

EFFECTIVE
06/19/2016

NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

177 NAC 1

TITLE 177 NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC HEALTH

CHAPTER 1 RULES AND REGULATIONS RELATING TO ANALYSES FOR THE
DETERMINATION OF THE ALCOHOL CONTENT IN BLOOD OR
BREATH

001 DEFINITIONS

001.01 Alcohol means ethyl alcohol.

001.02 Alcohol analysis means the use of a chemical test to determine the concentration of alcohol per 100 milliliters of blood, or the concentration of alcohol per 210 liters of breath.

001.03 Analyst means a holder of a Class A, B, or C permit.

001.04 Breath means exhaled lung air that is used for alcohol analysis which contains a large portion of air from the alveolar region of the lungs where the exchange of gases between the blood and air occurs.

001.05 Breath testing means the analysis of breath for alcohol content.

001.06 Body fluid refers to blood or breath.

001.07 Categories of Permits.

001.07A Class A Permit is a permit to perform a chemical test to analyze a subject's blood for alcohol content by an approved laboratory method.

001.07B Class B Permit is a permit to perform a chemical test to analyze a subject's breath for alcohol content by an approved method.

001.07C Class C Permit is a permit to perform preliminary breath tests for alcohol content by an approved method.

001.08 Chemical test means an examination which measures the alcohol content in a chemical reaction, or chemical transformation such as infrared absorption.

001.09 Department means the Department of Health and Human Services, Division of Public Health.

001.10 DHHS means the Department of Health and Human Services.

001.11 Dry Gas Standard means a premixed, certified mixture of alcohol and nitrogen.

001.12 Into service means that an instrument is being placed for the first time at a testing site, not when it is returned from being repaired.

001.13 Instrument means an item of testing equipment used for performing chemical tests.

001.14 Laboratory method means a chemical analysis using laboratory procedures and instrumentation.

001.15 Maintenance officer means the person responsible for maintenance and calibration verification at a testing site.

001.16 Method means the name of the principle of analysis. The method may be a laboratory method.

001.17 mg/ml means milligrams per milliliter.

001.18 Test record means any results printed/transmitted/produced by an evidentiary breath testing device.

001.19 Refusal or deficient sample means the failure to provide a sufficient sample of body fluid to complete a blood or breath test or the refusal to submit to a chemical test of blood or breath.

001.20 Stoppered means any cork, plug, or other object used to close a bottle, drain, tube and so on, to prevent leakage of liquid or vapor.

001.21 Technique means a set of written instructions which describe the procedure, equipment, and equipment preventive maintenance necessary to obtain an accurate alcohol content test result.

001.22 Test means a chemical analysis to determine the presence of or quantification of alcohol.

001.23 Test run means the performance of test(s) which begin at a time and are carried to completion for a sample, or samples grouped in a consecutive manner.

001.24 Testing site means the physical location where a testing device(s) is located; and where testing is conducted.

001.25 Valid permit means an authorization issued by the Department to an individual to allow the holder of the permit to perform alcohol analysis. Permits are non-expiring. Permits issued under prior regulations are valid permits.

001.26 Valid test means an analysis performed according to methods approved by the Department by an individual possessing a valid permit.

001.27 Wet bath simulator solution means a premixed, certified ethyl alcohol and water solution.

002 REPORT OF ALCOHOL TEST RESULTS FOR MEDICO-LEGAL PURPOSES

002.01 Breath Test Results. Report of Breath Test Results of a test for alcohol content of breath shall be reported as thousandths of a gram of alcohol per 210 liters of breath on the checklist.

002.01A No digital result shall be reported on the checklist unless the device has received a sufficient breath sample and completely executes its prescribed program and prints a test record to indicate that the program has been completed.

002.01B Prescribed Program. When a test record indicates an incomplete or deficient sample, this indicates that the device has not completed its prescribed program. Such deficient sample does not constitute a completed test or sufficient sample of breath and would be considered to be a refusal. Such deficient sample does not constitute a completed test, but is scientifically probative up to the amount indicated by the testing device at the time that the breath testing procedure stopped.

002.01B1 Preliminary breath testing devices are not required to produce a printed test record. When a sufficient breath sample is provided, the results of a preliminary breath test may be reported as a digital readout or as a pass or fail.

002.01C The completed checklist as found in these rules and regulations shall be the official record of breath test results.

002.01D Record Requirements in Performance of Tests. The testing records must show adherence to the approved method, and techniques.

002.02 Blood Test Results. Results of a test of blood for alcohol content shall be reported in terms of thousandths of a gram of alcohol per 100 milliliters of blood.

003 PERMITS

003.01 Permit Issuance. The permit shall be issued by the Department, and shall state the class of permit, and the approved method. The Department shall keep record of all permits issued. The Department may re-issue a permit when a written request is received from the permit holder.

003.02 Application. The applications shall be Attachment 8, Attachment 9, or Attachment 10, attached and incorporated herein by reference.

003.03 Name Change. The Department may reissue a permit when a permit holder changes his or her name and a written request is received from the permit holder.

004 REVOCATION OF PERMITS

004.01 Class A, B, or C permits are nonexpiring permits. Class A, B, or C permits may be revoked by the Department whenever the Department determines a permit holder is in noncompliance with these rules and regulations.

005 BLOOD SPECIMEN COLLECTION AND PRESERVATION

005.01 Blood specimens shall be taken by personnel authorized by law. The antiseptic solution used shall be non-alcoholic.

005.02 Blood specimens shall be collected in clean containers/tubes and stoppered. The container/tube shall contain an anticoagulant-preservative substance.

005.03 Specimen containers shall be labeled and shall show the following information on the label: name of person tested, date and time of specimen collection, and initials of person collecting the specimen.

005.04 While not in transit to be tested, or while not under examination, all blood specimens shall be refrigerated as soon as practical.

006 CLASS A PERMITS

006.01 Qualifications for Class A Permit Holder. A Class A permit holder shall have knowledge of the chemistry of alcohol and other substances of proper concern in body fluid alcohol tests and the ability to perform satisfactory tests for alcohol as demonstrated by:

006.01A Twelve semester hours of academic work in chemistry from a recognized college or university; or

006.01B Two years of experience consisting of performance of routine laboratory tests in a usual and customary laboratory organization.

006.02 Issuance of Class A Permits.

006.02A Applications for Class A permits shall be made on Attachment 8, attached and incorporated herein by reference.

006.03 Initial Performance Evaluation Studies Prior to Permit Issuance. A performance evaluation study for permit issuance shall consist of four audit samples. Satisfactory performance of analyses on the audit samples is defined as the ability to produce acceptable data on all samples.

006.03A Unacceptable data is defined, for the purpose of section 006 of these regulations, as an error in the analysis of an audit sample greater than a 10.00% deviation. Percent deviation shall be computed as the total deviation from the mean value, divided by the mean value, and multiplied by 100.

006.03B Results on audit samples shall be reported to the third decimal point.

006.03C A prospective permit holder shall be allowed two attempts to produce acceptable data.

006.04 List of Approved Methods for Class A Permits.

1. Gas Chromatography
2. Enzymatic Alcohol Dehydrogenase
3. Radiative Energy Attenuation

006.05 Operating Procedures for Class A Permit. A Class A permit holder for the determination of alcohol content in blood shall:

006.05A Be responsible for maintaining the legal continuity of all specimens received.

006.05B Conduct all tests with an inclusion of a quality control sample in the test run. The quality control sample result shall be used to:

006.05B1 Determine standard deviation data computed as shown:

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

where: N = number of measurements

X = value of single measurement

\bar{X} = mean of all X's

006.05B2 Determine if test results are to be reported. No test results shall be reported if a quality control sample result is greater than +/- three standard deviations.

006.05C On or before July 1 of each even-numbered year, Class A permit holders must submit his/her reports of standard deviation data for the previous 24 month period of time to the Department.

006.05D Ongoing Performance Evaluation Studies for Permit Holders. Ongoing performance evaluation studies shall be in effect with acceptable performance for test results to be valid. An ongoing performance evaluation study shall be enrollment in the College of American Pathologists' Whole Blood Alcohol/Volatiles survey program or a survey program at the Department's discretion. Unacceptable performance is defined as two or more values outside of the acceptable ranges in two successive survey shipments. On or before July 1 of each even-numbered year, Class A permit holders shall submit his/her copies of proficiency testing evaluations for the previous 24 month period of time to the Department.

006.05D1 Reporting of test results of alcohol content in blood of individuals shall not occur by a permit holder who has been notified of unacceptable performance in proficiency testing.

006.05D2 A permit holder shall be allowed two attempts to produce acceptable performance after being notified of unacceptable performance.

006.05D3 A permit holder shall not resume reporting of test results for alcohol content in blood of individuals until the Department notifies a permit holder that he/she is again in an acceptable performance status following an acceptable performance.

006.05E Maintain the following records:

006.05E1 The permit to perform chemical tests.

006.05E2 Records of specimen receipts, tests performed and results.

006.05E3 The method and description of steps used by the permit holder.

006.05E4 Records of quality control results and related data as prescribed in part 006.05D of this subsection.

006.05E5 A current copy of these rules and regulations.

006.05E6 Records of maintenance performed on instrument.

006.06 Inspection, Maintenance, and Repair of Laboratory Instruments for Class A Methods.

006.06A Maintenance of instruments shall be performed as prescribed in the Operators/manufacturers manual that is intended for an instrument which may be utilized to produce results in this regulation. Maintenance shall be performed by a person trained to do maintenance or a manufacturer's representative.

006.06B When inspection of an instrument reveals the need for repair, the repair shall be performed by a manufacturer's representative, or by a person trained for repair.

006.06C Malfunctions of instruments, maintenance activities, and repair occurrences shall be recorded and shall show the name of the person and the agency or business organization performing maintenance activities and repair work.

006.06D A Class A permit holder shall document that instrument maintenance has occurred with at least the frequency recommended by the manufacturer.

007 CLASS B PERMITS

007.01 Application for Class B Permit.

007.01A Application for a Class B Permit shall be made on a form prescribed by the Department as shown in Attachment 9, attached and incorporated by reference.

007.01B The Class B permit applicant shall be trained and tested in the following areas:

- a. The basic operation of the device and its proper use for evidentiary testing;
- b. The applicant shall demonstrate the ability to properly operate the appropriate device;
- c. Instruction may include physiology and pharmacology of alcohol as it pertains to driving, relevant legal matters, and court testimony.

007.01C To obtain a Class B permit, the applicant shall achieve at least 70% on a written examination from the Department.

007.02 Operating Rules for Class B Permit. To determine the alcohol content in breath, a Class B permit holder shall:

007.02A Ascertain that maintenance and calibration checks have been performed on devices prior to testing by reviewing the current 40-day maintenance and calibration checks performed on the testing device.

007.02B Use the appropriate checklist to record each test, and retain the test record produced by the instrument for each evidentiary test.

008 LIST OF APPROVED METHODS, BREATH TESTING INSTRUMENTS, CALIBRATION DEVICES, AND INTERNAL REFERENCE STANDARDS FOR CLASS B PERMIT HOLDERS

008.01 All evidentiary breath testing devices that have been evaluated and approved by the National Highway Traffic Safety Administration (NHTSA) and published on the Conforming Products Lists of Evidential Breath Measuring Devices are approved devices in the State of Nebraska for the purposes of this rule and for Drug and Alcohol Testing in the Workplace (Title 177 NAC 6). Prior to use of a NHTSA approved device for evidentiary breath tests conducted by law enforcement, the checklist technique and operating procedures for that device must be included in these regulations.

For Drug and Alcohol Testing in the Workplace (Title 177 NAC 6) testing, the operator is to conduct the test in accordance with the instructions provided by the manufacturer for the instrument. Although a checklist is not required, the test record produced by the instrument must be retained. The instrument is to be calibrated in conformance with the manufacturer's instructions.

008.01A Approved evidentiary breath testing methods and instruments conducted by law enforcement, except preliminary breath testing devices, are listed below.

- a. Intoxilyzer, all models
- b. DataMaster, all models
- c. Intoximeters, all models

008.01B Infrared absorption analysis using the Intoxilyzer and all instruments under the Intoxilyzer name. Checklist technique, as found in Attachment 16, attached and incorporated herein by reference, is approved for the Intoxilyzer.

008.01C Infrared absorption analysis using the Model DataMaster or Intoximeters and all instruments under the DataMaster or Intoximeters names. Checklist technique, as found in Attachment 16, is approved for the DataMaster or Intoximeters.

008.02 All calibration equipment that has been approved by the National Highway Traffic Safety Administration and published on the Conforming Product List of Calibrating Units for Breath Alcohol Testers is approved for calibration and verification of calibration of breath testing devices.

008.03 Approved reference standards and their use in calibration verification of evidentiary breath testing devices are described below and shall be used by a Class B permit holder with the applicable instrument.

008.03A DataMaster or Intoximeters with Internal Reference standard consisting of a known quartz filter used as a known standard specific to each instrument is an approved reference standard. Prior to placement into service at a testing site, the DataMaster or Intoximeters device with the internal quartz standard shall have the calibration checked with an alcohol wet bath simulator solution or dry gas standard.

008.03A1 Following the DataMaster or Intoximeters calibration check, an internal calibration analysis shall be performed. The results of this internal calibration check must be within +/- 5% of the target value.

008.03A1a If the internal check is not within +/- 5%, the instrument will abort the test and "Calibration Error" is displayed and printed on the test record.

008.03A2 Attachment 5, attached and incorporated herein by reference, shall be used for certifying the accuracy of the internal quartz standard used for calibration checks.

008.03B Intoxilyzer Internal Reference standard consisting of filters of predetermined values which correspond to the calibration setting of the instrument is an approved reference standard.

008.03B1 Prior to placement into service, the Intoxilyzer breath testing device with the internal reference standard(s) shall have the calibration checked with an alcohol wet bath simulator solution or dry gas standard.

008.03B2 Following the Intoxilyzer calibration check, an internal calibration analysis shall be performed. The result of this internal calibration check must indicate that all predetermined target values are within +/- 5% of the target values.

008.03B2a If any of the internal standards are not within +/- 5% of the target values, the instrument will abort the test and indicate the error by displaying and printing an error message.

008.03B3 Attachment 12, attached and incorporated herein by reference, shall be used for certifying the accuracy of the internal calibration reference standards.

008.04 Wet Bath Simulator Solutions or Dry Gas Standards. Testing device calibration and calibration verification shall be performed using either dry gas standards or wet bath simulator solutions as follows:

008.04A Certification. The wet bath simulator solution or dry gas standard must be accompanied by a certificate of analysis. The certificate of analysis must contain the following information:

- a. Name of the company which prepared the solution;
- b. Name of the person who tested the solution;
- c. Solution identification;
- d. Chemical analysis of the solution;
- e. Expected breath instrument calibration check test result;
- f. Name of the accreditation institution (ISO, NIST, etc.) for the testing

- laboratory; and
- g. A notarized signature of the responsible individual (company president or testing operator, e.g.).

008.04B Wet bath simulator solutions can be used for 100 analyses when used with devices that use vapor recirculation.

008.04C Dry gas standards may be used until their date of expiration.

008.04D Wet bath simulator solutions and dry gas standards may be stored at ambient room temperature. It shall be stored in a tightly stoppered device or other tightly stoppered container. The useful life of a wet bath simulator solution is 24 months.

009 MAINTENANCE OFFICER

009.01 Each testing site shall have a maintenance officer(s) who is responsible for maintenance and calibration verification of the testing device(s). The maintenance officer shall:

009.01A Be a Class B permit holder.

009.01B Be familiar with the testing device as a result of consultation with a manufacturer representative or other individual knowledgeable about the use of the device.

009.01C Notify the Department of the name of the maintenance officer(s) for each site and the serial number of each unit for which the maintenance officer is responsible.

009.01D Perform scheduled maintenance procedures for all approved evidentiary breath testing devices. Check the general condition of the instrument within 40 days prior to an analysis. This includes inspection of all display and operation lights and verification of printer operation. The maintenance may include simple replacement of peripherals such as keyboards, hoses or printers, basic cleaning, etc.

009.01E Within 40 days prior to an analysis, the maintenance officer is to conduct the calibration verification in accordance with the instructions provided by the manufacturer for the instrument and section 010. Results must be recorded in the maintenance log.

010 CALIBRATION VERIFICATION. Calibration verification of evidentiary breath testing devices will be conducted by a maintenance officer every 40 days. It will consist of two verifications using different target values from wet bath simulator solutions, dry gas standards, or internal references.

010.01 When calibration verification checks are performed with certified wet bath simulator solutions, all approved evidentiary breath testing instruments shall be able to produce results within +/- 5% of the target value of the wet bath simulator solution.

010.02 When calibration verification checks are performed by means of approved internal standard(s), all approved evidentiary breath testing instruments shall be able to produce results within +/- 5% of the known target values of the standard(s). This tolerance shall be verified by the normal prescribed program and operation of the testing devices.

010.03 When calibration verification checks are performed with dry gas standards, all approved evidentiary breath testing instruments shall be able to produce results within +/- 5% of the target value of the dry gas standard after applying applicable altitude or topographic elevation correction factor supplied by the manufacturer. Such correction factor may be applied by the operator, the dry gas standard supplier, or by the instrument if pre-programmed.

010.04 If the instrument calibration cannot be verified to be accurate within the above cited limits, the instrument will be taken out of service and repairs made as set forth in section 011.

011 REPAIR OF CLASS B BREATH TESTING DEVICES

011.01 When inspection of a testing device reveals the need for repair which may affect the validity of the test and requires the attention of a manufacturer's representative or an individual trained for repair, it shall be repaired by the appropriate repairman and a record of each repair will be retained at the testing site.

011.02 Repair of a testing device, as opposed to maintenance (009.01D), includes the removal of the malfunctioning part(s) and the installation of the repair part(s). The removal or installation of all parts or electronic boards shall be recorded.

011.03 Calibration verification procedures shall be performed on a testing device following its repair, before it is returned to service.

011.04 The records to be maintained for repair activities shall include the type of malfunction of a testing device, the nature of the repair, the date of the repair, and shall show the name of the person performing these activities or the name of the person's agency or business organization.

011.05 The repair records, or copies of the repair records, for a testing device shall be made available to the Department upon request.

012 CLASS C PERMITS

012.01 Qualifications For Class C Permit Holders. Permit holder qualifications to operate approved devices to perform preliminary breath tests are:

012.01A Have knowledge of calibration and use of the testing device.

012.01A1 Evidence of knowledge shall be a passing grade of at least 70% on a written examination which shall be taken by every applicant and successfully passed prior to issuance of a permit, be prepared and administered by the Department, and consist of questions regarding calibration and use of the testing device.

012.01B Have demonstrated ability and competence to the satisfaction of the Department by completing a two and one half hour class and the satisfactory performance of analyses on audit samples.

012.01B1 Unacceptable performance on audit samples is defined as an error in the analyses greater than +/- 0.010 of the target value.

012.01B2 A prospective permit holder shall be allowed two attempts to achieve acceptable results of audit samples.

012.02 Issuance of Class C Permit.

012.02A Application for a Class C Permit shall be made on Attachment 10, attached and incorporated herein by reference.

012.02B A Class C Permit is valid for all approved preliminary breath test instruments.

012.03 List of Approved Methods and Devices for Class C Permits. Fuel cell analysis is the approved method of analysis for the following preliminary breath testing devices, and the checklist technique as found in Attachment 4, attached and incorporated herein by reference, is approved for the following preliminary breath testing devices.

1. Alco-Sensor, all models
2. Intoxilyzer, all models that use fuel cell analysis
3. Lifeloc, all models that use fuel cell analysis

012.04 Maintenance and Repair of Preliminary Breath Testing Devices.

012.04A The periodic fuel cell replacement, recognized by inspection when it is not possible to adjust the calibration up to the desired value, shall be performed by a manufacturer's representative or person trained by manufacturer.

012.04B The periodic electrical battery replacement, recognized when the light display indicates a low battery, may be performed by a permit holder.

012.04C Repair of a testing device shall be performed by a manufacturer's representative or a person trained by the manufacturer.

012.04D Malfunctions of testing devices, maintenance, and repair occurrences shall be recorded and shall show the name of the agency or business organization performing these activities.

012.05 Calibration of Testing Devices. All preliminary breath test devices are to be calibrated, or calibration verified, within 30 days prior to testing, and a record kept of the activity.

013 BLOOD OR BREATH TESTS FOR FATALITY ACCIDENT REPORTS

013.01 Tests performed for purposes of accidents involving fatalities shall be performed by either a Class A permit holder or a Class B permit holder according to these rules and regulations.

013.02 The provisions of these rules and regulations apply to all samples and tests prescribed in Nebraska Revised Statutes sections 60-6,101 to 60-6,107 for determining alcohol content of blood in certain persons involved in fatality accidents.

014 BLOOD OR BREATH TESTS FOR BOATING WHILE INTOXICATED

014.01 Chemical tests performed for purposes of the determination of the alcohol content in blood or breath of any person operating any motorboat or vessel or manipulating any water skis, surfboard, or similar device while intoxicated shall be performed by either a Class A permit holder or a Class B permit holder, as authorized by Nebraska Revised Statutes Section 37-1254.

014.02 The provisions of these rules and regulations apply to all preliminary breath testing conducted pursuant to the provisions of Nebraska Revised Statutes Section 37-1254. Any violation of the provisions of Nebraska Revised Statutes Section 37-1254 shall be established by blood or breath tests conducted by either a Class A permit holder or a Class B permit holder with all provisions of this Rule, 177 NAC 1, pertaining to either a Class A or Class B permit applying thereto.

015 TRANSITION TO NEW RULES, VALID TESTS: Instruments may be maintained and tests may be administered in conformity with 177 NAC 1 for up to 40 days from the effective date of these amendments.

These Amended Regulations Replace Title 177, Chapter 1, Rules and Regulations Relating to Analyses for the Determination of the Alcohol Content in Blood or Breath, last effective date May 4, 2014.

Division of Public Health, Licensure Unit
P.O. Box 94986, Lincoln, Nebraska 68509-4986
402-471-2117

PRELIMINARY BREATH TESTS

Checklist Technique To Be Used by Class C Permit Holders

Case Identification #: _____

This analysis was on the breath specimen from: _____
(name of person tested)

CHECK TO SHOW COMPLETION

- Prior to step 1, verify that the instrument has been calibrated within 30 days prior to use.
- 1 Observe the subject for 15 minutes prior to testing. No smoking during waiting period.

Time observation began: _____

- 2 Attach the mouthpiece and prepare the instrument for testing.
- 3. Instruct the subject to blow continuously as long as possible with the breath sample taken toward the end of exhalation.
- 4. Record the results and the time the test was taken.

Results: _____ Time sample was taken: _____

Test administered by:

(Permit Holder)

(Date)

DATAMASTER OR INTOXIMETERS

Certification of Accuracy of the Internal Reference Standard used for Calibration Verification

DataMaster Serial Number: _____

Intoximeters Serial Number: _____

Date of analysis: _____

Simulator is operating at 34 degrees +/- 0.5 degrees C.

1. Calibration check with wet bath simulator solution lot #: _____, or
dry gas standard canister/cylinder #: _____
gave a reading of 0. _____ of a gram of alcohol per 210 liters of
simulated breath.

2. Run a normal test. The internal calibration check should indicate agreement within +/- 5% of the target value. Attach the test record to this form.

The above analysis was performed as set forth on this form by: _____
(Name of Permit Holder)

Testing Site address: _____

Application for Class A Permit

The undersigned applicant hereby makes application for a Class A permit to perform chemical tests to determine blood alcohol content as prescribed in 177 NAC 1 of the Nebraska DHHS and as set forth below.

1. Identify method selected from list of approved methods for a Class A permit:
 - Gas Chromatography
 - Enzymatic Alcohol Dehydrogenase
 - Radiative Energy Attenuation
2. Attach laboratory technique and instrument maintenance plan.
3. Name of Laboratory instrument and the manufacturer: _____

4. Total semester hours of chemistry _____(hours) completed at the following institutions:
(attach a copy of your transcript verifying these hours)
 - (a) _____ (College or University) _____ (City and State)
 - (b) _____ (College or University) _____ (City and State)
 - (c) _____ (College or University) _____ (City and State)

Work experience consisting of performance of routine laboratory tests amounts to _____ from the following laboratory, or laboratories. (Years)

- (a) _____ (Laboratory Name) _____ (City and State)
- (b) _____ (Laboratory Name) _____ (City and State)
- (c) _____

5. A performance evaluation study will be conducted as prescribed for Class A Permits in 177 NAC 1, section 006.03. You must submit a copy of the completed performance evaluation study which consisted of at least 4 audit samples.

(Print Name of Applicant - First/Middle/Last)

(Applicant's Signature)

Business (Laboratory) Name and Address

Application for Class B Permit

INFRARED ABSORPTION ANALYSIS

The undersigned applicant hereby makes application for a Class B permit to perform chemical tests to determine body fluid alcohol content as prescribed in 177 NAC 1 of the Nebraska **DHHS** and as set forth below.

1. Identify instrument:

- Intoxilyzer
- DataMaster
- Intoximeters

(Type or Print Name of Applicant – First/Middle/Last)

Name and Address of Agency:

Agency Name: _____

Agency Address: _____

Agency Phone #: _____

(Signed Name of Applicant)

(Date)

Application for Class C Permit

The undersigned applicant hereby makes application for a Class C permit to perform preliminary breath tests with breath testing instruments as prescribed in 177 NAC 1 using fuel cell analysis.

1. PERFORMANCE EVALUATION STUDY RESULTS as prescribed for Class C Permits in 177 NAC 1 of the **DHHS**. Record your audit sample results in the space provided below.

PERFORMANCE EVALUATION STUDY

Number of Audit Sample of Breath	Record Analysis Results	Target Value

 (Type or Print Name of Applicant – First/Middle/Last)

 Date of Analyses

Name and Address of Agency:

Agency Name: _____

Agency Address: _____

Agency Phone #: _____

 (Signed Name of Applicant)

 (Date)

INTOXILYZER
Certification of Accuracy of the Internal Reference Standards
used for Calibration Verification

Intoxilyzer Serial Number: _____

Date of analysis: _____

Simulator is operating at 34 degrees +/- 0.5 degrees C.

1. Calibration check with simulator solution lot #. _____, or
dry gas standard canister/cylinder #: _____
gave a reading of 0. _____ of a gram of alcohol per 210 liters of simulated
breath.

2. The Internal Reference Standards Check should indicate that all predetermined target values are within +/- 5%
of the target values. Attach test record of printed values to this form.

The above analysis was performed as set forth on this form by: _____
(Name of Permit Holder)

At this address: _____

Division of Public Health, Licensure Unit
P.O. Box 94986, Lincoln, Nebraska 68509-4986
402-471-2117

INFRARED ABSORPTION Checklist Technique

This checklist technique is approved and prescribed by 177 NAC 1 of the DHHS for the INFRARED ABSORPTION ANALYSIS FOR BREATH SPECIMENS.

This analysis is on the breath specimen from:

(Name of Person Tested)

CHECK TO SHOW COMPLETION

- Prior to step 1, verify that maintenance, repair, and calibration verification have been performed by reviewing the maintenance record.

- 1. Observe the subject for 15 minutes prior to testing.
Record the time observation began:_____

- 2. START TEST. Insert test record when instructed to do so, if applicable.

- 3. Attach a clean mouthpiece when instructed to "Please Blow".

- 4. Have the subject blow into the breath tube until a sufficient sample is delivered. If the breath sample is insufficient the display panel will instruct you to "PLEASE BLOW" and will continue to do so until a proper test is completed. The testing device will terminate the test if a proper breath test has not been obtained by the testing instrument.

- 5. SUBJECT DIGITAL READING:
0._____of a gram of alcohol per 210 liters of breath.

- 6. Discard the used mouthpiece and remove the test record at completion of printing.

Permit Holder

(Date)

TITLE 177 NEBRASKA DEPARTMENT OF HEALTH/LABORATORY SERVICES/REGULATIONS

CHAPTER 4 RULES AND REGULATIONS RELATING TO BIOLOGICAL PRODUCTS AND THE DISTRIBUTION OF MATERIALS CONTAINING LIVE MICRO-ORGANISMS

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Title 177 NEBRASKA DEPARTMENT OF HEALTH

Chapter 4 RULES AND REGULATIONS RELATING TO BIOLOGICAL PRODUCTS AND THE DISTRIBUTION OF MATERIALS CONTAINING LIVE MICRO-ORGANISMS

001 STORAGE. Toxins, toxoids, antitoxins, bacterins and bacterial vaccines shall be stored in a refrigerator at not less than 2° C (36° F) nor higher than 10° C (50° F). Freezing shall not be permitted.

Modified smallpox vaccine and rabies vaccine shall be refrigerated at as low a temperature as possible, preferably well below freezing temperature.

Tuberculin in tablet form (P.P.D.) and dried plasma shall be stored in a cool dry place.

002 DISPENSING. Biologicals shall be dispensed only in the unopened original package in which they were placed and sealed by the manufacturer.

003 DATING. Biologicals shall not be dispensed beyond the expiration date which has been indicated on each package by the manufacturer.

004 DISTRIBUTION OF MATERIALS CONTAINING LIVE MICRO-ORGANISMS.

004.01 Application for Permit. Application for permit for the use of aforementioned materials in the prevention or control of diseases of animals shall be made to the State Veterinarian in a manner prescribed by the Department of Agriculture and Inspection. Application for permits for the use of these materials for any other purpose shall be made to the Director of Health, State Department of Health, on forms provided for that purpose. The aforementioned Departments shall keep a record of the date of issuance and other contents of all permits issued.

004.02 Distribution Prohibited Except to Individuals Possessing a Permit. No vaccine, bacterin, immunogen or other material containing live micro-organisms capable of infecting humans and inciting therein any disease or pathological condition shall be transmitted by sale, gift or in any other manner except to an individual possessing a valid permit as provided by these regulations.

004.03 Form of Permits. Permits shall be on forms provided by the respective State Departments. Permits for use of materials referred to herein in veterinary medicine shall be issued by the State Veterinarian; those for all other purposes by the Director of Health, State Department of Health. Permits involving the manufacture or sale of any such product used in veterinary medicine shall bear the endorsement of the State Veterinarian.

Title 177
Chapter 4

004.04 Micro-Organisms Pathogenic to Humans. The following named or described micro-organisms are hereby declared to be pathogenic to humans:

004.04A Bacillus anthracis.

004.04B All varieties of malarial plasmodii including P. vivax, P. malariae and P. falciparum.

004.04C Mycobacterium tuberculosis, human, bovine and avian strains.

004.04D Erysipelathrix rhusiopathiea (swine erysipelas vaccine).

004.04E Salmonellae (all species).

004.04F Newcastle Disease virus.

004.04G Any other species of micro-organism capable of inciting disease in humans, and not listed herein. Exceptions: Virus prepared for the prophylactic treatment of rabies in humans, and smallpox vaccine when manufactured according to the standards of the United States Public Health Service.

004.05 Records of Sale to be Kept. Records of all transfers by sale or otherwise of material containing such pathogens as named herein or supplementally named shall be kept by the individual distributing the pathogen. Such record shall show the date of transfer, the item or items containing pathogenic micro-organisms and the identity of the organisms, the name and address of the person receiving same, and the number of his valid permit, and shall at all times be available for inspection by an authorized representative of the Nebraska State Department of Health or an authorized representative of the state Department of Agriculture and Inspection.

004.06 Renewal of Permits. Permits shall expire on the 31st day of December of the year issued unless revoked prior to that date. Application for renewal must be in writing. In case the information furnished in the application for the original permit is still applicable, the applicant shall so state in his application for renewal. Should changes in the condition under which the original permit was issued have occurred, a new written application shall be submitted and passed on before reissuance of the permit.

004.07 Revocation of Permit. Any permit may be revoked by the Department issuing same when deemed necessary to protect the public health. The individual concerned shall be given an opportunity for a hearing, said hearing to be subject to such rules as may be adopted by the Director of the Department issuing the permit.

SOURCE: Section 71-1802

TITLE 177 HEALTH/LABORATORY SERVICES

CHAPTER 5 FEES FOR DEPARTMENT LABORATORY TESTS AND SERVICES

5-001 SCOPE AND AUTHORITY: These regulations establish formulas for fees for laboratory tests and services and responsibility for payment. The authority is found in Neb. Rev. Stat. §§ 71-2619 to 71-2621, 71-5301, and 71-5306.

5-002 DEFINITIONS

Chain of Custody means the documentation and other activities done to ensure the identity of a sample and to ensure that no substantial change has taken place in the sample to make it misleading. It includes all those activities that protect the integrity of the sample.

Department means the Department of Health and Human Services Regulation and Licensure.

Elective test means a drinking water sample test which is performed for a reason other than to meet the public water system testing requirements found in Title 179.

Equipment means any tool, instrument, appliance, or utensil necessary to perform the task of analyzing laboratory samples which has a life expectancy greater than two years.

Person means any individual, firm, partnership, limited liability company, association, company, corporation, political subdivision, or other entity.

Public water system has the definition found in the Nebraska Safe Drinking Water Act, Neb. Rev. Stat. §71-5301.

Sample means a representative portion of any substance submitted to the laboratory for testing.

Shipping means conveying from one location to another.

Test means the application of prescribed procedures designed to identify or measure the microbiological, chemical, radiological, or physical characteristics of materials and substances.

5-003 COMPONENTS OF FEES IN THE FORMULAS

Where: Cost of Labor = 3 times the cost of the average salary and benefits of Department Laboratory employee(s) who conduct the analysis for the period of time required to complete the test. The multiplier is used to account for employee time spent

on laboratory related tasks such as professional training and certification, quality assurance, documentation and reporting, and equipment calibration and cleaning.

$$\text{Equipment Cost} = \frac{\text{Cost of Equipment}}{\text{Life Expectancy of Equipment}} + \text{Maintenance} + \text{Repairs}$$

Materials cost includes disposable equipment, reagents and other items having a life expectancy of less than 2 years.

Overhead costs are the business expenses not chargeable to a particular part of the work or product, such as rent, utilities, travel, administration and computers.

Sample collection kit cost means all costs associated with the container and chemicals for preservation of samples required to take samples relating to testing of drinking water, environmental samples and blood alcohol.

Shipping cost includes all costs associated with the sample collection kits, mailing containers, sample collection forms and instructions, labor, cost of postage or transportation, and mailroom equipment and anything else necessary to carry out the function of shipping.

Chain of Custody costs include all costs associated with the special documentation and maintenance of samples.

5-004 FORMULA FOR DETERMINING SAMPLE COLLECTING FEES

$$\text{Fee} = \text{Shipping Cost} + \text{Overhead}$$

5-005 FORMULA FOR DETERMINING BLOOD ALCOHOL SAMPLES TESTING

$$\text{Fee} = \frac{\text{Labor Cost} + \text{Materials Cost} + \text{Equipment Cost} + \text{Overhead} + \text{Chain of Custody}}{\text{Estimated Number of Tests}}$$

5-006 FORMULA FOR ESTABLISHING FEES FOR ROUTINE DRINKING WATER SAMPLES

$$\text{Fee} = \frac{\text{Labor Cost} + \text{Materials Cost} + \text{Equipment Cost} + \text{Overhead} + \text{Chain of Custody}}{\text{Estimated Number of Tests}}$$

5-007 FORMULA FOR ESTABLISHING FEES FOR ENVIRONMENTAL SAMPLES TESTING

$$\text{Fee} = \frac{\text{Labor Cost} + \text{Materials Cost} + \text{Equipment Cost} + \text{Overhead} + \text{Chain of Custody}}{\text{Estimated Number of Tests}}$$

5-008 OTHER FEES

5-008.01 Elective Test Fees: These fees are determined using the formula(s) established for other like samples.

5-008.02 Additional Fees: Special requests, such as requests for samples to be tested at another laboratory to obtain a second opinion, will be charged at actual costs incurred by the Laboratory.

5-008.03 Fees for Contracted Tests: If the Department Laboratory contracts with another laboratory to perform certain tests, the fee will be the contracted cost plus any related expenses the Department Laboratory incurs.

5-008.04 Expedited Service Fee: If a request is made to assign higher priority to testing specific samples, and the laboratory workload is rescheduled to accommodate this request, any extra cost will be added to the listed fee. Extra cost may include overtime work and/or the cost of referring work to another laboratory.

5-009 RESPONSIBILITY FOR PAYMENT: Each sample submitted for analysis shall identify the person responsible for paying the appropriate fee.

5-010 OWNER RESPONSIBILITY: The owner of the public water system is responsible for collecting and transmitting samples in containers provided by the laboratory and at times prescribed by the laboratory. Delay or damage occurring prior to receipt of the samples by the laboratory will require submission of an additional sample.

TITLE 177 - NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
CHAPTER 6 - DRUG AND ALCOHOL TESTING IN THE WORKPLACE

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TITLE 177 - NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

CHAPTER 6 - DRUG AND ALCOHOL TESTING IN THE WORKPLACE

001 PRELIMINARY SCREENING WITH BREATH TESTING DEVICES.

001.01 A person is not required to hold a permit to perform preliminary breath tests for alcohol content in the workplace.

002 BREATH SAMPLE CONFIRMATION TESTING OF A POSITIVE FINDING OF ALCOHOL IN A PRELIMINARY SCREENING PROCEDURE.

002.01 All evidentiary breath testing devices that have been evaluated and approved by the National Highway Traffic Safety Administration (NHTSA) and published on the Conforming Products Lists of Evidential Breath Measuring Devices are approved devices in the State of Nebraska for Drug and Alcohol Testing in the Workplace. The instrument is to be calibrated in conformance with the manufacturer's instructions. The operator is to conduct the test in accordance with the instructions provided by the manufacturer for the instrument. Although a checklist is not required, the test record card or tape produced by the instrument must be retained.

002.02 A positive result must be confirmed with a second breath sample or a blood sample. If the second sample is breath, the result must be within 20% of the original sample.

002.02A If the two breath tests do not agree within 20%, a blood test, as set forth in section 003, shall be performed. A blood test may be performed in lieu of the second breath test; if so, it is considered the final result, regardless of whether it agrees with the original breath test.

002.03 Breath sample confirming tests shall be performed by a breath-testing-device operator. Breath Testing Device operators shall obtain a valid Class B permit for testing in the workplace as follows:

002.03A Application for a Class B Permit shall be made on a form prescribed by the Department as shown in Attachment 1, attached and incorporated by reference.

002.03B The Class B permit applicant shall attend a training session consisting of a minimum of six hours of instruction. The course shall include the method and technique of the testing device. It will include the basic operation of the device and its proper use for evidentiary testing. The applicant shall demonstrate the ability to properly operate the appropriate device.

002.03C To obtain a Class B permit, the applicant shall achieve at least 70% on an examination from the Department of Health and Human Services.

003 BLOOD SAMPLE CONFIRMATION TESTING OF POSITIVE FINDINGS OF ALCOHOL IN A PRELIMINARY SCREENING PROCEDURE.

003.01 Confirmatory alcohol testing on blood samples shall be performed in compliance with 177 NAC 1.

004 DRUG TESTING BY CONFIRMATION TESTING FOLLOWING A POSITIVE FINDING OF DRUGS IN A PRELIMINARY SCREENING PROCEDURE.

004.01 Confirmatory drug testing shall be performed in compliance with 177 NAC 7.

Approved by the Attorney General:
Approved by the Governor:
Filed with the Secretary of State:

December 3, 2009
December 18, 2009
December 18, 2009

EFFECTIVE DATE:

December 23, 2009

Effective Date
12/23/2009

NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

177 NAC 6



ATTACHMENT 1

Division of Public Health (DHHS), Licensure Unit
P.O. Box 94986, Lincoln, Nebraska 68509-4986
402-471-2117

Application for Class B Permit – Workplace Testing

The undersigned applicant hereby makes application for a Class B permit to perform chemical tests to determine body fluid alcohol content as prescribed in 177 NAC 6 of the Nebraska **DHHS** and as set forth below.

1. I have attended a training session consisting of a minimum of six hours of instruction. The course included the method and technique of the testing device, the basic operation of the device and its proper use for evidentiary testing.

Yes No, if no, please explain: _____

2. Identify the device(s) you plan to operate:

_____	_____
_____	_____
_____	_____

Name and Address of Agency: _____

Agency Name: _____

Agency Address: PO/Street _____

City, State Zip _____

Agency Phone #: _____

Type/Print Name of Applicant – First/Middle/Last

Signed Name of Applicant

Date: _____

2007

STATE OF NEBRASKA

Regulations Relating to:

**ANALYSES FOR THE DETERMINATION OF THE DRUG CONTENT
IN URINE WHILE DRIVING
UNDER THE INFLUENCE OF DRUGS**

TITLE 177 NAC 7

**NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES**

Division of Public Health



Credentialing Division
Nebraska State Office Building
301 Centennial Mall South -Third Floor
P.O. Box 94986
Lincoln, NE 68509-4986
402-471-2117

Effective Date: September 19, 2007

TITLE 177 NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
CHAPTER 7 RULES AND REGULATIONS RELATING TO ANALYSES FOR THE
DETERMINATION OF THE DRUG CONTENT IN URINE WHILE DRIVING UNDER THE
INFLUENCE OF DRUGS

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TITLE 177 NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES

CHAPTER 7 RULES AND REGULATIONS RELATING TO ANALYSES FOR THE
DETERMINATION OF THE DRUG CONTENT IN URINE WHILE DRIVING
UNDER THE INFLUENCE OF DRUGS

7-001 DEFINITIONS

7-001.01 Categories of Permits Issued by the Department of Health and Human Services are:

001.01A CLASS D PERMIT, which means a permit to perform a chemical test to analyze an individual's urine for drug content by an approved chemical laboratory method(s).

7-001.02 Methods and techniques approved by the Department of Health and Human Services are defined as:

7-001.02A Method means the name of the principle of analysis. The method may be a LABORATORY METHOD, which in these rules and regulations means a method of chemical analysis for drug content.

7-001.02B Technique means a set of written instructions which describe the procedure, equipment, and equipment preventive maintenance necessary to obtain an accurate drug content test result.

7-001.03 Test run means the performance of test(s) which begin at a time and are carried to completion for a sample, or samples grouped in a consecutive manner.

7-001.04 Drug analysis means the use of a chemical test to find the presence of a drug in the urine.

7-001.05 Chemical test means an examination which measure's the presence of a drug by a chemical reaction, or chemical detection using a laboratory instrument.

7-001.06 Test means a chemical test.

7-001.07 Initial screen means an immunoassay which has the ability to recognize the presence or absence of drugs in the urine.

7-001.08 Confirmatory test means an analysis of the urine for drug content by using a Gas Chromatograph/Mass Spectrometer.

7-001.09 Metabolite means the specific substance produced when the human body metabolizes a drug as it passes through the body and is excreted in the urine. Chemical tests of drug metabolites may be used as specified in these regulations to determine the presence of drugs.

7-001.10 Cutoff level means the amount of drug detected which determines the absence or presence of drug. The amount of drug shall be stated in nanograms per milliliter (ng/ml).

7-001.11 Body fluid refers to urine for purposes of this regulation.

7-001.12 ng/ml means nanograms per milliliter.

7-001.13 Drug means any of the following. Marijuana, cocaine, morphine, codeine, phencyclidine, amphetamine, or methamphetamine.

7-001.14 Analyst means a holder of a Class D permit.

7-001.15 Valid permit means a permit which has been executed with proper legal authority and is in force.

7-001.16 Valid test means an analysis performed according to methods approved by the Department of Health and Human Services and by an individual possessing a valid permit.

7-001.17 Assay means a test technique for a particular drug or drug metabolite.

7-001.18 Panel means a grouping of test techniques for particular drugs or drug metabolites.

7-001.19 Instrument means an item of testing equipment used for performing chemical tests.

7-002 REPORT OF RESULTS FOR MEDICO-LEGAL PURPOSES AND VALID TESTS

7-002.01 The presence of a drug shall mean any laboratory confirmatory test result, signal, or finding that shall be equal to or greater than the cutoff level. The cutoff levels are as follows: marijuana metabolite 50 ng/ml, cocaine metabolite 500 ng/ml, morphine 500 ng/ml, codeine 500 ng/ml, phencyclidine 25 ng/ml, amphetamines 500 ng/ml, and methamphetamine 500 ng/ml. The specific metabolite of marijuana shall be delta-9-tetra-hydrocannabinol-9-carboxylic acid and the cocaine metabolite shall be benzoylecgonine.

7-002.02 The presence of a drug shall be determined by analysis using a Gas Chromatograph/Mass Spectrometer. The absence of a drug may be determined by an initial screening method.

7-003 LIMITATION OF PERMITS

7-003.01 For each permit holder, the permit shall state the class of permit, the approved method(s) in use, the name of the instrument. A permit holder shall be limited to the class, the method(s), and the instruments specified on the permit.

7-003.02 Permits will be issued only for approved methods, techniques, and instruments, as found in these rules and regulations.

7-003.03 Duplicate permits will not be issued. Notarized copies of an originally issued permit will be provided upon written request. Changes of information carried on a permit or replacement of a permit requires reapplication.

7-004 REVOCATION OF PERMITS

7-004.01 Class D permits are nonexpiring permits. Class D permits may be revoked by the Director of Public Health of the Division of Public Health whenever a permit holder is in noncompliance with these rules and regulations.

7-005 SPECIMEN COLLECTION AND PRESERVATION

7-005.01 The urine specimen.

7-005.01A The collection of urine shall include saving a portion of an initial urination in a clean, dry, sample container and capped.

7-005.01B Sample collection shall be in the presence of collection personnel designated by the law enforcement agency to assure that adulteration of the sample does not occur.

7-005.01C Specimen containers shall be labeled and shall show the following information on the label: name of person tested, date and time of specimen collection, and initials of person supervising the collection of the specimen.

7-005.01D Specimen containers, with collected urine, shall be sealed and refrigerated as soon as practical as described in 177 NAC 7-005.01E.

7-005.01E While not in transit to a site for screening or to a site for confirmatory testing, and while not under actual testing, all urine specimens shall be in secured refrigerated storage at four (4) degrees centigrade or less.

7-005.02 The evidence seal. At the testing site the evidence seal shall be broken and the sample analyzed. The seal shall not be broken except by the Class D permit holder at the time just prior to testing.

7-005.03 Retention of specimen following testing. Any remaining specimen after testing shall be retained in a secured frozen storage for a period of not less than one year, unless requested and receipted for by a defendant's legal counsel. If the defendant is acting as his/her own legal counsel, the sample shall be transferred directly to another testing site if so requested. The sample shall be analyzed within ten days of receipt by the defendant's legal counsel at another testing site as requested in the transfer instructions.

7-006 CLASS D PERMITS FOR INITIAL SCREENS BY CHEMICAL METHODS.

7-006.01 Qualifications for Class D Permit Holder. Class D permit holder qualifications for analysis by chemical tests of an individual's urine for drug content are:

7-006.01A Be not less than the legal age of majority as established by state statutes.

7-006.01B Have knowledge of the theory of the instrument used for initial screens, the operation of the instrument, the calibration of the instrument, the maintenance of the instrument, and the steps in the technique of initial screen drug detection.

7-006.01C Have proof of knowledge and ability consisting of a letter or certificate of training provided to the Department of Health and Human Services from the instrument manufacturer certifying attendance and completion of at least sixteen hours of training covering the topics in 177 NAC 7-006.01B.

7-006.01D Have demonstrated competence to the satisfaction of the Department of Health and Human Services. Satisfactory competence shall be, for the purpose of these rules and regulations, the satisfactory performance of analysis on proficiency samples in a performance evaluation study as described in 177 NAC 7-006.03.

7-006.02 Issuance of Class D Permits for Initial Screens.

7-006.02A Applications for Class D permits shall be made on forms provided by the Department of Health and Human Services. The application shall be of the form as shown in Attachment 1, attached and incorporated herein by reference.

7-006.02B An applicant for a Class D permit shall, at the time of making application:

7-006.02B1 State the identity of the method(s) that has been selected for use from the list of approved methods in 177 NAC 7-006.04.

7-006.02B2 Submit the technique showing the written instructions which describes the procedure, equipment, and equipment preventive maintenance schedule.

7-006.03 Performance Evaluation Studies. A performance evaluation for permit issuance shall consist of providing copies of the results of sample testing or the graded performance from a recognized proficiency testing service.

For the purpose of these regulations an ASCLD-LAB approved proficiency test provider must be used. Unacceptable performance is defined as a false positive result for any drug in a one shipment survey.

7-006.03A Ongoing performance evaluation studies shall be in effect, with acceptable performance, for test results to be valid. Ongoing performance evaluation shall be enrollment in an ASCLD-LAB approved drug proficiency testing program. Unacceptable performance is defined as a false positive result for a drug in two successive survey shipments. Copies of proficiency testing evaluations shall be provided to the Department of Health and Human Services.

7-006.03B Initial screen testing shall not be subject to participation in a recognized proficiency testing service as specified in 177 NAC 7-006.03 and 177 NAC 7-006.03A. Initial screen permit holders shall participate in a performance evaluation by the Department of Health and Human Services. Unacceptable performance as defined in 177 NAC 7-006.03 applies to initial screen permit applicants, and as defined in 177 NAC 7-006.03A for ongoing performance evaluation surveys. An ongoing performance evaluation shall be one survey shipment annually for initial screen permit holders.

7-006.03C Reporting of test results for the presence or absence of drugs in the urine of individuals shall not occur by a permit holder who has been notified of unacceptable performance in proficiency testing.

7-006.03D A permit holder shall be allowed two attempts to produce acceptable performance after being notified of unacceptable performance.

7-006.03E A permit holder shall not resume reporting of test results for the presence or absence of drugs in the urine of individuals until the Department of Health and Human Services notifies a permit holder that he/she is again in an acceptable performance status following unacceptable performance.

7-006.04 List of Approved Methods and Techniques for Initial Screen Testing.

7-006.04A ENZYME MULTIPLIED IMMUNOASSAY TECHNIQUE (EMIT)

7-006.04A1 The enzyme multiplied immunoassay technique is an approved initial screen method. Testing must be performed according to the instrument manufacturer's instructions.

7-006.04B FLUORESCENCE POLARIZATION IMMUNOASSAY (FPIA).

7-006.04B1 The fluorescence polarization immunoassay method is an approved initial screen method. Testing must be performed according to the instrument manufacturer's instructions.

7-006.05 Operating Rules for Class D Permit. A Class 5 permit holder for the determination of drug content in urine shall:

7-006.05A Accept for testing only the specimen type of urine, as listed on the permit.

7-006.05B Be responsible for maintaining the legal continuity of all specimens received.

7-006.05C Perform all tests using the approved method as named on the Class D permit and in a manner that consists of the technique for the method as found in these rules and regulations.

7-006.05D Conduct all tests for each drug with the inclusion of quality control samples in the test run. The test run may include more than one person's sample for a particular drug; the quality control samples shall be of the same drug that is tested in a test run. The quality control sample result shall be used to:

7-006.05D1 Determine standard deviation data computed as shown:

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

where:

N = number of measurements

X = value of single measurement

\bar{X} = mean of all X's

7-006.05D2 Determine if test results are to be reported. No test results shall be reported if a quality control sample result is outside of acceptable limits. Acceptable limits for reporting test results shall be no greater than \pm three standard deviations, except for initial screen techniques that utilize an instrument that does not produce numerical data.

7-006.05D3 The EMIT technique in 177 NAC 7-006.04A utilizes an instrument that does not produce numerical data, therefore, no test result shall be reported if a positive control sample does not give a positive result or if a negative control sample does not give a negative result.

7-006.05F Maintain the following records:

7-006.05F1 The permit to perform chemical tests.

7-006.05F2 Records of specimen receipts, tests performed and results.

7-006.05F3 The method and description of technique steps in use by the permit holder along with documentation of validation of technique.

7-006.05F4 The records of quality control results and related data as prescribed in 177 NAC 7-006.05D of this subsection.

7-006.05F5 A current copy of these rules and regulations.

7-006.05F6 The records of maintenance and repair performed on an instrument, as prescribed in 177 NAC 7-006.06.

7-006.06 Maintenance and Repair of Instruments.

7-006.06A Maintenance of instruments shall be performed as prescribed in the operators manual that is intended for an instrument which may be utilized to produce results with a technique in this regulation. Maintenance shall be performed by a person trained by the manufacturer as specified in 177 NAC 7-006.01B and 177 NAC 7-006.01C. Maintenance may also be performed by a manufacturer's representative.

7-006.06B Repair of an instrument shall be performed by a manufacturer's representative or by a person trained by the manufacturer.

7-006.06C Malfunctions of instruments, maintenance activities, and repair occurrences shall be recorded and shall show the name of the person and the agency or business organization performing maintenance activities and repair work.

7-007 CLASS D PERMITS FOR CONFIRMATORY TESTING

7-007.01 Qualifications for Class D Permit Holder. Class D permit holder qualifications for the chemical analyses of an individual's urine, for drug content by confirmatory testing using an approved method(s) and a Gas Chromatograph/Mass Spectrometer (GC/MS) are:

7-007.01A Be not less than the legal age of majority as established by state statutes.

7-007.01B Have knowledge of the chemistry of drugs and drug metabolites. Have the ability to perform confirmatory tests for the presence of drugs in urine. Evidence of knowledge and ability consists of the following proof:

7-007.01B1 Twelve semester hours of academic work in chemistry from a recognized college or university.

7-007.01C Have knowledge of the theory of Gas Chromatograph/Mass Spectrometer (GC/MS) methods, the operation of the GC/MS, including its calibration and maintenance. Evidence of knowledge and ability consists of the following proof:

7-007.01C1 Documentation of education or training covering GC/MS applications.

7-007.01D Have demonstrated competence to the satisfaction of the Department of Health and Human Services. Satisfactory competence shall be, for the purpose of these rules and regulations, the satisfactory performance of analysis on proficiency samples in a performance evaluation study as described in 177 NAC 7-006.03.

7-007.02 Issuance of Class D Permits for GC/MS Confirming tests.

7-007.02A Application for Class D permits shall be made on forms provided by the Department of Health and Human Services. The application shall be of the form as shown in Attachment 2, attached and incorporated herein by reference.

7-007.02B An applicant for a Class D permit shall, at the time of making application:

7-007.02B1 state the identity of the manufacturer of the GC/MS intended to be used. The applicant will notify the Division of Public Health if there is a change in GC/MS information.

7-007.03 Performance Evaluation Studies.

7-007.03A Ongoing performance evaluation studies shall be in effect, with acceptable performance, for confirmatory tests to be valid. Ongoing performance shall be enrollment in a recognized proficiency testing service as specified in 177 NAC 7-006.03. All provisions in 177 NAC 7-006.03, except 177 NAC 7-006.03B, apply to confirmatory testing using a GC/MS method and technique. Copies of proficiency testing evaluations for proficiency test samples analyzed on the GC/MS shall be provided to the Department of Health and Human Services.

7-007.04 List of Approved Methods.

7-007.04A GC/MS analysis which shall include scientifically accepted techniques that have been validated by the laboratory utilizing them.

7-007.05 Sample Handling for GC/MS Confirmatory Testing.

7-007.05A When samples must be transported to a testing site for confirmatory testing, it is the responsibility of the originating agency to forward all positive initial screening samples to a Class D permit holder authorized to perform confirmatory testing.

7-007.05B While not in transit to a site for confirmatory testing and while not under actual testing, the sample shall be placed in secured refrigerated storage at four degrees centigrade, or less.

7-007.05C When transporting samples to another site for confirmatory testing, the sample shall be repackaged and sealed with an evidence seal. The repackaging shall include all containers, papers, and materials submitted to the initial testing site.

7-007.06 Approved Technique for use with an approved GC/MS method.

7-007.06A Scientifically acceptable solid phase or liquid/liquid extraction technique which has been validated by the laboratory performing the extraction.

7-007.07 Operating Rules for Class D Perm for GC/MS Confirmatory Tests.

7-007.07A A Class D permit holder for the confirmatory tests to determine the presence of a drug in urine shall follow all of the provisions in 177 NAC 7-006.05.

7-007.08 Maintenance and Repair of GC/MS Instruments

7-007.08A Maintenance of GC/MS instruments shall be performed as prescribed in the operators manual that is intended for the GC/MS which may be utilized to produce results with a confirmatory testing technique in this regulation. Maintenance shall be performed by a person trained by the manufacturer as specified in 177 NAC 7-007.01C and 177 NAC 7-007.01C1. Maintenance may also be performed by a manufacturer's representative.

7-007.08B Repair of an instrument shall be performed by a manufacturer's representative or by a person trained by the manufacturer.

7-007.08C Malfunctions of the GC/MS, maintenance activities, and repair occurrences shall be recorded and shall show the name of the person and the agency or business organization performing maintenance activities and repair work.

Approved by Attorney General:	August 27, 2007
Approved by Governor:	September 14, 2007
Filed with Secretary of State:	September 14, 2007
Effective Date:	September 19, 2007

Nebraska Department of Health and Human Services



Division of Public Health
Credentialing Division
P.O. Box 94986, Lincoln, Nebraska 68509-4986
402-471-2117

ATTACHMENT 1

Application for Class D Permit to Perform Chemical Tests to Determine Drug Content by Initial Screening

The undersigned applicant hereby makes application for a Class D permit to perform chemical tests to determine drug content as prescribed in 177 NAC 7 of the Nebraska Department of Health and Human Services and as set forth below.

1. Identify method from the list of approved methods for a Class D permit:
 ENZYME MULTIPLIED IMMUNOASSAY TECHNIQUE (EMIT)
 FLUORESCENCE POLARIZATION IMMUNOASSAY (FPIA)
2. Is the Laboratory Technique attached to this application? yes no
3. Indicate the type of specimen to be tested: urine
4. Proof of knowledge and ability consists of a letter or certificate of attendance and completion of at least 16 hours of training covering instrument operation.

Check below for each of the topics, if the training covered the topic:

- A. Theory of Instrument Operation? yes
- B. Operating Procedure of the Instrument? yes
- C. Calibration of the Instrument? yes
- D. Maintenance of the Instrument? yes
- E. The Steps in the Technique of Drug Detection? yes

Is a letter of certificate of training from the instrument manufacturer stating your attendance and completion of training covering each of the topics above attached to this certificate? yes

5. A Performance Evaluation Study is required as prescribed for Class D Permits in 177 NAC 7 of the Department of Health and Human Services. A copy of your performance evaluation will be required as prescribed in 177 NAC 7-006.03.

(type or print name of applicant)

(age)

(continued on next page)

Attachment 1, Continued

PERFORMANCE EVALUATION STUDY

Number of Audit Sample	Your Analysis Results	FOR DEPARTMENT OF HEALTH USE	
		Value of Audit Sample	Total Deviation From Mean Value

Signature of person performing evaluation study above

_____ Date of Analyses

Name and Address of Agency: _____

Agency Name: _____

Agency Address: _____

Agency Phone #: _____

Nebraska Department of Health and Human Services



Division of Public Health
Credentialing Division
P.O. Box 94986, Lincoln, Nebraska 68509-4986
402-471-2117

ATTACHMENT 2

Application for Class D Permit to Perform Chemical Tests to Determine Drug Content by Confirmatory Tests

The undersigned applicant hereby makes application for a Class D permit to perform chemical tests to determine drug content as prescribed in 177 NAC 7 of the Nebraska Department of Health and Human Services and as set forth below.

1. Identify method from the list of approved methods for a Class D permit:

Gas Chromatograph/Mass Spectrometer (GC/MS); State the identity of the manufacturer of the GC/MS intended to be used:

2. Is the Laboratory Technique attached to this application? yes no

3. Indicate the type of specimen to be tested: urine

4. Proof of knowledge and ability consists of a letter or certificate of attendance and completion of at least 16 hours of training covering instrument operation.

Check below for each of the topics, if the training covered the topic:

- | | | |
|----|---|------------------------------|
| A. | Theory of Instrument Operation? | <input type="checkbox"/> yes |
| B. | Operating Procedure of the Instrument? | <input type="checkbox"/> yes |
| C. | Calibration of the Instrument? | <input type="checkbox"/> yes |
| D. | Maintenance of the Instrument? | <input type="checkbox"/> yes |
| E. | The Steps in the Technique of Drug Detection? | <input type="checkbox"/> yes |

Is a letter of certificate of training from the instrument manufacturer stating your attendance and completion of training covering each of the topics above attached to this certificate? yes

5. A Performance Evaluation Study is required as prescribed for Class D Permits in 177 NAC 7 of the Department of Health and Human Services. A copy of your performance evaluation will be required as prescribed in 177 NAC 7-006.03.

(type or print name of applicant)

(age)

(continued on next page)

PERFORMANCE EVALUATION STUDY

Number of Audit Sample	Your Analysis Results	FOR DEPARTMENT OF HEALTH USE	
		Value of Audit Sample	Total Deviation From Mean Value

Signature of person performing evaluation study above

_____ Date of Analyses

Name and Address of Agency:

Agency Name: _____

Agency Address: _____

Agency Phone #: _____

2007