clean area. In some hospitals, a stand containing these supplies is kept outside the room. The new modern hospital often has an anteroom which serves as the "clean area." Here, the person entering the room can gown, etc., before entering the patient's room. Doctors' suitcoats, jackets, etc., are left here.

9.8.3 ***Isolation Room***

9.8.3.1 *Before entering the isolation room:*

(1) Read the isolation sign on the door. It will explain the type of isolation and what must be worn and done. Follow these instructions carefully.

(2) Check your orders and assemble the equipment needed for the patient. Remember, anything taken into the room must be left there, discarded, or cleansed carefully if taken from the room.

(3) Take in the minimum equipment needed: a syringe and needle, a tourniquet, proper tubes, four or five dry sponges, four or five sponges soaked with alcohol, glass slides if necessary, a plastic bag if the patient has hepatitis, and a small roll of bandages.

(4) Never take trays into the isolation room.

9.8.3.2 *On entering the room:*

(1) Place four or five paper towels on the table and place the equipment on one or two towels that have been spread open.

(2) Wash your hands.

(3) If the patient is in protective isolation, wash and dry the tourniquet.

(4) Obtain blood specimens in the usual manner, avoiding any unnecessary contact with the patient and bed.

(5) After mixing, place the filled tubes on a clean paper towel.

(6) If a syringe is used, lay the syringe and needle on a paper towel before bandaging the patient's arm. Pick up the empty tubes with dry sponges. Fill the tubes. Hold the syringe and needle in your right hand when filling the tubes or the reverse if you are left handed.

(7) Discard the syringe and needle in a discard receptacle in the patient's room.

(8) Remove your gown and dispose of it in the proper container.

(9) Wash your hands and the tourniquet with soap and water and dry them.

(10) Turn off the faucet with a clean paper towel so you do not contaminate your hands.

(11) Pick up the tubes from the paper towel and clean them with an alcohol pad. Put them in the block on the cart. This is not necessary if the patient is in protective isolation.

(12) If the patient has hepatitis, note same on the tube label—put tube in a labeled plastic bag.

(13) If blood smears were made, place the smears on two clean paper towels. When you are ready to leave, wrap the smears and tubes in the top paper towel and discard the bottom paper towel.

9.8.4 ***Evaluate blood collection techniques carefully to minimize risk to the laboratory staff.***

(1) Observe aseptic blood drawing techniques.

(2) Wash your hands thoroughly before going to the next patient.

(3) If the outside of the tube is contaminated with blood, wipe the tube with disinfectant before further handling or transfer.

(4) After all of the above procedures, discard all needles and syringes in a suitable container.

9.8.5 Immediately report to the employee health service accidental needle prick or contamination of a break in the skin by blood or excreta from an infected patient.

9.8.6 Hepatitis, often associated with jaundice, is a sometimes serious viral disease affecting the liver. The virus can be transmitted by the fecal-oral route, by contaminated foods or water, and through breaks in the skin. There are two types of hepatitis, caused by two different viruses; both are present in all body fluids, including urine, and in intestinal contents.

The patient known to have infectious hepatitis is isolated during the acute phase of the disease. All laboratory requisitions must indicate that the patient is infected with hepatitis. All laboratory specimens must be labeled clearly as coming from a patient with hepatitis. Not all hepatitis-infected individuals are jaundiced, or in isolation.

9.9 Patient Problems

9.9.1 *Syncope (fainting)*

(1) If the patient is sitting, lower his/her head and arms.

(2) Loosen tight clothing.

(3) Administer ammonia inhalant. The patient will respond by coughing.

(4) Apply cold compresses to the forehead and the back of the neck if necessary.

(5) If the patient does not respond, notify a physician.

9.9.2 *Nausea*

(1) Make the patient as comfortable as possible.

(2) Instruct the patient to breathe deeply and slowly.

(3) Apply cold compresses to the patient's forehead.

9.9.3 *Vomiting*

(1) Give the patient an emesis basin or carton, and have tissues ready.

(2) Give the patient water to rinse out his/her mouth.

(3) Report the incident to a nurse.

9.9.4 *Convulsions*

(1) Prevent the patient from injuring himself/herself. Do not restrain the movements of the patient's extremities completely, but try to prevent him/her from being injured.

(2) Call the physician or nurse.

9.9.5 *Patient Inquiry* If possible, do not inform the patient of the tests being done. The physician can better inform the patient.

9.9.6 *Patient Who Objects to Tests*

(1) Do not argue with the patient.

(2) Report the patient's objections to the physician. He/she can better explain to the patient why the tests are needed.

9.9.7 *Physician Relationship* The doctor has priority with the patient. The venipuncturist should not enter the room while the doctor is visiting with the patient. You should come back at another time. However, if you have a stat order, politely ask if the physician would like the sample drawn at another time.

10.0 FACTORS THAT AFFECT LABORATORY VALUES

Interpretation of laboratory data has assumed new importance and attracted increased attention with both more frequent testing and multiple testing. The increased use of laboratories predictably yields abnormal unsolicited data that requires interpretation and may lead to costly, unproductive, and unnecessary sequential testing. A frequently heard means of disposing of an unwanted unexpected laboratory value is calling it "lab error" (6). Even when an analytical procedure has been performed correctly and precisely, variables can affect the test result. Knowledge of these variables and standardization of laboratory testing procedures are essential for correct interpretation and optimal use of the data.

Major causes of "laboratory error" can be related to nonanalytical factors such as specimen collection, handling, and transport. Nonbiological factors, such as patient

misidentification, and biological factors, such as patient posture and the time of taking a specimen, all contribute to the total "laboratory error."

Physiological factors that influence results include age, activity, bed rest, food ingestion, alcohol ingestion, menstrual cycle, obesity, oral contraceptives, posture, pregnancy, race, sex, smoking, and time of day. All biological phenomena exhibit rhythms, with the circadian rhythm (the change in a 24-hour period) being the most important to laboratory testing.

Many factors whose effects on laboratory values have been documented have been reviewed (9, 12, 13, 14).

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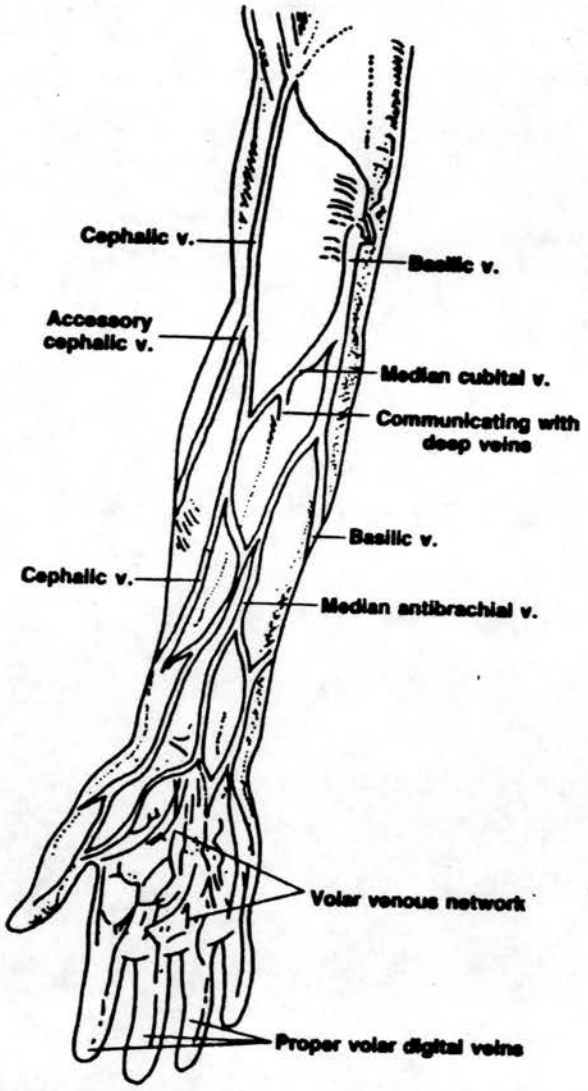

Fig. 1 Superficial veins of the anterior surface of the upper extremity

APPENDIX A

A1.0 TRAINING PROGRAM

A1.1 Selecting Trainees for the Training Program

A1.1.1 One might think, at first, that almost any intelligent individual can perform a venipuncture. However, those who are familiar with venipuncture know that this is not the case. Venipuncture is a complex procedure requiring both knowledge and skill to perform properly. For this reason, it is wise to consider the attributes most necessary for a successful venipuncture candidate. The following are suggestions to keep in mind when selecting applicants for the training program.

A1.1.2 *Considerations in Selecting Applicants for an Interview*

(1) dependability as shown in a high school attendance record

(2) favorable comments from employer or school counselor

(3) satisfactory work references from previous employers

(4) good health record

(5) willingness to work different shifts and on weekends

A1.1.3 *Characteristics to Look for in an Interview*

(1) neat appearance. Neatness and good grooming are extremely important because the venipuncturist represents the laboratory.

(2) poise (composure, relaxed nature)

(3) alertness (comprehension, prompt responses)

(4) pleasant personality (likeability, friendliness)

(5) maturity

(6) enthusiasm and sincerity

(7) initiative

(8) ability to be understood

(9) cooperation (positive attitude, eagerness to please)

(10) attention to detail. It is most important to note if the applicant has a reading problem and/or dyslexia.

A1.2 Objectives of Training Program

After training, the trainee should be able to perform the following tasks:

A1.2.1 explain the physical layout of the blood drawing area or hospital floors

A1.2.2 identify the various pieces of equipment used in the venipuncture procedure and describe how they are used

A1.2.3 identify the various forms associated with the venipuncture

A1.2.4 identify the veins normally used in performing a venipuncture

A1.2.5 perform a venipuncture on a simulated arm

A1.2.6 perform the 25 basic steps that constitute the venipuncture procedure. These steps are listed in 6.0. Particular emphasis is placed on the procedures used for identifying patients by name and identification number.

A1.2.7 After the venipuncturist has achieved objectives A1.2.1 through A1.2.6, he/she should have acquired a professional attitude and a bedside manner. The venipuncturist's manner in approaching the patient may have a direct bearing on the patient's response to the venipuncture. Emphasis should be placed on a pleasant bedside manner. The venipuncturist is a public relations ambassador for the Department of Laboratory Medicine because the venipuncturist may be the only contact the patient has with the department.

The venipuncturist should identify himself/herself and explain the procedure to the patient. He/she must gain the confidence of the patient, reassure the patient, and try to relieve any apprehension the patient might feel.

A1.3 **Training Program** The training program should consist of both didactic instruction and empirical training.

A1.3.1 ***Didactic Instruction*** Before any empirical training, the trainee should receive a minimum of didactic instruction in the following subjects:

A1.3.1.1 *Physical Layout of Location* The trainee should become totally familiar with the outpatient blood drawing area, the hospital floors, and the clinical laboratories. A guided tour is an ideal way to familiarize the trainee with both the areas and the work done within those areas.

A1.3.1.2 *Equipment* The trainee should become familiar with the equipment and know when and how to use it. The equipment is listed in 5.0.

A1.3.1.3 *Forms Processing* The trainee should become familiar with the various forms used within the area, and be able to explain how and when each one is used.

A1.3.1.4 *Vein Anatomy* The trainee should be able to identify and locate the various veins used in performing a venipuncture (see Fig. 1).

A1.3.1.5 *Basic Steps in Performing a Venipuncture* Most of the didactic instruction should focus on this subject. These steps are included in 6.0.

A1.3.1.6 *Simulated Patient Arm* The simulated patient arm is an artificial arm that is constructed of materials ordinarily available in the clinical laboratory (9). Using the simulated arm, the trainee should perform the venipuncture following the steps outlined in 6.0. There are several advantages to using the simulated arm during the training stage.

(1) the trainee can become familiar with the equipment

(2) the trainee can practice the venipuncture procedure

(3) the trainee can develop self-confidence

A1.3.1.7 *Medical Laboratory Terminology* The trainee should be exposed to relevant medical terminology.

A1.3.1.8 *Tests* The trainee should be familiar with each of the laboratory tests.

A1.3.2 ***Empirical Training*** The empirical training phase gives the trainee a chance to become more familiar with procedures, equipment, and types of patients. It also gives him/her the opportunity to become familiar with the occasional problems and the best ways to deal with them.

A1.3.2.1 *Suggested Procedure* The trainee should observe the entire venipuncture procedure and should be allowed to assist the instructor for a minimum of 8 to 16 h before attempting a venipuncture. While assisting the instructor, the trainee should perform the following tasks:

(1) identify the patient

(2) assemble the necessary supplies

(3) apply the tourniquet

(4) select the vein site

(5) cleanse the venipuncture site

A1.3.2.2 *Empirical Training—Performance Phase*

(1) This phase gives the trainee the opportunity to develop the confidence and experience that are needed to perform venipuncture successfully.

(2) *Suggested Procedure* While working under the guidance of an instructor, the trainee should attempt a venipuncture on a patient who has good veins and who needs only a small amount of blood to be drawn. If the trainee experiences difficulty, the instructor should take over and complete the procedure.

After the trainee has performed the first successful venipuncture, he/she should be given the opportunity to do other venipunctures, first on patients with good veins and then on patients with difficult veins.

After 1 to 2 weeks of close supervision, the trainee should be allowed to work alone in a clinic area; he/she should be allowed to work in the hospital after 5 to 6 weeks of close supervision. The longer training period is necessary in the hospital due to complexity and patient conditions.

APPENDIX D: Clinical Laboratory Procedure Manuals

Approved Guideline

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Clinical Laboratory Procedure Manuals

VOLUME 4 NUMBER 2

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We invite comments from all of our readers — those not active, as well as those active, in NCCLS.

We always seek improvement and welcome suggestions that will help us make our publications more useful. Our National Office will record your comments and forward them to the appropriate chairholder.

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FOREWORD

There are a wide variety of procedure manual designs in the clinical laboratory field. These designs range from well-organized, detailed, and well-reviewed material to outdated, plastic-covered manufacturer product literature. The laboratory community has asked for a practical and useful format for preparing technical procedure manuals which meet the requirements of regulatory and voluntary accreditation agencies. (A review of these requirements, by agency, is provided in Appendix A.)

In late summer of 1979, NCCLS assembled a subcommittee to establish guidelines for laboratory procedure manuals. The first draft of a procedure manual publication was prepared by February 1980. Revisions were made, and by May 1980 it was approved by the Area Committee on General Laboratory Practices and the Board of Directors. The publication, entitled *Clinical Laboratory Procedure Manuals; Proposed Guideline* was made available to the clinical laboratory community, and their comments were solicited. Further revisions and reviews took these comments into consideration and resulted in the present document, which should be immediately applicable to the clinical laboratory. Not all viewpoints could be accommodated, however; comments not leading to change and the responses of the committee are included as Appendix E.

Procedure manuals are required in the clinical laboratory. Preparation of such manuals should be the first step in establishing acceptable procedures which include quality control as an integral part. Medicare laboratory regulations for independent laboratories (Title 42, Code of Federal Regulations (CFR) Section 405.1317(a) (4), Subpart M) and non-accredited hospital laboratories (Title 42 CFR Section 405.1028, Subpart J) as well as the Clinical Laboratories Improvement Act of 1967 (Title 42 CFR, Section 74.2(d), Subpart C) state that "quality control practiced by the laboratory must assure availability at all times, in the immediate bench area of personnel engaged in examining specimens and performing related procedures within a category...current laboratory manuals or other complete written descriptions and instructions relating to the analytical methods used by those personnel, properly designated and dated to reflect the most recent supervisory reviews."

The guidelines that follow represent input from several knowledgeable sources. Individuals serving on the subcommittee have experience in or represent clinical laboratory in-service education and methods coordination, a state public health laboratory, medical technology education and quality control, clinical pathology and College of American Pathologists (CAP) accreditation, Centers for Disease Control (CDC) licensure and proficiency testing, laboratory directors, bench level clinical laboratory personnel, and the laboratory product and device industry. The subcommittee hopes the guidelines are flexible enough to apply to all clinical laboratory situations, but also specific enough to give adequate guidance regarding the preparation, maintenance, and use of effective procedure manuals.

Two samples of procedures written using these guidelines appear in Appendices B and C. A sample flow chart appears in Appendix D. These should be considered as *examples only*.

KEY WORDS

Procedure manual, technical procedure, quality control, laboratory procedure, labeling, package inserts, reagents, equipment, references, document review.

for the Handling and Transport of Domestic Diagnostic Specimens and Etiological Agents; Approved Standard (H5-A, 1980); and *Percutaneous Collection of Arterial Blood for Laboratory Analysis; Approved Standard* (H11-A, 1983).

5.1.5 ***Reagents—Special Supplies and Equipment***

5.1.5.1 List the reagents, supplies, and equipment used in the procedure. Include:

(1) the name and chemical formula when possible
(2) the acceptable grade
(3) a bold statement of any extraordinary health or safety information associated with the reagent, supplies, equipment, or material used in the procedure. Include the general category or class of hazard, i.e., toxic, corrosive, explosive, biohazard, radiation, electrical, etc.
(4) the usual source supply company for reagent kits and prepared reagents

5.1.5.2 State the directions for preparation of each reagent that may be produced in the laboratory.

(1) Note any instructions for special cleaning or handling of glassware and volumetric equipment.
(2) State the degree of accuracy required for measuring reagents.
(3) Specify the quality of glassware and volumetric equipment required to meet performance requirements.

5.1.5.3 List those parameters used to determine acceptable reagent performance.

5.1.5.4 List storage requirements, including:

(1) container
(2) temperature
(3) stability (shelf life)
(4) labeling, specifically stating:
  (a) substance
  (b) lot number
  (c) date of preparation
  (d) expiration date
  (e) include any special storage instructions, such as "Store in Flammables Safety Cabinet; Keep in Explosion-proof Refrigerator; Work under Safety Hood," etc.

(Refer to the NCCLS publications: *Labeling of Clinical Laboratory Materials — Second Edition; Approved Standard* (GP1-A2, 1980) and to *Labeling of Laboratory Prepared Material; Proposed Guideline* (GP4-P, 1983) for additional information on labeling reagents.)

5.1.6 ***Calibration***

5.1.6.1 *Standard Preparation*

(1) List the standards used. Include:
  (a) name and chemical formula when possible
  (b) acceptable grade of standard
  (c) usual source/supply company
(2) State the directions for preparation of the standard.
(3) Note any special instructions for cleaning or quality of glassware and volumetric equipment.

(4) State the degree of accuracy required for measuring standards.
(5) List storage requirements. Include:
  (a) container
  (b) temperature
  (c) stability (shelf life)
  (d) labeling

5.1.6.2 *Calibration Procedure*

(1) Give detailed, stepwise instructions. Present dilutions of working standards in tabular form.
(2) State frequency with which calibration procedures should be performed.
(3) State specifications for photometric readings (see 5.1.8.4).
(4) State the type of calibration graph obtained, point of origin (when calibration graphs are used), and type of graph paper. Include a sample.
(5) Specify acceptable tolerances and what to do when tolerances are not met.

(Refer to these NCCLS publications for additional information: *Calibration Materials in Clinical Chemistry; Tentative Guideline* (C22-T, 1982), and *Control Materials in Clinical Chemistry; Tentative Guideline* (C23-T, 1982).

5.1.7 ***Quality Control***

5.1.7.1 Identify the control materials to be used

5.1.7.2 Give instructions for preparing and handling control materials.

5.1.7.3 State the frequency with which control materials are to be run.

5.1.7.4 Describe how tolerance limits for controls are to be established.

5.1.7.5 State the corrective actions to be taken when tolerance limits are exceeded.

5.1.7.6 Describe how quality control data are recorded and stored.

5.1.7.7 If no controls are available, list alternatives.

5.1.8 ***Procedure — Stepwise***

5.1.8.1 Write detailed instructions in a stepwise manner.

(1) Use the present imperative form.
  Example: Fill the container with reagent water, Type II.
  Not: The container is filled with reagent water, Type II.
(2) Keep the instructions free of extraneous matter, such as explanations or justifications (see 5.1.11).

5.1.8.2 Describe the stepwise preparation of filtrates or centrifugation requirements.

(1) Specify types of stoppers or caps to be used.
(2) Specify the kind of filter paper to be used.
(3) Specify speed or centrifugal force, length of time, and temperature for centrifugation, if critical.

5.1.8.3 Specify special glassware and/or pipets needed. Include any requirements for special cleaning.

5.1.8.4 Specify the following for photometric measurements:

(1) type of instrument
(2) wavelength
(3) cuvette size

(4) solution used as a blank
(5) linearity
(6) how the raw data are read (%T, absorbance, etc.)
(7) allowable time interval between preparation and reading of the solution; any stopping points in the methodology
(8) stability of the final solution

(Refer to NCCLS publication: *Relating Spectrophotometer Performance Characteristics to Analytical Goals; Approved Standard* (I3-A, 1980).

5.1.8.5 Indicate hazards and course of action to be taken in handling and disposing of hazardous materials.

(1) Specify any protective clothing and safety equipment required such as safety glasses, sterile gloves, clip-on monitors, etc.
(2) Type of spill kit to be used, or disposal method to be used.
(3) Set health and safety instructions in a boxed or underlined area.

Example:

> **Caution:** Hazardous material, wear safety glasses when handling this reagent.

5.1.9 ***Calculations***

5.1.9.1 Give stepwise instructions.

5.1.9.2 Give the equation, if applicable, in its basic form. Show the steps involved in simplification of the equation so the process can be followed logically.

5.1.9.3 Give a precise example.

5.1.10 ***Reporting Results***

5.1.10.1 State reference range(s), if applicable. Include:

(1) range of values for each type of sample
(2) demographic variables such as age and sex where applicable
(3) confidence limits used to establish the range

5.1.10.2 Identify procedures to be used in reporting abnormal results to the physician.

5.1.10.3 Give guidelines on acceptable reporting format: rounding off procedure, acceptable units, established detection limits, and preferred terminology to be used.

Note: Include the appropriate explanation for those procedures that require interpretive reporting.

5.1.11 ***Procedure Notes***

List information concerning the procedure that is too voluminous to include in the **Principle** or **Procedure**.

5.1.11.1 Explain reasons for special precautions.

5.1.11.2 List the possible sources of error.

5.1.11.3 Include helpful hints.

5.1.11.4 Include a statement describing the clinical situations that may influence the performance validity of the test results.

5.1.11.5 Describe acceptable alternative procedures indicated; list expected differences when manual procedures replace automated tests.

5.1.11.6 Enlarge upon clinical applications.

5.1.12 ***Limitations of Procedure***

5.1.12.1 State linearity and/or detection limits.

5.1.12.2 State known interfering substances.

(1) Chemical interferences: those substances that cause sources of error in the analytical system, e.g., preservatives, drugs.
(2) *In vivo* interferences: usually drugs that cause abnormally high or low results that do not reflect the true physiological state.

5.1.13 ***References***

The following items should be included in the Reference Section when used as sources of information.

5.1.13.1 Literature References: Use a format for laboratory references acceptable in scientific literature. Refer to *Council of Biology Editors Style Manual*, fifth edition, 1983, for style.

5.1.13.2 Manufacturer Product Literature: State manufacturer's name/location, title of literature, publication code number, lot number, and revision date.

5.1.13.3 Textbooks: List author, title, edition number, page(s), publisher, place of publication, and year.

5.1.13.4 Standards Publications: For example, Grainick et al., *Standardized Collection, Transport and Preparation of Blood Specimens for Coagulation Testing; Tentative Guideline* (H21-T, 1982).

5.1.13.5 Written personal communications

5.1.13.6 Research including supporting data for validation of methods

5.2 **Supplemental Materials**

Certain materials to be used at the bench to implement procedures may be extracted from the procedure manual. These materials may include flow diagrams, index cards, and manufacturer product literature. However, these supplemental materials must not be substituted for the procedure manual. Such materials must be current and be referenced to the procedure manual by date, procedure number, reviewer's initials, etc

5.2.1 ***Manufacturer Product Literature (Labeling)***

Develop a system to assure that product or package literature is current with and applicable to the kits or reagents actually in use. Lot numbers or other identifying information should be referenced on the literature since product changes also might result in changes in the labeling.

5.2.1.1 Set up a *Title Page* using the laboratory's standard format and numerical coding system for each piece of literature used. Append the actual copy to be used in proper page sequence.

5.2.1.2 Mark clearly those parts of the product literature that reflect the method followed by the laboratory.

5.2.1.3 Identify clearly the ancillary information that must be included to meet the standards for a procedure manual (e.g., calibration information, quality control information, etc.) (see 2.1).

5.2.1.4 Cross out or black out irrelevant information or alternative procedures, unless the alternates serve as back-up procedures. If so, they must be clearly identified as such.

5.2.1.5 Document any revisions (manufacturer) or modifications (laboratory). If a manufacturer's protocol is modified, clearly justify the modification in writing. Include the justification in the formal authorized procedure, and document the validation of the modification.

5.2.1.6 A copy of this material must be part of the procedure manual.

5.2.2 *Flow Diagrams*

5.2.2.1 Use waterproof writing materials to prepare the diagrams because this system of procedure manual format is usually posted in the open working area of the laboratory.

Consider the use of cellulose, plastic, or other "reagent-proof" covering.

5.2.2.2 Consider a flow diagram as supplemental material if it contains only the step-by-step working procedure and not the other essential elements of a procedure manual. As such, it must be included as part of the overall procedure manual.

5.2.3 *Card Index System*

5.2.3.1 Each card must contain the information referenced in 2.1 (2.1.1 through 2.1.6).

5.2.3.2 Start each procedure on a new card.

5.2.3.3 Consider the use of tabs for each reference.

5.2.3.4 Color codes for cards may be used to differentiate procedures or groups of related procedures.

5.2.3.5 Develop a tracking or retrieval system to assure return of cards that have been removed.

5.2.3.6 A copy of the procedure card must be part of the overall procedure manual.

6.0 REVIEW AND UPDATE

6.1 Procedure

6.1.1 Establish who has the authority to conduct a review. This authority will vary with the administrative structure of the laboratory, but might include the director and/or associate, doctoral division/section manager, qualified supervisor, or delegated committee.

6.1.2 Review the procedure whenever a change is made in methodology, instrumentation, reagents, etc.

6.1.3 Review each procedure at least annually. At the time of the review, decide if the procedure can be reapproved as it is currently written, needs to be revised, or is obsolete.

6.1.4 Essential points to consider in the review include:

6.1.4.1 conformity of the procedure to the guidelines described in 5.0.

6.1.4.2 conformity of the procedure to current methodology (i.e., Does it reflect what is being done in the laboratory?).

(1) Minor changes can be added to the original, signed, dated, and noted on review page (see 5.1.1.5).

(2) Major changes require retyping the entire procedure.

6.1.5 Sign and date each procedure as evidence of the review. Use a date box on the first page as a means of organizing the review.

Example:

Prepared by

Adopted		
Reviewed		
Reviewed		
Reviewed		
Revised		

Supersedes

6.2 Manual Review

6.2.1 Review each manual at least annually. Reviewer may be the same person designated in 6.1.1.

6.2.1.1 Does the manual contain all required material?

6.2.1.2 Are all the procedures in the manual current? Is there evidence of a recent review?

6.2.1.3 Does the manual contain outdated or obsolete material?

6.2.1.4 Are the bench manual, flow diagram, or card file current with the master manual?

6.2.2 Document the review. The authorized reviewer should sign and date an updated index or approval page. If there are multiple copies of a procedure or manual, all copies must be reviewed as described, and that review documented. A log of copies should be kept by the responsible person.

6.2.3 Obsolete or superseded procedures should be removed to a retired file for historical review and liability reasons. Such a retired records file should be kept for a minimum of two years in accordance with recommended practices.

BIBLIOGRAPHY

1. National Committee for Clinical Laboratory Standards. Procedures for the collection of diagnostic blood specimens by venipuncture; Approved Standard. NCCLS publication H3-A. Villanova, Pa.: NCCLS; 1983.

2. National Committee for Clinical Laboratory Standards. Procedures for the collection of diagnostic blood specimens by skin puncture; Approved Standard. NCCLS publication H4-A. Villanova, Pa.: NCCLS; 1982.

3. National Committee for Clinical Laboratory Standards. Procedures for the handling and transport of domestic diagnostic specimens and etiological agents; Approved Standard. NCCLS publication H5-A. Villanova, Pa.: NCCLS; 1980.

4. National Committee for Clinical Laboratory Standards. Percutaneous collection of arterial blood for laboratory analysis; Approved Standard. NCCLS publication H11-A. Villanova, Pa.: NCCLS; 1983.

5. National Committee for Clinical Laboratory Standards. Labeling of clinical laboratory materials, 2d ed.; Approved Standard. NCCLS publication GP1-A2. Villanova, Pa.: NCCLS; 1980.

6. National Committee for Clinical Laboratory Standards. Calibration materials in clinical chemistry, Tentative Guideline. NCCLS publication C22-T. Villanova, Pa.: NCCLS, 1982.

7. National Committee for Clinical Laboratory Standards. Control materials in clinical chemistry, Tentative Guideline. NCCLS publication C23-T. Villanova, Pa.: NCCLS; 1982.

8. National Committee for Clinical Laboratory Standards. Relating spectrophotometer performance characteristics to analytical goals; Approved Standard. NCCLS publication I3-A. Villanova, Pa.: NCCLS; 1980.

APPENDIX A

REQUIREMENTS FOR TECHNICAL PROCEDURE MANUALS[a]

National Regulatory Agencies[b]

	CLIA Medicare 1967	CAP 1979	AABB 1981	JCAH 1980
GENERAL				
Manual must be written. Textbook not acceptable	X	X	X-1	X
Complete and current; contains only those tests done in the section	X	X	X	X
Reviewed and approved annually	X	X	X	X
Changes dated and approved	X	X	X	
Available at the bench	X	X	X	X
SPECIMEN				
Patient preparation	X	X	X	X
Specimen collection	X	X	X	X
Specimen handling	X	X	X	X
Specimen storage	X	X	X	X
Criteria for unacceptable specimen	X	X	X	X
QUALITY CONTROL				
Preparation of controls	X	X	X-2	X
Mean value and upper/lower limits	X	X	X-2	X
Lot number and date of preparation	X	X	X-2	X
Remedial action to be taken with unacceptable results	X	X	X-2	X
PROCEDURE				
Preparation/storage of reagents, standards	X	X	X-2	X
Methodology	X	X	X-2	X
Calibration/linearity	X	X	X-2	X

Code:
X = listed as required
0 = not listed specifically

APPENDIX A

REQUIREMENTS FOR TECHNICAL PROCEDURE MANUALS[a]
National Regulatory Agencies[b]

PROCEDURE	CLIA/Medicare 1967	CAP 1978	AABB 1981	JCAH 1980		
Derivation of results	X	X	X-2	0		
Alternate procedure for automated tests	X	0	X-2	X		
Normal ranges/results	X	X	X-2	X		
Criteria for handling abnormal/alert values	X	X	X-2	X		
Flow sheets, keys, tables	0	X	X-2	0		
Notes	0	X	0	0		
References	X	X	X-2	0		

Code:
X = listed as required
0 = not listed specifically

[a] Consult the regulations in question as to manual requirements for specific sections (e.g., microbiology, parasitology, hematology).

[b] Consult state and local regulatory agencies for additional requirements.

X-1. AABB does not accept textbooks.
X-2. Required in procedure manuals of AABB-accredited blood banks and transfusion services by the National Committee on Inspection and Accreditation.

APPENDIX B

ALKALINE PHOSPHATASE (ALP)

Prepared: October, 1977 By: John Smith
Accepted: November, 1977
By: John Jones
(Signature/title)
Title: Assistant Chief Clinical Chemistry
Reviewed:

Date	By

APPENDIX B

ALKALINE PHOSPHATASE IN SERUM OR PLASMA

PRINCIPLE

This procedure utilizes the Boehringer Mannheim "optimized" colorimetric method and is based on the hydrolysis of p-nitrophenolophosphate to p-nitrophenol at 30°C. This conversion is catalyzed by alkaline phosphatase in the presence of magnesium ions, and the resulting yellow color is read at 405 nanometers on a Coleman 124D recording spectrophotometer.

Alkaline phosphatase determinations are useful in the diagnosis of hepatobiliary disease and bone disease associated with increased osteoblastic activity.

SPECIMEN

Serum: Use serum free of hemolysis. This is the preferred sample.

Plasma: EDTA and citrate should not be used as anticoagulants. Sodium fluoride in concentrations less than 5 mg/mL blood, oxalate, and heparin will not interfere with the assay.

Minimum sample size is 0.2 mL; optimum size is 0.5 mL or larger.

The specimen may be stored at 2-8°C for up to four days. Freeze if longer storage is required.

Hemolyzed specimens are known to give falsely elevated results; results on hemolyzed specimens must include this notification on the report form.

REAGENTS

(1) Buffer: supplied by manufacturer (bottle 1); use as is.
1.0 M diethanolamine buffer, pH 9.8
0.5 mM magnesium chloride

If the solution shows evidence of bacterial contamination, turbidity, or sedimentation, discard.

(2) Substrate. p-nitrophenylphosphate tablets containing: 0.21 mmoles p-nitrophenyl-phosphate, 5.73 mmoles sodium chloride

If tablets become moist, discard.

(3) Working solution: place one tablet (substrate) into 20 mL of buffer. This is sufficient for six assays. Store in an amber bottle. Working solution is stable for 1 day at 20-25°C, 5 days at 2-8°C, and 3 weeks at -20°C.

CALIBRATION

No standards are used in this procedure. Alkaline phosphatase activity is measured kinetically by the increasing intensity of the yellow color formed during the reaction.

QUALITY CONTROL

Control materials consist of two commercial lyophilized materials, one normal and one abnormal level. (Refer to Chemistry Quality Control Manual for names of current controls and established acceptable ranges). These 10 mL controls are prepared fresh daily and used for a variety of the procedures performed in the laboratory. One control from each level must be run with each set of unknowns. Control limits are +/- 2 S.D. from a minimum of 10 interassay determinations. Values exceeding these limits are to be treated in accordance with the established policy (reference Standard Operating Procedure Manual: Quality Control Procedure).

PROCEDURE

(1) Allow 30 min warm-up for instrumental system (Coleman 124D) and attachments:

Power unit: on
Operation switch (124D): on
Wavelength: 405 nanometers
Mode: visible (left side of 124D)
Slit: 1.0 (middle position, back of 124D)
Scale: 0 - 2
Tungsten lamp: on
Recorder: amp
Range: 10 mv
Power: 20 mm/min
Cell Programmer: on
Measurement period: 15 seconds
Heating Unit: on (see Note 2)
Circulating water: on

(2) Using a volumetric pipet, pipet 3.0 mL of working solution into a 1.0 cm disposable cuvette and place in a 30°C water bath for a minimum of 8 min.

(3) Add 0.05 mL of patient specimen or control (Eppendorf pipet), cap cuvette, mix well by inversion, remove cap, and place in cuvette holder currently in light path.

(4) Repeat step 3 until all four positions in the cell chamber are filled, inserting the 2nd, 3rd, and 4th cuvettes in a counter clockwise manner from the first (see Note 4).

(5) When the final cuvette is in place, activate the cell programmer by going from the manual to auto mode, and immediately switching the recorder to "chart" position.

(6) Record absorbance readings over a five-minute period and determine the average A/minute (see Note 5).

CALCULATIONS

The following formula is used:

$$\frac{\Delta \text{A/minute} \times \text{total assay volume(mL)} \times 1000}{\text{absorbancy coefficient} \times \text{light path(cm)} \times \text{specimen volume(mL)}} = \text{mU/mL specimen}$$

where the absorbancy coefficient = 18.5cm²/ μmole p-nitrophenol at 405 nm

This calculation then reduces to:

$$\frac{\Delta \text{A/minute} \times 3.05 \text{ mL} \times 1000}{18.5 \times 1 \text{ cm} \times 0.05 \text{ mL}} \qquad \Delta \text{ A/minute} \times 3300 = \text{mU/mL specimen}$$

From the attached recorder graph, the following Δ A/minute are observed:

(1) $\frac{(1.000 - 0.330)}{4 \text{ min}} \times 2 = 0.335/\text{min}$ (see Note 5)

(2) $\frac{(0.483 - 0.300)}{5 \text{ min}} \times 2 = 0.073/\text{min}$

(3) $\frac{(0.637 - 0.282)}{5 \text{ min}} \times 2 = 0.142/\text{min}$

(4) $\frac{(0.320 - 0.245)}{5 \text{ min}} \times 2 = 0.030/\text{min}$

(the factor of 2 comes from the scale expansion)

When inserted into the above formula, the following values are obtained:

(1) 1106 mU/mL
(2) 241 mU/mL
(3) 469 mU/mL
(4) 89 mU/mL

RESULTS

The expected values for this test are as follows:

males:	87 - 212 mU/mL at 30°C
females:	66 - 220 mU/mL at 30°C
children:	178 - 556 mU/mL at 30°C (3-15 years of age)

These values were taken from information supplied with the product insert, and were verified at the lab in a 1975 study.

(Results which require immediate notification of physician should be noted.)

NOTES

(1) This test should only be run after one has become familiar with the information provided by BMC in the product insert (10/78 edition). A copy is attached.

(2) The heating unit is set at 31°C. By the time the circulating water reaches the cell chamber, it is at 30°C.

(3) Each patient specimen is done in duplicate and in separate runs with the mean value reported; at least one control is included in each run; a run is comprised of four assays being monitored simultaneously at 15 second intervals.

(4) The cover should be removed only to insert a cuvette in order to maintain the temperature at 30°C.

(5) Δ A greater than 0.250/min indicates high activity (greater than 825 mU/mL); the assay should be repeated with the specimen diluted 1:1 with saline. The final result is then multiplied by 2. (Note example 1 in calculations).

(6) Critical parameters: wavelength, slit width, clean cuvettes, reaction temperature.

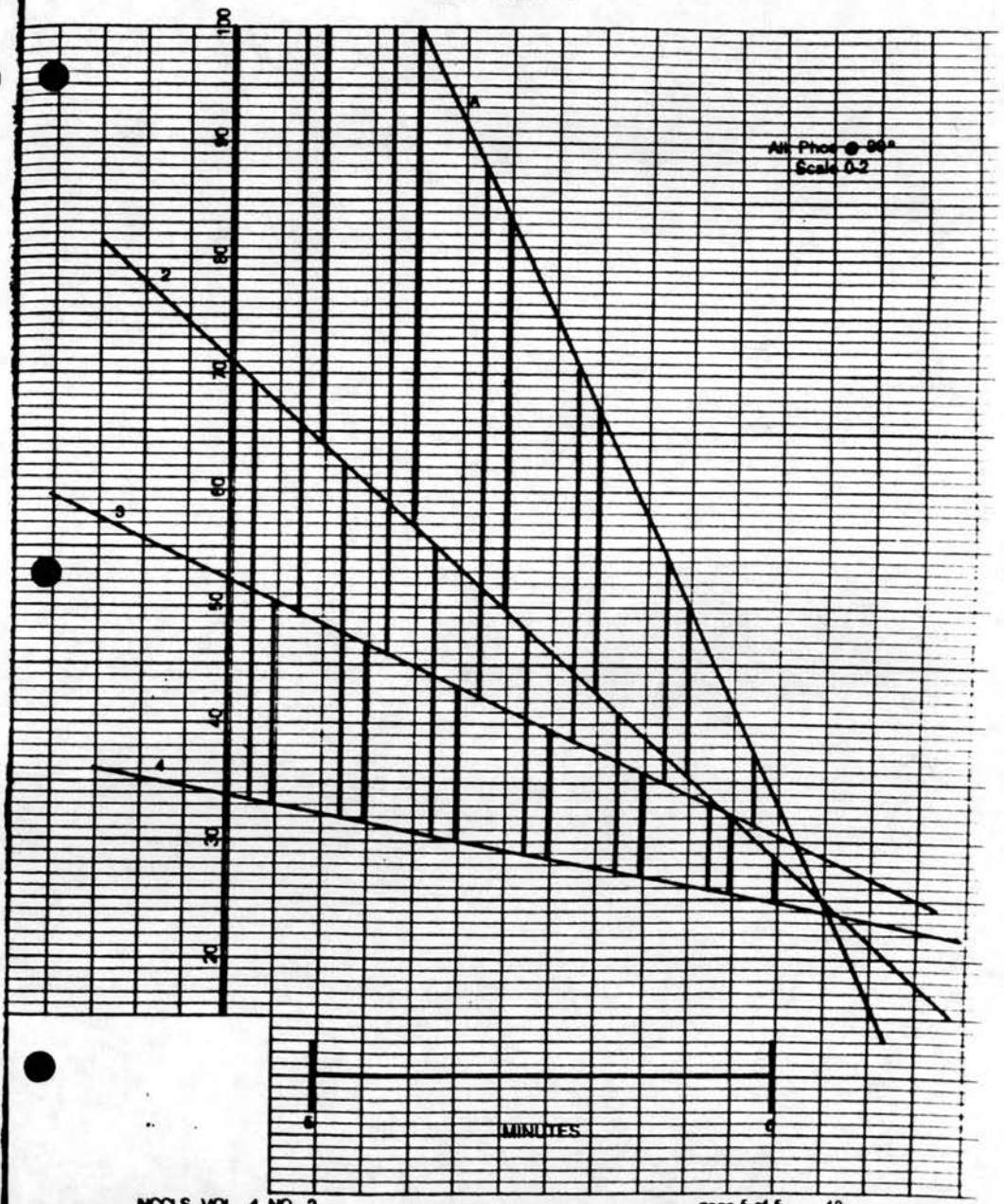
(7) The optical density of the substrate should be measured prior to each run and recorded in the record book.

REFERENCES

Tietz, N., Fundamentals of clinical chemistry. Philadelphia: W. B. Saunders Company; 1976, pp. 602-610.

Henry, R. J., Cannon, D.C., and Winkelman, J. W., Clinical chemistry: principles and techniques. Hagerstown, MD: Harper and Row; 1974, pp. 924-934.

APPENDIX B



APPENDIX C

March, 1990
Replaces method of
May, 1976

Adopted		
Reviewed		
Reviewed		
Reviewed		
Reviewed		
Under Revision		

GRAM STAIN PROCEDURE

PRINCIPLE

The Gram stain ranks among the most important stains for bacteria. It was devised by Christian Gram in 1844, and it allows the microbiologist to broadly distinguish between various bacteria that may exhibit a similar morphology. On microscopic examination of a Gram-stained smear, the differential features of the method will become apparent. Many bacteria will have retained the crystal violet-iodine combination and stain purple (gram-positive) while others will have stained red by the counterstain (gram-negative). Thus, in using this procedure not only are the form, size, and other structural details made visible, but the microorganisms present can be grouped artificially into gram-positive and gram-negative types by their reactions. This is an important diagnostic tool in subsequent identification procedures.

SPECIMEN

The specimen may consist of all types of clinical material or cultures of microorganisms in liquid or solid media.

(1) Make smears on clean, new 1" X 3" glass slides.

(2) For smears of pus or similar exudates, spread the sample to a thin film over a large area (1.5 X 3.0 cm) on the slide by using a sterile wire loop or applicator stick.

(3) When swabs are used to prepare the smear, take care to roll the swab across the slide to avoid destruction of cellular entities by brisk rubbing.

(4) When paired swab specimens are submitted, roll the material from one of the swabs directly on the slide.

(5) For specimens where only one swab is submitted, inoculate the culture first then use the swab to prepare the smear.

(6) Prepare smears from swabs containing dried material or small amounts of the specimen by emulsification in a drop of normal saline on the slide.

(7) For smears of specimens such as sputum or feces, select any flecks of mucus or blood-tinged particles present, since they are more likely to yield infectious agents.

(8) Prepare smears of concentrated centrifuged specimens by using a sterile, rubber-bulbed, capillary pipet to place a drop on the slide. Use the tip of the pipet to spread the drop to an even film of proper density.

(9) Smears of clinical materials must be thicker than smears of bacterial growth from liquid or solid culture media.

(10) For fluid cultures, prepare smears by taking a loopful of the medium and spreading it on a glass slide.

a. If growth is turbid, spread the broth over an area about the size of a dime.

b. If growth is scant, allow two or three loopfuls to dry in a concentrated film on the slide.

(11) For smears from a culture on solid medium, pick a minute amount of growth from a pure colony with a sterile loop or needle and emulsify in a droplet of bacteria-free water on a glass slide. The suspension of organisms should be only slightly cloudy, otherwise the smear will be too thick for microscopic observation of individual cells.

(12) Allow the smears to air-dry or allow to dry on a 65°C warming tray for 20 min. Heat-fix the air-dried slide by holding the slide against the front of the incinerator for 5-10 seconds or by placing the slide on the slide warmer for 60 seconds or until the smear is dry.

PREPARATION OF REAGENTS

(1) Crystal violet stock solution

(a) Dissolve in distilled water in an appropriate glass flask, using a magnetic stirrer:

Crystal violet dye	36 g
95% ethanol (SDA)	720 mL

(b) Store in a glass bottle.

(c) Label as "Crystal violet stock solution" with the date of preparation and an expiration date of one year. Store at room temperature.

(2) Sodium oxalate solution (1%)

(a) Combine in a flask

Sodium oxalate (reagent grade)	8 g
Reagent water Type II	800 mL

(See NCCLS Standard C3-A)

(b) After dissolution, transfer to a brown glass bottle.

(c) Label as "Sodium oxalate 1%" with the date of preparation and an expiration date of one year. Store at room temperature.

(3) Crystal violet working solution

(a) Filter 25 mL crystal violet stock solution for each 100 mL of 1% sodium oxalate.

(b) Allow crystal violet to filter completely before filtering sodium oxalate.

(c) Bottle and label "Crystal violet" with date of preparation. Expiration date is the earliest date of stock solution.

(d) Store at room temperature.

(4) Gram's iodine solution

(a) Solution 1:

Sodium bicarbonate ($NaHCO_3$) (reagent grade)	9 g
Reagent water Type II	180 mL

Dissolve in a 250 mL flask. Set aside at room temperature.

(b) Solution 2:

Potassium iodide crystals (reagent grade)	6 g
Iodine crystals (reagent grade)	3 g
Reagent water Type II	720 mL

Dissolve crystals in a 1 liter flask by adding 5 mL of the water and swirling until dissolved. Add the remaining water and stir well.

(c) Add solution 1 to the flask and mix well.

(d) Transfer to a brown glass bottle and label "Gram's Iodine," date of preparation, and an expiration date of six months. Store at room temperature.

(5) Acetone-alcohol decolorizer

(a) Combine and store in a 1 liter brown bottle:

Acetone (Reagent grade)	400 mL
95% ethanol (SDA)	400 mL

(b) Label "Acetone-alcohol decolorizer" with date of preparation and an expiration date of one year. Store at room temperature.

(6) Basic fuchsin 0.2% w/v counterstain

(a) Dissolve in a 2 liter flask using a magnetic stirrer:

Basic fuchsin (reagent grade)	3.2 g
Deionized water	1600.0 mL

(b) Label "Basic fuchsin 0.2%" with date of preparation and an expiration date of one year. Store at room temperature in a brown glass bottle.

QUALITY ASSURANCE

(1) Check the Gram stain reagents in use on the laboratory bench at least once daily.

(2) Stain a prepared smear of *E. coli* and *S. epidermidis* as described in the PROCEDURE. The results of the staining should show:

(a) Gram-negative bacilli

(b) Gram-positive cocci

PROCEDURE

(1) Cover the heat-fixed smear with the crystal violet solution, allowing the stain to remain for 15 seconds.

(2) Decant crystal violet and rinse slide with iodine until clear.

(3) Flood the slide with the iodine solution for 15 seconds.

(4) Rinse gently with flowing tap water.

(5) Treat with decolorizer solution by flowing the reagent dropwise over the smear while the slide is held at an angle. Stop the decolorization as soon as the dripping from the slide becomes clear.

(6) Remove the excess decolorizer with a gentle flow of water.

(7) Apply the basic fuchsin counterstain for 30 seconds and remove the excess with a gentle flow of tap water.

(8) Drain the slide and blot dry with bibulous paper.

(9) Examine the smear microscopically using the oil immersion objective.

RESULTS

(1) Gram-positive bacteria will stain purple.

(2) Gram-negative bacteria will stain red.

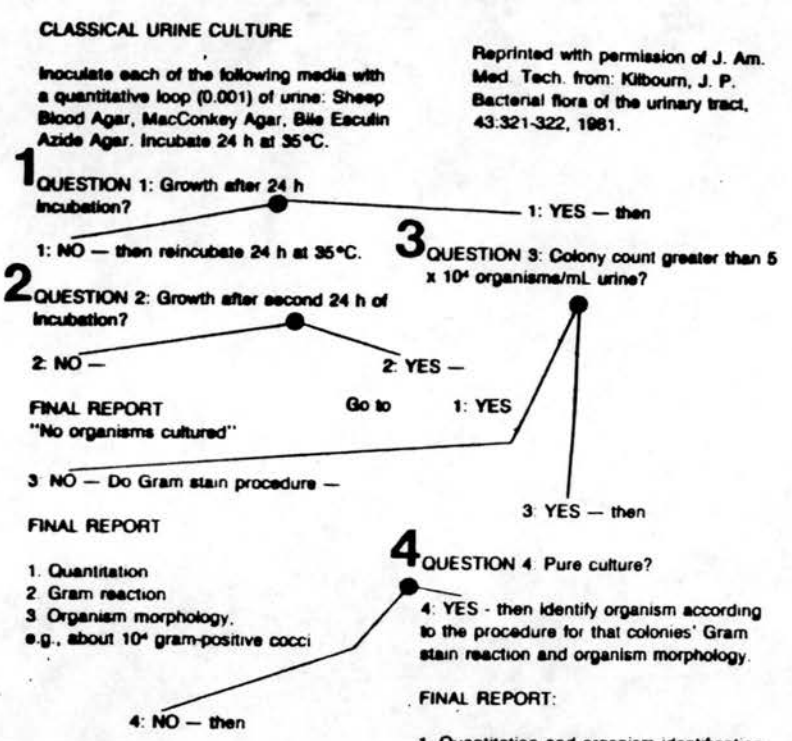
REFERENCE

Bailey, W. R. and Scott, E. G., Diagnostic microbiology, 4th ed., St. Louis: C. V. Mosby Co.; 1974.

AUTHOR

APPENDIX D

SAMPLE FLOW CHART



APPENDIX E: Technical Advisory Group

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STATEMENT OF NEED AND REASONABLENESS

Minnesota Statutes, Chapter 181.953, Subdivision 1 (d) requires the Commissioner of Health to establish fees to approximately equal the costs of conducting a licensure program for laboratories performing drug and alcohol tests of employees in the state. The statute reads as follows:

The commissioner shall charge laboratories an annual license fee. The fee may vary depending on the number of Minnesota employee samples tested annually at a laboratory. Fee receipts must be deposited in the state treasury and credited to a special account and are appropriated to the commissioner to administer this subdivision, and to purchase or lease laboratory equipment as accumulated fee receipts make equipment purchases or leases possible. Nothwithstanding section 144.122, the commissioner shall set the license fee at an amount so that the total fees collected will recover the costs of administering this subdivision and allow an additional amount to be credited to the special account each year sufficient to allow the commissioner to obtain appropriate laboratory equipment for use in administering this subdivision by July 1, 1994.

Under the proposed rule, the laboratory will submit the annual license and inspection fee with the application for license. These fees are not refundable. A license will be granted only when a laboratory meets standards set by rule, completes an application form and pays the fees in full.

License fees will be as follows:

Part A Application Fee

Laboratory Annual Gross Income	License Fee $
<$500,000	600
$500,00 to 2.0 Mill	1200
$2.0 Mill to 10.0 Mill	1800
>$10.0 Million	2400

Part B Inspection Fee

$1200 per year per per lab

If the laboratory satisfies application criteria and pays the entire fee, the laboratory will receive a provisional license. Full licensure may be granted after an on-site inspection to include, but not be limited to, assessment of external and internal quality control, examination of written laboratory procedures, review of records of sample receipt and storage, and an audit of records to ascertain the validity of statistics submitted to the Minnesota Department of Health. Demonstrated compliance with licensure standards will be required to qualify for a license.
Drug and alcohol tests used by laboratories are sophisticated and varied. Initial tests use a variety of chromatographic or

immuno-chemical technologies. The confirmatory test method, Gas Chromatography/Mass Spectrometry (GC/MS) demands a high level of training and skill. Knowledge of chain-of-custody procedures is essential. Therefore, a toxicologist consultant will be hired to perform on-site inspection. A professional-level employee (0.5 FTE) will manage the program and will work with the toxicologist on initial laboratory inspections. A clerk-typist (0.5 FTE) will provide office support.

The fees collected will be used to support the licensure program. We estimate that approximately twenty laboratories performing approximately 22,000 drug and alcohol test of Minnesota employees per year will apply for a license. The fees have been set to permit the greatest amount of laboratory participation, consistent with the revenue requirement.

Estimated Expenses

Expenses in FY88 and FY89 are for rule making. Expenses for FY88 were $23,400. Expenses for FY89 are expected to be $30,150. Total expenses over the two year period are estimated at $53,550 (see Table I). No on-site inspections will be conducted during the period.

Estimated expenses in FY90 are $54,000 for licensure and inspection (see Table II).

Estimated Revenue

The license fee is based on two components. Part "A" is based on laboratory annual gross income. The Part "B" inspection fee is fixed at $1200. Fee revenue for FY89 is as follows. It is assumed the revenue for FY90 will be identical.

Part A Application Fee

Laboratory Annual Gross Income	License Fee Per Lab	# Labs	Total Revenue
<$500,000	600	5	3,000
$500,000 to 2.0 Mill	1200	5	6,000
$2.0 Mill to 10.0 Mill	1800	5	9,000
>$10.0 Million	2400	5	12,000
		Total Part A Revenue	30,000

Part B Inspection Fee

$1200 per year per lab x 20 labs = $24,000 Total Inspection Revenue

Laboratories located outside Minnesota are assessed actual cost of additional labor, travel, and lodging expenses the department incurs in the laboratory inspection.

Total Fee Revenue $30,000 + $24,000 = $54,000

Licensure of Laboratories Performing Drug and Alcohol Testing in the Workplace Income and Revenue FY 88-90

FY	Income	Expenses	Expenses to General Fund	Special Account Balance
88	$47,000	23,400	-0-	23,600
89	$54,000	30,150	47,000	450
90	$54,000	54,000	-0-	450

The license fees are necessary to complete the tasks required by M.S. 181.953. The fees are reasonable, they meet the statutory criteria for covering estimated rule-making and program expenses and they have been reviewed by affected laboratories and other interested parties.

1-18-89
Date

R Lindner
Robert Lindner, Ph.D., M.D., Director
Public Health Laboratories

Table I
Estimated Rule Making and Other Costs
Associated With Drug and Alcohol Lab Licensure

Division of Public Health Laboratories

Expense Item	**FY88**	**FY89 YTD**	**FY89 Bal**
Professional	11,600	9,600	7,500
Clerk/Typist, 0.25 FTE	4,300	2,000	2,300
Attorney	3,500	1,500	1,000
State Register	150	400	400
Communications	500	400	400
Supplies and Duplicating	500	500	500
Total	20,550	14,400	12,100
Indirect Costs @ 13.6%	2,800	2,000	1,650
	23,400	16,400	13,750

Total Costs FY88 $23,400 FY89 $30,150

Total Costs FY88 + FY89 = $53,550

JI:db

Table II
Division of Public Health Laboratories
Estimated Costs of Drug and Alcohol Lab Licensure

MDH Inspections

Twenty Participant Labs

Toxicologist Consultant (alcohol and drug lab inspections) 16 hr/lab x $50/hr x 20 labs	16,000
.5 FTE Professional @ $17.50/hr wages & benefits	18,000
.5 FTE Clerk-Typist @ 9.50/hr wages and benefits	10,000
Supplies	1,000
Communications	1,000
Travel (In State)	1,500
Total Costs	47,500
Indirect Costs (13/6%)	6,500
Total Costs	54,000

JI:db

SF-00006-05 (4/86)

STATE OF MINNESOTA

Office Memorandum

DEPARTMENT : HEALTH

RECEIVED
APR 7 1989
FINANCIAL MANAGEMENT

DATE : April 6, 1989

TO : Bruce Reddemann, Director
Budget Operations

FROM : David Hovet, Director
Financial Management



PHONE : 623-5072

SUBJECT : Fee Request

Please find enclosed for your review, a statement of Need and Reasonableness for a proposed fee request for licensing laboratories that do drug and alcohol testing. We originally received a $47,000 loan from the General Fund to get the rules adopted. The loan will be paid back over a four year period. These payback costs are included in the Fee Review. If you should have any questions, please contact me.

Upon review of the attached supporting information justifying the need and the amount of the proposed fees, and pursuant to the authority vested in the Department of Finance under Minnesota Statutes 16A.128, the fees set forth in the proposal are hereby appoved.

4-7-89
Date

Bruce Reddemann, Director
Budget Operations

Minnesota Statutes, Chapter 181.953, Subdivision 1 (d) requires the Commissioner of Health to establish fees to approximately equal the costs of conducting a licensure program for laboratories performing drug and alcohol tests of employees in the state. The statute reads as follows:

The commissioner shall charge laboratories an annual license fee. The fee may vary depending on the number of Minnesota employee samples tested annually at a laboratory. Fee receipts must be deposited in the state treasury and credited to a special account and are appropriated to the commissioner to administer this subdivision, and to purchase or lease laboratory equipment as accumulated fee receipts make equipment purchases or leases possible. Nothwithstanding section 144.122, the commissioner shall set the license fee at an amount so that the total fees collected will recover the costs of administering this subdivision and allow an additional amount to be credited to the special account each year sufficient to allow the commissioner to obtain appropriate laboratory equipment for use in administering this subdivision by July 1, 1994.

Under the proposed rule, the laboratory will submit the annual license and inspection fee with the application for license. These fees are not refundable. A license will be granted only when a laboratory meets standards set by rule, completes an application form and pays the fees in full.

License fees will be as follows:

Part A Application Fee

Laboratory Annual Gross Income	License Fee $
<$500,000	600
$500,00 to 2.0 Mill	1200
$2.0 Mill to 10.0 Mill	1800
>$10.0 Million	2400

Part B Inspection Fee

$1200 per year per per lab

If the laboratory satisfies application criteria and pays the entire fee, the laboratory will receive a provisional license. Full licensure may be granted after an on-site inspection to include, but not be limited to, assessment of external and internal quality control, examination of written laboratory procedures, review of records of sample receipt and storage, and an audit of records to ascertain the validity of statistics submitted to the Minnesota Department of Health. Demonstrated compliance with licensure standards will be required to qualify for a license.

Drug and alcohol tests used by laboratories are sophisticated and varied. Initial tests use a variety of chromatographic or immuno-chemical technologies. The confirmatory test method, Gas Chromatography/Mass Spectrometry (GC/MS) demands a high level of training and skill and knowledge of chain-of-custody procedures. Therefore, a toxicologist consultant will be hired to perform on-site inspection. A professional-level employee (0.5 FTE) will manage the program and will work with the toxicologist on initial laboratory inspections. A clerk-typist (0.5 FTE) will provide office support.

The fees collected will be used to support the licensure program. We estimate that approximately twenty laboratories performing approximately 22,000 drug and alcohol test of Minnesota employees per year will apply for a license. The fees have been set to permit the greatest amount of laboratory participation, consistent with the revenue requirement.

Estimated Expenses

Expenses in FY88 and FY89 are for rule making. Expenses for FY88 were $20,200. Expenses for FY89 are expected to be $17,400. Total expenses over the two year period are estimated at $37,600. No on-site inspections will be conducted during the period.

Estimated expenses in FY90 are $54,000 for licensure and inspection.

Estimated Revenue

The license fee is based on two components. Part "A" is based on laboratory annual gross income. The Part "B" inspection fee is fixed at $1200. Fee revenue for FY89 is as follows. It is assumed the revenue for FY90 will be identical.

Part A Application Fee

Laboratory Annual Gross Income	License Fee Per Lab	# Labs	Total Revenue
<$500,000	600	5	3,000
$500,000 to 2.0 Mill	1200	5	6,000
$2.0 Mill to 10.0 Mill	1800	5	9,000
>$10.0 Million	2400	5	12,000
		Total Part A Revenue	30,000

Part B Inspection Fee

$1200 per year per lab x 20 labs = $24,000 Total Inspection Revenue

Laboratories located outside Minnesota are assessed actual cost of additional labor, travel, and lodging expenses the department incurs in the laboratory inspection.

Total Fee Revenue $30,000 + $24,000 = $54,000

FI-00194-06 (12/87)

Department of Finance
FEE REVIEW

Date Prepared: 04/05/89

Department/Agency: Health, Department of	Budget Activity: Public Health Laboratories
Fee Name: Drug and Alcohol Testing License	
Legal Citation: Minnesota Laws of 1987, Chapter 388	Fee Set By: [ ] Law [X] Agency
Purpose of Fee: To license all laboratories that perform laboratory tests for presence of drugs and alcohol on Minnesota employees.	
[X] Dedicated [ ] Non-Dedicated	Revenue Code: 310
APID: 40300:81 / Fund: 20 / Accumulated Difference Thru 1986: $-0-	Dollars in Thousands (137,522 = 137.5)

Fiscal Year	Actual F.Y. 87	Actual F.Y. 88	Estimated F.Y. 89	Requested F.Y. 90	Requested F.Y. 91
Actual/Anticipated Receipts		47*	30	54	54
Less Actual/ Anticipated Costs		(20)	(29)**	(65)**	(68)**
Current Difference		27	1	(11)	(14)
Accumulated Difference		27	28	17	3
Number Paying Fee			20		
Present Fee			See Below		
Date Fee Last Changed					

Remarks:

I. Application Fee

Laboratory Annual Gross Income	License Fee
$ <500,000	$ 600
500,000 to $ 2,000,000	1,200
2,000,000 to 10,000,000	1,800
>10,000,000	2,400

II. Inspection Fee

$1,200 per year per Laboratory

The Department will be reviewing this program after State Fiscal 1991 to determine direction and any fee increase.

*Loan from General Fund
**Includes 1/4 of General Fund Payback

Department Authorized Signature:

Finance Department Recommendation:

Executive Budget Officer Signature:

FI-00195-01

Department of Finance
FEE REVIEW – Details of Costs

Date Prepared: 04/05/89

Department/Agency: Health, Department of

Budget Activity: Public Health Laboratories

Fee Name: Drug and Alcohol Testing License

Fiscal Year	Actual F.Y. 87	Actual F.Y. 88	Estimated F.Y. 89	Requested F.Y. 90	Requested F.Y. 91
Detailed Listing of Items Included as Costs on Fee Review Form FI-00194-06				Dollars in Thousands (137,522 = 137.5)	
Agency Direct Expenditures		16	14	46	48
Salary Increases	XXXXXXXXX	XXXXXXXXX	XXXXXXXXX	2	2
Attorney General		2	1		
Statewide Indirect				1	1
Agency Indirect		2*	2*	5	5
Totals – must agree with cost on Fee Review Form		20	17	54	56

Remarks:

*Includes statewide because statewide is <1,000.

INSTRUCTIONS CHECKLIST FOR SECRETARY IN RULE REVIEW -- RULES APPROVED BY ATTORNEY GENERAL'S OFFICE

1. Check that attorney has signed and dated 4 copies of rule as adopted. ✓

2. Place documents in order following checklist. _____

3. Place correspondence and notes at end of file. _____

4. Take 4 copies of rule as adopted to Donna or anyone at the counter at Secretary of State's office, Room 180 S.O.B. She will stamp copies "filed" and the time and date. She will keep the two copies with the revisor's certification on them. You keep the other two. (Donna leaves at 3:30.) ✓

5. Type approval memo. (RITA 47) ✓

6. Make 7 copies of memo ✓
   Distribution:
   - Original to SAAG or Agency (whoever sent it to us) ✓
   - Yellow file copy ✓
   - Chrono ✓
   - Linda F. Close ✓
   - Hruby (LCRAR, 55 SOB) ✓
   - Harves (Chief ALJ) ✓
   - 7th copy to agency contact with rule copy stamped "approved," comments and any extra documents. (If no agency contact, throw away 7th copy and send other stuff to SAAG) _____

7. Put in rule log book the date the rule was approved and the date it was filed with Secretary of State ✓

8. Put date filed with Secretary of State and date rule returned to agency on checklist ✓

9. Put office copy of approved rule on top of documents, then put approval memo, then checklist. Punch holes and bracket in place. Put folder in cabinet. ✓