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,

Approved by Revisor

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

Approved
by Revisor _____

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

Approved
by Revisor _____

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.

Approved
by Revisor _____

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

Approved by Revisor _____

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

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, 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.

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;

Approved by Revisor _____

~~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 _____