Colorado Department
of Public Health
and Environment

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Laboratory Services Division

5 CCR 1005-2

RULES PERTAINING TO TESTING FOR ALCOHOL AND OTHER DRUGS (PROMULGATED BY THE STATE BOARD OF HEALTH)

Last amended 11/15/06, effective 1/30/07

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STATE BOARD OF HEALTH
RULES PERTAINING TO TESTING FOR ALCOHOL AND OTHER DRUGS

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Part 1: General

1.1 Purpose and Scope

This rule establishes minimum standards for certification and approval of entities and processes utilized for alcohol and drug testing. This rule is applicable to: samples taken while driving under the influence, driving while impaired, driving with excessive alcohol content; vehicular assaults and vehicular homicides involving an operator while under the influence of alcohol or one or more drugs or both; the testing of samples of blood or other bodily substances from the bodies of pilots in command, motorboat or sailboat operators in command, or drivers and pedestrians fifteen years of age or older who die within four hours after involvement in a crash involving a motor vehicle, a motorboat, a sailboat or an aircraft; and consumption of alcohol by underage persons and records related thereto.

1.2 Based on evidence gathered through testing and evaluation by the Colorado Department of Public Health and Environment and presented to the Board, the Department and the State Board of Health have determined that the results obtained from the Intoxilyzer 5000EN with software 1358.XX installed are scientifically accurate, precise and reliable, and the collection and preservation of a delayed breath alcohol specimen is not required when this device is properly operated as described in these rules and regulations.

1.3 Evidential Breath Alcohol Testing (EBAT) facilities will operate under Part 5 of these rules and regulations until their Intoxilyzer 5000EN software is upgraded. After an EBAT facility's Intoxilyzer 5000EN software is upgraded, the EBAT facility will operate under Part 6 of these rules and regulations. All EBAT facilities performing direct evidential breath alcohol tests must comply with Part 6 of these rules and regulations by June 30, 2007.

1.4 Testing of delayed breath specimens operates under Part 5 of these rules and regulations. Testing of blood alcohol, blood drugs and urine drugs operates under Parts 5 and 6 of these rules and regulations.

1.5 Definitions

"Alcohol Percent (%)" – grams of ethanol per 100 milliliters of blood or grams of ethanol per 210 liters of breath.

"Appropriate clinical or public safety facility" – provides for the health and safety of a person whose blood is collected (subject) and meets the following criteria: 1) provide for the washing or cleansing of hands of the blood collection personnel, 2) provide a comfortable chair for the subject with arm supports to assure the elbow remains straight and both arms are accessible to the blood collection personnel, 3) have precautions to assure the subject does not fall out of the chair, 4) provide for cot or other reclining surfaces for subjects who prefer to lie down or who have adverse response to the blood collection procedures, 5) provide for the adverse response to blood collection by providing procedures and equipment for subjects who become faint, nauseous, vomit, bleed excessively, or convulse including the provision of drinking water, and 6) provide for the cleaning and disinfect ion of the blood collection area.

"Certification" – the official approval by the Department of an evidential breath alcohol test (EBAT) DEVICE, operator, operator instructor or laboratory to function under these rules and regulations.

"Certified Instructor" – an employee of any approved law enforcement agency or the Colorado Department of Public Health and Environment who meets the requirements of Section 2.2 *Et. Seq*. of these regulations.

"Certified Laboratory" – a laboratory certified by the Department to perform analytical testing of bodily fluids for alcohol or other drugs.

"Certified Operator" – an employee of any approved law enforcement agency or the Colorado Department of Public Health and Environment who meets the requirements of Section 2.1 *Et. Seq.* of these regulations.

"Delayed Breath Alcohol Specimens" – the saved ethanol or other analytical components of the EBAT specimen(s).

"Department" – refers to The Colorado Department of Public Health and Environment, Laboratory Services Division.

"Evidential" or "Evidentiary" – refers to a sample which, when tested, gives rise to test results that are sufficiently reliable to be admissible as evidence in a court of law.

"Evidential Breath Alcohol Test (EBAT)" – is an evidentiary breath alcohol test performed using a certified evidential breath alcohol test device approved by the Department as described by Section 42-4-1301, C.R.S. (2006).

"Evidential Breath Alcohol Test (EBAT) device" – any instrument certified to perform "Evidential" Breath Alcohol Tests as identified in Section 42-4-1301, C.R.S. (2006). The Intoxilyzer 5000EN is the only evidential breath alcohol testing device certified for use in performing evidential breath alcohol tests.

"Facility" – any location that meets the requirements of these regulations and which is approved by the Department to perform evidential breath alcohol testing.

"Proficiency Testing" – The evaluation of unknown specimens supplied by a provider which determines target values for those unknown specimens.

"Representative of a certified laboratory" – any employee of a certified laboratory or a courier employed by or contracted by the certified laboratory to transport specimens for the certified laboratory.

Part 2: Certified Operators and Instructors of Evidential Breath Alcohol Test (EBAT) Devices

2.1 Certification of Operators of EBAT Devices to Determine Alcohol Concentration of Breath Specimens.

2.1.1 To initially be certified as an EBAT operator an individual must:

2.1.1.1 be currently employed by a law enforcement agency or the Department;

2.1.1.2 attend a minimum of eight (8) hours of instruction following the Department's Operator Training Manual;

2.1.1.3 score 80% or greater on a written exam; and

2.1.1.4 complete a comprehensive practical exam as specified in the Department Operator Training Manual.

2.1.1.5 upon successful completion of the course requirements, a certificate shall be issued by the Department stating the operator's name, the course instructor(s) and the initial date of certification.

2.1.2 To maintain certification an operator must:

2.1.2.1 proficiently perform without errors, one EBAT following the procedure specified in Appendix 2A of this regulation in the presence of a certified instructor within a 180 day period.

2.1.2.2 the test performed must be a complete EBAT test.

2.1.2.3 the printout obtained from the certification test shall be signed and dated by the certifying operator and the instructor.

2.1.2.4 the printout must be retained by the law enforcement agency as proof that the certification test was performed in accordance with this regulation.

2.1.3 An operator who fails to certify within the 180 day period must:

2.1.3.1 be decertified by the instructor, and

2.1.3.2 must repeat the 8-hour operator course.

2.1.4 Operators who return after being called to active military service may renew their expired certification by completing the following procedure:

2.1.4.1 document proof of active duty (period of absence must not exceed 2 years.);

2.1.4.2 document proof of last operator certification prior to going on active duty;

2.1.4.3 pass the current operator test with a score of 80% or better;

2.1.4.4 proficiently perform without errors, one Evidential Breath Alcohol Test (EBAT) following the procedure specified in Appendix 2A in the presence of a certified instructor;

2.1.4.5 the documented proof of active duty, documented proof of last operator certification prior to going on active duty, operator test material and *print-out* of the certification EBAT must be sent to the Department's Evidential Breath Alcohol Testing Program.

2.1.4.6 upon successful completion of the requirements in Section 2.1.4 *Et. Seq.*, a certificate shall be issued by the Department indicating the operator name, the agency certified instructor, the date of certification and "Reinstatement After Military Service."

2.1.5 A facility must retain records showing each certified operator's date of original certification and all subsequent dates of certification.

2.2 Certification of Operator Instructors of EBAT Devices to Determine Alcohol Concentration of Breath Specimens

2.2.1 To initially be certified as an EBAT instructor an individual must:

2.2.1.1 be currently employed by a law enforcement agency or the Department;

2.2.1.2 be a currently certified EBAT operator;

2.2.1.3 attend a minimum of sixteen (16) hours of instruction provided by the Department using the Instructor Training Manual;

2.2.1.4 score 80% or greater on a written exam; and

2.2.1.5 complete a comprehensive practical exam as specified in the Department Instructor Training Manual.

2.2.2 Upon successful completion of the course requirements, a certificate shall be issued by the Department stating the instructor's name, the Department's course trainer(s) and the initial date of certification.

2.2.3 A certified instructor is also a certified operator and is authorized to train and certify operators of EBAT devices.

2.2.4 To maintain certification an instructor must:

2.2.4.1 participate in teaching one EBAT operator certification class, or

2.2.4.2 pass a written instructor certification examination within a 365-day period.

2.2.5 An instructor who fails to certify in the 365-day period must be decertified by the Department and must repeat the 16-hour instructor course provided by the Department.

2.2.6 EBAT Instructors who return after being called to active military service may renew their expired certification by completing the following procedure:

2.2.6.1 document proof of active duty (period of absence must not exceed 2 years.);

2.2.6.2 document proof of last instructor certification prior to going on active duty;

2.2.6.3 pass the current instructor test with a score of 80% or better; and

2.2.6.4 proficiently perform without errors, one EBAT test following the procedures specified in Appendix 2A in the presence of a certified instructor.

2.2.6.5 the documented proof of active duty, documented proof of last instructor certification prior to going on active duty, instructor test material and *print-out* of the certification EBAT must be sent to the Department's Evidential Breath Alcohol Testing Program.

2.2.7 Upon successful completion of the above requirements, a certificate shall be issued by the Department stating the instructor's name, the agency certifying the instructor, the Department's Program Manager or designee, the date of certification and "Reinstatement After Military Service."

2.2.8 A facility must retain records showing each certified instructor's date of original certification and dates of all classes taught and written exams taken.

Part 3 Blood Testing

3.1 Evidential Specimen Collection

3.1.1 Living Persons

3.1.1.1 Evidential Blood specimen(s) must be:

3.1.1.1.1 collected in the presence of the arresting officer or other responsible person who can authenticate the specimens.

3.1.1.1.2 collected by venipuncture by a physician, nurse, paramedic, emergency medical technician, medical technologist, or a person whose training and normal duties include withdrawing blood specimens under the supervision of a physician or nurse.

3.1.1.1.3 collected only in an appropriate clinical or public safety facility (e.g., hospital, medical clinic, ambulance, police station, fire station or other approved facility). In no event will the collection of blood specimens interfere with the provision of essential medical care or the ready availability of emergency medical services to the public.

3.1.1.1.4 collected using sterile equipment. The skin at the area of puncture must be thoroughly cleansed and disinfected with an aqueous solution of nonvolatile antiseptic. Alcohol or phenolic solutions must not be used as a skin antiseptic.

3.1.2 Deceased Persons

3.1.2.1 Collection of specimens from deceased persons is conducted as per Section 42-4-1304, C.R.S. (2006), by a person whose training and normal duties include the collection of blood specimens from deceased persons.

3.1.3 Living and Deceased Persons

3.1.3.1 After collection, evidential blood specimens must be:

3.1.3.1.1 dispensed or collected directly into two sterile tubes resulting in a sodium fluoride concentration greater than 0.90 percent weight.

3.1.3.1.2 inverted several times to properly mix the blood with the sodium fluoride.

3.1.3.1.3 affixed with an identification label and evidence seal.

3.1.3.1.4 shipped to a certified laboratory. If shipment is delayed for more than 72 hours, the specimens must be placed in secured temporary refrigerated storage at less than 8 degrees Centigrade until shipped but not to exceed 7 days.

3.1.3.2 At the Certified Laboratory:

3.1.3.2.1 one tube of blood must be analyzed for the State's test(s). The State's test(s) must be completed within 15 days of collection.

3.1.3.2.2 the second tube of blood must be refrigerated by the certified laboratory at less than 8 degrees Centigrade for a period of not less than 12 months from the date of collection.

3.1.3.2.3 The second specimen may be released if it is requested and receipted for by a representative of another Certified Laboratory.

3.1.3.2.4 The second specimen must be analyzed within 15 days of its receipt by the Certified Laboratory representative.

Part 4: Urine Testing

4.1 Evidential Specimen Collection

4.1.1 Living Persons

4.1.1.1 Urine specimen(s) must be collected in the presence of collection personnel who can authenticate the specimen(s).

4.2 Deceased Persons

4.2.1 Collection of specimens from deceased persons is conducted as per Section 42-4-1304, C.R.S. (2006) by a person whose training and normal duties include the collection of urine samples from deceased persons.

4.3 Living and Deceased Persons

4.3.1 Urine specimen(s) must be:

4.3.1.1 collected in a clean container.

4.3.1.2 affixed with an identification label and evidence seal.

4.3.1.3 shipped to a laboratory certified by the Department. If shipment is delayed for more than 72 hours, the specimens must be placed in secured temporary refrigerated storage at less than 8 degrees Centigrade until shipped but not to exceed 7 days.

4.3.2 At the Certified Laboratory:

4.3.2.1 The State's test must be completed within 15 days of collection.

4.3.2.2 Any remaining specimen(s) must be retained by the laboratory in frozen storage for a period of not less than 12 months unless requested and receipted for by a representative of another Certified Laboratory.

4.3.2.3 The second specimen must be analyzed by a certified laboratory designated by the defendant or defendant's legal counsel within 15 days of its receipt by the representative of that Certified Laboratory.

Part 5 Evidential Breath Testing - Collection and Testing Procedures Under Intoxilyzer 5000EN Software Prior to Software Upgrade

5.1 Scope

5.1.1 Part 5 establishes minimum standards for certification and approval of entities and processes utilized for alcohol and drug testing prior to the installation of Intoxilyzer 5000EN software revision 1358.XX.

5.2 Evidential Specimen Collection

5.2.1 Breath – Evidential

5.2.1.1 Evidential breath specimens must be analyzed on EBAT devices approved by the Department. Approval or disapproval of EBAT devices will be based on scientific standards of performance established by the Department. The Intoxilyzer 5000EN is the only EBAT device that may be used for evidential breath alcohol testing.

5.2.1.2 The Department must certify each EBAT device initially and annually thereafter.

5.2.1.3 The Department must issue a certificate for each certified EBAT device after initial certification and after each annual certification. The certificate must reflect the EBAT device approved facility name, the EBAT device serial number and the inclusive dates for the certification period. The certificate for EBAT devices placed in approved mobile facilities must also include the vehicle identification number.

5.2.1.4 An evidential breath alcohol test specimen must only be collected and tested by certified EBAT operators or instructors using a certified EBAT device and following the steps outlined in these regulations.

5.2.1.5 Breath specimens consisting of end-expiratory alveolar air are analyzed to determine their ethyl alcohol concentration.

5.2.2 Breath – Delayed

5.2.2.1 A delayed breath alcohol specimen must be collected with each evidential breath alcohol test pursuant to Appendix 1A.

5.2.2.2 Delayed breath alcohol specimens are considered the personal property of the defendant and retained by the facility for 12 months from the date of collection unless requested and receipted for by a representative of another Certified Laboratory.

5.3 Methods of Analysis

5.3.1 Alcohol in Evidential Breath Specimens

5.3.1.1 The checklist for Evidential Breath Alcohol Tests must be followed as found in Appendix 1A.

5.3.1.2 A system blank(s) analysis must be used with each EBAT.

5.3.1.3 For each EBAT, a Department certified reference standard(s) of known ethanol concentration must be used.

5.3.1.4 A completed EBAT is one in which the checklist contained within Appendix 1A is followed and a printout obtained.

5.4 Laboratory Analysis of Delayed Breath Specimens

5.4.1 Laboratories must be certified by the Department to provide analysis. Certification is based on successful on-site inspection, successful participation in proficiency testing and ongoing compliance.

5.4.2 Laboratories will be certified to perform tests for delayed breath alcohol.

5.4.3 Laboratories must meet standards of performance as established by these regulations. Standards of performance will include personnel qualifications, standard operating procedure manual, analytical process, proficiency testing, quality control, security, chain of custody, specimen retention, space, records, and results reporting.

5.4.4 Laboratory inspections must be performed prior to initial certification and annually thereafter by Department staff as established by these regulations. A laboratory meeting the certification requirements of these regulations will be issued a certificate initially. Recertification shall be required each July 1.

Part 6: Evidential Breath Testing - Collection and Testing Procedures After Installation of Intoxilyzer 5000EN software revision 1358.XX

6.1 Purpose and Scope

6.1.1 Part 6 establishes minimum standards for certification and approval of entities and processes utilized for alcohol and drug testing after installation of Intoxilyzer 5000EN software revision 1358.XX.

6.2 Evidential Specimen Collection

6.2.1 Breath

6.2.1.1 Evidential breath specimens must be analyzed on EBAT devices approved by the Department. Approval or disapproval of EBAT devices will be based on scientific standards of performance established by the Department. The Intoxilyzer 5000EN is the only EBAT device that may be used for Evidential Breath Alcohol Testing.

6.2.1.2 The Department must certify each EBAT device initially and annually thereafter.

6.2.1.3 The Department must issue a certificate for each certified EBAT device after initial certification and after each annual certification. The certificate must reflect the EBAT device approved facility name, the EBAT device serial number and the inclusive dates for the certification period. The certificate for EBAT devices placed in approved mobile EBAT facilities must also include the vehicle identification number.

6.2.1.4 An evidential breath alcohol test specimen must only be collected and tested by certified EBAT operators or instructors using a certified EBAT device and following the steps outlined in these regulations.

6.2.1.5 Breath specimens consisting of end-expiratory alveolar air are analyzed to determine their ethyl alcohol concentration.

6.2.1.6 Unless otherwise provided by law, the subject must be given a choice of which type of evidential chemical test they wish to take to determine the alcohol concentration in their body (evidential breath alcohol test or evidential blood alcohol test) or they may refuse to take either evidential chemical test. Nothing in this regulation is intended to exempt or exonerate an individual from the penalties proscribed in Sections 42 42-4-1301.1 and 42-4-1301.2, C.R.S, or any other relevant law, for the failure to submit to such test.

6.2.1.7 Before the subject is given the choice of the type of evidential chemical test they will take, the certified operator or instructor will include the following information:

"You are required to take, complete or cooperate in completing an evidential chemical test to determine the alcoholic content of your blood or breath (C.R.S. 42-4- 1301.1(2) (A) (I). The chemical test you choose is the test you will be taking. You cannot choose a different test later. (C.R.S. 42-4- 1301.1(2) (A) (II). If you choose a blood test, two (2) tubes of blood will be drawn. One tube belongs to you and you may have it tested at a Health Department Certified Independent Laboratory of your choice. If you choose a breath test, two (2) breath samples will be analyzed by a certified evidential breath alcohol testing device following an approved standard operating procedure. You will not receive a sample to have independently tested by a certified laboratory.

If you refuse to take, complete or cooperate in completing an evidential chemical test to determine the alcoholic content of your blood or breath your driving privilege may be revoked. (C.R.S. 42-2-126(2)(A)(II))"

6.3 Methods of Analysis

6.3.1 Alcohol in Evidential Breath Specimens

6.3.1.1 The EBAT operator or instructor must follow the procedures specified in these regulations for evidential breath alcohol tests.

6.3.1.2 The EBAT operator or instructor must document compliance with these testing procedures by completion of the Department's checklist form, which is available in Appendix 2A of these regulations or on the Department's website.

6.3.1.2.1 Information included in Steps 1 through 7 of Appendix 2A must not be changed in any way.

6.3.1.2.2 Steps 1 through 7 must be performed in the order listed.

6.3.1.3 The certified operator or instructor conducting the EBAT test must initial inside the parentheses to the left of each step (1 through 7). Initialing each step indicates that step is properly completed.

6.3.1.4 Step 1. "Turn power switch on or observe the power switch has been activated. If the EBAT device is in the standby mode, press the start test switch."

6.3.1.4.1 EBAT devices at approved EBAT facilities must always be powered on. This is indicated by the small red light below the power switch being illuminated.

6.3.1.4.2 When the certified operator or instructor first enters the EBAT room he/she shall determine if the EBAT device is in the standby mode. The EBAT device is in the standby mode if the display is blank, the small red light under the power switch is lit and the simulator display reads "idle."

6.3.1.4.3 If the EBAT device is in the standby mode, press the start test switch.

6.3.1.4.4 If the EBAT device is in the ready mode, instrument display scrolling or flashing and simulator display lit, proceed to Step 2.

6.3.1.5 Step 2. “The subject must remove foreign objects from the nose and mouth including dentures. The subject must be closely and continuously observed for 20 minutes prior to testing to assure no belching, regurgitation or intake of any foreign material by nose or mouth has occurred. If such occurs, another 20 minutes of close and continuous observation must elapse under the same conditions.”

6.3.1.5.1 Check the subject for foreign objects in the nose or mouth including dentures. There are two types of dentures, permanent and removable. Permanent dentures are typically anchored to the mouth and cannot be removed. Permanent dentures need not be removed. They will not interfere with the results obtained during the EBAT. Removable dentures are typically held in place by an adhesive and must be removed.

6.3.1.5.2 During the observation period the operator or instructor must be close enough to the subject to detect any belching, regurgitation or intake of foreign material.

6.3.1.5.3 The observation period must be conducted at the EBAT facility by a certified operator, instructor or law enforcement officer.

6.3.1.5.4 The observation period must not be conducted in the patrol car while driving to the EBAT facility.

6.3.1.5.5 Start and stop times for the observation period must be recorded from the EBAT device or the facility dispatch clock.

6.3.1.6 Step 3. “Verify that the external breath tube and simulator vapor tube are both warm.”

6.3.1.6.1 Touch the external breath tube to ensure that it is warm.

6.3.1.6.2 Touch the simulator vapor tube to ensure that it is warm.

6.3.1.6.3 If either tube is cold to the touch, stop the test and call an intoxilyzer instructor for assistance.

6.3.1.7 Step 4. “Observe the simulator temperature is between 33.8 degrees centigrade and 34.2 degrees centigrade.”

6.3.1.7.1 Allow the simulator to equilibrate for a minimum of ten (10) minutes after reaching the correct temperature when it has been in standby mode or is first turned on.

6.3.1.8 Step 5. “Press the start test switch.”

6.3.1.8.1 Press the green start test switch to initiate the automated test sequence.

6.3.1.9 Step 6. “Follow the instructions and sequence of events as they appear on the EBAT device display.”

6.3.1.9.1 A system blank(s) analysis must be used during the test sequence of each evidential breath alcohol test.

6.3.1.9.2 For each EBAT, Department certified reference standard(s) of known ethanol concentration must be analyzed. The results of such analysis must agree with the reference standard(s) target value (s) of 0.100 grams of alcohol/210 liters of breath within ±10% (0.090 – 0.110 grams of alcohol/ 210 liters of breath).

6.3.1.9.3 The results of analyzing more than one reference standard of the same value for each EBAT must agree with each other within ±10%.

6.3.1.9.4 If the ±10% calibration correlation is not obtained, the instrument will abort the test and print a “No Calibration Correlation” error message.

6.3.1.9.5 For each EBAT, the results of the two subject breath alcohol tests must agree with each other within 0.020 grams of alcohol/210 liters of breath.

6.3.1.9.5.1 If the 0.020 grams of alcohol/210 liters of breath correlation is not obtained, the instrument will abort the test and print a “No .02 agreement” error message.

6.3.1.9.5.1.1 The EBAT operator must perform the EBAT test procedure over again after another 20-minute observation period. A new checklist, Appendix 2A, must be filled out for this test.

6.3.1.9.6 During the two minute period between subject breath tests the subject must be closely and continuously observed and the operator or instructor must be close enough to the subject to detect any belching, regurgitation or foreign material in the mouth or nose.

6.3.1.9.7 During the two minute period between subject breath tests the subject must be removed from the area in close proximity to the EBAT device.

6.3.1.9.8 A clean mouth piece will be used each time the subject blows into the intoxilyzer.

6.3.1.10 Step 7. “Retain all printouts generated by the EBAT device with the DUI packet. (ie., error message printouts)

6.3.1.10.1 The officer conducting the EBAT must sign the checklist(s) and completed EBAT printout(s).

6.3.1.10.2 All printouts generated by the EBAT device must be retained with the DUI packet, including error message printouts.

6.3.1.10.3 All records pertaining to the EBAT specimens must be retained by the facility for 2 years.

6.3.1.10.4 A new checklist, Appendix 2A, must be filled out for each EBAT performed.

6.3.1.10.4.1 A completed evidential breath alcohol Test (EBAT) is one in which the checklist, Appendix 2A, is followed and a printout with no error messages is obtained.

Part 7: Certification of Laboratories

7.1 Laboratory Analysis of Blood, and Urine Specimens

7.1.1 Laboratories must be certified by the Department to provide analysis. Certification is based on successful on-site inspection, successful participation in proficiency testing and ongoing compliance.

7.1.2 Laboratories will be certified to perform tests for one or more of the following categories: blood alcohol, blood drugs, and urine drugs.

7.1.3 Laboratories must meet standards of performance as established by these regulations. Standards of performance will include personnel qualifications, standard operating procedure manual, analytical process, proficiency testing, quality control, security, chain of custody, specimen retention, space, records, and results reporting.

7.1.4 Laboratory inspections must be performed prior to initial certification and annually thereafter by Department staff as established by these regulations. A laboratory meeting their certification requirements of these regulations will be issued a certificate initially. Recertification shall be required each July 1.

7.2 Initial Application

7.2.1 Laboratory directors must submit to the Department a written request for certification of their laboratory.

7.2.2 The Department will acknowledge request and provide a copy of the rules and regulations.

7.2.3 To be certified, laboratories shall meet all requirements in Part 7 of these regulations and pass an on-site inspection.

7.3 Application for Continued Certification

7.3.1 Annually the laboratory director must provide a completed application (Appendix 2B) to the Department to be considered for continued certification.

7.3.2 Laboratories must be recertified every July 1.

7.3.3 In order to be recertified on July 1, laboratories must submit their applications for continued certification no later than June 1, which is 30 days prior to the date for recertification.

7.3.4 To maintain certification, laboratories shall meet all requirements in Part 7 of these regulations and pass an on-site inspection.

7.4 General Requirements

7.4.1 In addition to the laboratory's application, the laboratory must provide the following information to the Department: written evidence concerning the education, scientific training, and experience of the laboratory director and personnel performing the testing.

7.4.2 Prior to independently analyzing samples, testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls). The laboratory must have a system to evaluate employee competency at regular intervals, not to exceed 12 months.

7.4.3 The laboratory must notify the Department in writing within thirty days of any changes pertaining to Laboratory location, personnel, and analytical methods.

7.4.4 The laboratory director is directly responsible for the accuracy of the tests performed, the accuracy of the reports issued, and adherence to these regulations.

7.4.5 The laboratory must have adequate space, equipment, materials, and controls available to perform the tests reported.

7.4.5.1 Samples which serve as test controls must be of such quality as could be determined "Certifiable" by National Institute of Standards and Technology ("NIST") standards, although such samples need not actually be NIST-Certified. Relevant documentation must be available for inspection.

7.4.5.2 If non-traceable standards are used, the laboratory must establish a system to identify each standard, document its preparation, and data to prove agreement within 5% of the expected value when compared to a NIST traceable standard.

7.4.6 The laboratory must document evidence of the utilization of a written method of analysis (Standard Operating Procedure (SOP)) to perform the tests reported. Critical elements that must be addressed in the SOP are in Appendix 2C, Section B5 (a-t).

7.4.7 The laboratory must demonstrate compliance with these regulations through a successful on-site inspection conducted by Department staff prior to certification. Certified laboratories will be inspected on an annual announced basis. Certified laboratories will be inspected on an unannounced basis to evaluate complaints.

7.4.8 The laboratory must maintain all records related to analysis for a minimum of two years. Records to be maintained include instrument maintenance, quality control and quality assurance of all analyses performed, specimen processing, results and reports of analysis, dates of analysis and the identity of the person performing the analysis. Retained records must be open to inspection by Department personnel.

7.5 Proficiency Testing of Blood and Urine Samples

7.5.1 Proficiency Testing (PT) is the evaluation of unknown specimens supplied by a provider that determines target values for those unknown specimens. PT is required for each approved category.

7.5.2 Prior to initial certification the laboratory must have successfully participated in one proficiency test event within the past 12 months.

7.5.3 To maintain continued laboratory certification, a laboratory must participate in the PT program and maintain satisfactory performance.

7.5.4 PT samples shall be tested by the same procedure used for all samples, including, but not limited to, the same number of replicate analyses, the same standards, same testing personnel and equipment, and all other pertinent factors.

7.5.5 Blood Alcohol

7.5.5.1 The Department will make arrangements to provide blood alcohol PT samples to the laboratories through a PT provider.

7.5.5.2 A laboratory must participate in PT testing through 3 events per year, consisting of 5 specimens each. The laboratory will submit results to the PT provider. The PT provider will evaluate the results and forward them to the laboratory as well as the Department.

7.5.5.3 Other volatile forensically significant interferents, such as acetone or toluene, may be included in one or more samples. The inclusions of interferents determine the laboratory's capability of differentiating the volatile interferent from ethyl alcohol. Identification of these interfering volatiles will be used as a criterion for acceptable performance.

7.5.5.4 Grading Criteria for Blood Alcohol Proficiency Testing

7.5.5.4.1 Proficiency test results must be returned to the PT provider within the time specified by the PT provider. Results received after the due date will not be graded and will be considered an unsatisfactory performance resulting in a score of 0 for the testing event. The laboratory must contact the PT provider if extenuating circumstances prevent timely response to a PT event.

7.5.5.4.2 The laboratory must investigate any score less than 100% and undertake corrective action as needed. The investigation outcome and corrective action shall be submitted to and approved by the Department.

7.5.5.4.3 The PT provider will score each event as "satisfactory or "unsatisfactory". If a laboratory has two consecutive "unsatisfactory" evaluations, or achieves an "unsatisfactory" score in 2 of any 3 consecutive PT events, the PT performance is deemed "unsuccessful". The "unsuccessful" determination may result in a "directed plan of correction" specified by the Department, or suspension/ limitation of certification for the failed analyte.

7.5.6 Urine-drugs and Blood-drugs

7.5.6.1 For blood and urine drug analyte screening and confirmation certification a laboratory must successfully participate in the appropriate College of American Pathologists (CAP) proficiency test programs.

7.5.6.1.1 For blood-drug certification the required program is the Forensic Toxicology (Criminalistics) FTC.

7.5.6.1.2 For urine-drug certification the required program is Urine Drug Testing (Confirmatory) UDC.

7.5.6.2 A satisfactory event score is the identification of 80% of the target analytes present with no false positives.

7.5.6.3 The laboratory must request CAP to mail a consultant copy of their survey results to:

Colorado Department of Public Health and Environment
Laboratory Services Division
Certification Program
8100 Lowry Boulevard
Denver, CO 80230-6828

7.5.6.4 A laboratory will be suspended from a category if two consecutive unsuccessful PT events occur. A laboratory may be reinstated to active status after successful participation in the next test event. Failure to successfully participate in the next test event will result in the denial, suspension or revocation of the certificate and require two successful PT events before the laboratory may reapply for certification. The laboratory may request the PT provider to send, at the expense of the laboratory, one extra set of PT samples when in suspension status.

7.6 On-Site Laboratory Inspection

7.6.1 On-site laboratory inspections must be performed prior to initial certification and annually thereafter by the Department.

7.6.2 The on-site inspection will include a review of the laboratory's practices to assure compliance with these regulations. The requirements are in checklist format in Appendix 2C.

7.6.3 Laboratories will be contacted to arrange routine inspection dates approximately three weeks prior to a proposed date. A letter confirming the inspection date will be sent to the laboratory.

7.6.4 The on-site inspection's checklist will be used systematically to evaluate and assess a laboratory's compliance. Each item listed on the checklist will be answered by the department inspector as, Yes ("Y"), No ("N") or Not Applicable ("NA"). Each item answered as "N" will be described in a report to include the noncompliant practice, the source of information and the scope and extent of the noncompliant practice.

7.6.5 Following the on-site inspection, a written report will be prepared and reviewed by a peer inspector or supervisor prior to mailing. The report should be mailed to the laboratory within 15 days of inspection.

7.6.6 The laboratory must provide a written response to the report when noncompliant practices are identified. The laboratory must provide a written plan of correction within 15 days of receipt of the written inspection report for each noncompliant item cited as a result of items marked "N" on the inspection checklist. A response will not be required from the laboratory if all items on an inspection checklist are marked either "Y" or "NA".

7.6.7 The written plan of correction will be reviewed by the inspector and if appropriate will be approved. Any items requiring clarification will be resolved by phone or written correspondence.

7.6.8 Documents must be provided to the Department by the laboratory within 90 days of the inspection for verification and proof of implementation of the corrections described in the

written plan of correction. A subsequent on-site inspection will be conducted if the verification documents are not received, if compliance with corrective actions are difficult to verify by documentation, or if practices subject to correction have significant potential for direct impact on the quality of laboratory results.

7.6.9 Identification of noncompliant practices directly resulting in inaccurate laboratory reports, failure to provide a plan of correction or failure to correct adequately any noncompliant practice may result in inspector's recommendation to deny initial certification or limit, deny, suspend or revoke the laboratory certificate. Such action shall be governed by section 24-4-105, C.R.S.

7.6.10 A certificate will be issued by the Department to the laboratory to show certification has been approved. The certificate will reflect the laboratory name, location, the analytical categories approved and the effective dates of the certification period. The certification period will not exceed twelve months.

7.6.11 The Department will annually publish a list of certified laboratories.

7.7 Standards for approved permanent, temporary and mobile Evidential Breath Alcohol Testing (EBAT) facilities

7.7.1 Evidential Breath Alcohol Test(s) must be conducted only in facilities that have been approved by the Department.

7.7.2 Department standards for all approved EBAT facilities are specified in these regulations.

7.7.3 All approved EBAT facilities must meet standards of performance as established by this section of these regulations.

7.7.4 Inspections of permanent, temporary and mobile facilities must be performed prior to initial approval and once in a calendar year thereafter by Department staff.

7.7.5 Initial inspections of permanent and temporary EBAT facilities must be conducted by Department staff using sections 7.7.12.1 *Et. Seq.* to 7.7.12.7 *Et. Seq.* of these regulations.

7.7.6 Annual, complaint and follow up inspections of permanent and temporary EBAT facilities must be conducted by Department staff using sections 7.7.12.2 *Et. Seq.* to 7.7.12.8 *Et. Seq.* of these regulations.

7.7.7 Initial inspections of mobile EBAT facilities must be conducted by Department staff using sections7.7.12.1 *Et. Seq.*; 7.7.12.3 *Et. Seq.* to 7.7.12.7 *Et. Seq.*; and 7.7.12.9 *Et. Seq.* of these regulations.

7.7.8 Annual complaint and follow up inspections of mobile EBAT facilities must be conducted by Department staff using sections 7.7.12.3 *Et. Seq.* to 7.7.12.9 *Et. Seq.* of these regulations.

7.7.9 Mobile EBAT facilities, the EBAT device and its associated equipment must be brought to the Department each time a facility inspection is required.

7.7.10 An EBAT device that is used in a mobile EBAT facility must not be used at a permanent or temporary facility unless approved by the Department.

7.7.11 An EBAT device that is used in a permanent or temporary facility must not be used at a mobile facility unless approved by the Department

7.7.12 Department inspection procedure for permanent, temporary and mobile Evidential Breath Alcohol Test Facilities

7.7.12.1 Initial approval – permanent, temporary and mobile EBAT facilities

7.7.12.1.1 Facilities must submit a written request to the Department for approval of an EBAT facility.

7.7.12.1.2 After receipt of the written request for approval, the Department shall supply a copy of these regulations to the requesting facility.

7.7.12.1.3 The facility EBAT device instructor or DUI enforcement officer is responsible for monitoring the construction of the EBAT facility and verifying compliance with the requirements of this section.

7.7.12.1.4 After the facility is constructed and ready for use, written verification of compliance with the requirement of this section must be sent to the Department by the facility. The written verification must include a letter from a certified electrician that the power line to the EBAT device is an isolated line.

7.7.12.1.5 Department staff must perform an initial facility inspection to verify compliance with the requirements of this section. Subsequent facility inspections must be performed once in a calendar year by department staff.

7.7.12.1.5.1 The EBAT device must not be moved from its approved location within the approved facility without authorization from the department.

7.7.12.2 Power requirements – permanent and temporary facilities

7.7.12.2.1 AC line voltage of 120VAC ±10%, 60 HZ with a grounded 3 prong outlet(s) and a 20 ampere or less circuit breaker.

7.7.12.2.2 The power line to the EBAT device must be an isolated line. Written verification of compliance with this requirement from a certified electrician must be provided to the Department.

7.7.12.2.3 A surge protection device approved by the Department must be placed between the EBAT device and the isolated power outlet.

7.7.12.2.4 Only the EBAT device and its associated equipment shall be connected to the surge protection device or the isolated power outlet.

7.7.12.3 Environment – permanent, temporary and mobile EBAT facilities

7.7.12.3.1 The temperature of the EBAT device facility must be maintained between 70 and 80 degrees Fahrenheit.

7.7.12.3.2 The facility must have adequate lighting so the EBAT operator can see to safely conduct the evidential breath alcohol test and complete the required forms.

7.7.12.3.3 The area around and under the EBAT device must be free of dust and dirt.

7.7.12.3.4 The Evidential Breath Alcohol Testing facility must be kept orderly.

7.7.12.3.5 The EBAT device and breath alcohol simulator must be located on the organizer stand.

7.7.12.3.6 The organizer stand must be placed on a sturdy and adequate work surface.

7.7.12.3.7 The EBAT device shall be in a smoke free environment.

7.7.12.3.8 The facility must have adequate ventilation to prevent vapor build up around the EBAT device be ventilated.

7.7.12.3.9 The facility must not be used to store any cleaning compounds or volatile organics to include gasoline and petroleum products.

7.7.12.3.10 The facility must be secure and not readily accessible to unauthorized individuals.

7.7.12.4 Documents – Permanent, temporary and mobile EBAT facilities

7.7.12.4.1 The following documents must be maintained at the EBAT facility with the EBAT device.

7.7.12.4.1.1 Current original certificate for the Evidential Breath Alcohol Testing device.

7.7.12.4.1.2 Checklist, Appendix 2A

7.7.12.4.1.3 No Smoking sign (not necessary if facility is in a no smoking building)

7.7.12.4.1.4 Error message sheet

7.7.12.4.1.5 Current list of certified operators and instructors from all agencies that regularly use this EBAT device to include original date of certification, date of last certification and date next certification is due.

7.7.12.4.1.6 Current Standard Solution Log Sheet.

7.7.12.5 Supplies – permanent, temporary and mobile EBAT facilities

7.7.12.5.1 The following supplies must be maintained at the EBAT facility with the EBAT device.

7.7.12.5.1.1 Mouth pieces;

7.7.12.5.1.2 Standard simulator solution;

7.7.12.5.1.3 Printer paper; and

7.7.12.5.1.4 DMV and DUI forms.

7.7.12.6 Evidential Breath Alcohol device functions – permanent, temporary and mobile EBAT facilities

7.7.12.6.1 EBAT device time and date must be correct.

7.7.12.6.2 External breath tube must be heating.

7.7.12.6.3 Simulator vapor tube must be heating

7.7.12.6.4 EBAT device test sequence must be correct.

7.7.12.6.5 EBAT device certification date on the printout must be the same as the EBAT device certification date on the posted EBAT device certificate.– Permanent locations only.

7.7.12.6.6 EBAT device must be connected to an active analog telephone line at all times – Permanent locations only.

7.7.12.7 Simulator functions – Permanent, temporary and mobile EBAT facilities

7.7.12.7.1 Active simulator

7.7.12.7.1.1 Record serial number

7.7.12.7.1.2 Display must read between 33.8°C and 34.2°C.

7.7.12.7.1.3 Simulator solution temperature must be between 33.8°C and 34.2°C measured by a calibrated, NIST traceable, digital thermometer.

7.7.12.7.1.4 Simulator must be functioning properly.

7.7.12.7.2 Backup simulator(s)

7.7.12.7.2.1 Record serial number(s).

7.7.12.7.2.2 Display(s) must read between 33.8°C and 34.2°C.

7.7.12.7.2.3 Simulator solution temperature must be between 33.8°C and 34.2°C measured by a calibrated, NIST traceable, digital thermometer.

7.7.12.7.2.4 Simulator must be functioning properly.

7.7.12.8 Records review – Permanent, temporary and mobile EBAT facilities.

7.7.12.8.1 Review of the Standard Solution Log Sheets must show precise standard results within ±10% of the target value.

7.7.12.8.2 Review of the Standard Solution Log Sheet must not indicate an unacceptable number of error messages.

7.7.12.8.3 The Standard Simulator Solution must be changed every 30 days or 100 tests, whichever comes first.

7.7.12.8.4 Diagnostic checks must be performed every 30 days and printouts must be retained with the Standard Solution Log Sheet.

7.7.12.8.5 Calibration checks must be performed every 7 days and printouts must be retained with the Standard Solution Log Sheet.

7.7.12.8.6 All EBAT sequence numbers must be recorded on the Standard Solution Log Sheet.

7.7.12.8.7 All records pertaining to Evidential Breath Alcohol Tests must be retained by the EBAT facility for 2 years.

7.7.12.9 Additional requirements for mobile EBAT facilities

7.7.12.9.1 Power

7.7.12.9.1.1 Acceptable power sources are:

7.7.12.9.1.1.1 Square wave power inverter capable of generating an AC line voltage of 140 volts RMS± 10%.

7.7.12.9.1.1.2 Power inverter/sine wave converter combination that generates 120 volts AC ± 10% from 14 VOLTS DC.

7.7.12.9.1.1.3 Electric motor/generator combinations that use a 12 volt AC ± 10% 60 HZ generator.

7.7.12.9.1.1.4 The isolated power line to the EBAT device must be verified by Department staff.

7.7.12.9.1.1.5 A surge protection device approved by the Department must be placed between the EBAT device and the isolated power outlet.

7.7.12.9.1.1.6 Only the EBAT device and its associated equipment shall be connected to the surge protection device or the isolated power outlet.

7.7.12.9.2 Environment

7.7.12.9.2.1 Automobile emissions must not be allowed in the EBAT facility.

PART 8: Violations and Remedies

8.1 Violations

8.1.1 It is a violation of these rules and regulations to perform testing without an appropriate certificate.

8.1.2 Violation of these rules and regulations may result in denial, suspension or revocation of certification as outlined in Part 8 of these rules and regulations.

8.1.3 Generally, a violation will not be cited if:

8.1.3.1 The violation was unavoidable to prevent loss of life, personal injury or severe property damage or there were no feasible alternatives, and provided that proper notification was given to the Department.

8.1.3.2 The violations resulted from matters beyond the control of the facility or laboratory, such as equipment failures that were unavoidable by reasonable quality assurance measures or management controls.

8.2 Right to appeal the denial, suspension or revocation of certification.

8.2.1 Any facility, laboratory, operator or operator instructor whose certification is denied, suspended or revoked under these regulations may seek appeal of that determination pursuant to section 24-4-105, C.R.S. (2006).

8.3 Denial, Suspension or Revocation of Certification:

8.3.1 The Department may deny, suspend or revoke the certification of EBAT device(s) located in a facility, the certification of an operator, the certification of an operator instructor or the certification of a laboratory for one or more of the following causes:

8.3.1.1 Falsification of data or other deceptive practices including false statements by omission or commission relevant to the certification process.

8.3.1.2 Gross incompetence or negligent practice.

8.3.1.3 Willful or repeated violation of any lawful rule, regulation or order of the Department or the Board of Health and its officers.

8.3.1.4 Inadequate space, equipment, or methods utilized for testing.

8.3.1.5 Submission of any test results of another person as those of the subject being evaluated.

8.3.1.6 For a laboratory, failure to continuously participate in proficiency testing.

8.3.1.7 For a laboratory, the receipt of two consecutive “unsatisfactory” evaluations, or achievement of an “unsatisfactory” score in 2 of any 3 consecutive proficiency test events.

8.3.1.8 For a laboratory, contact with another laboratory concerning proficiency test results prior to the due date of those results.

8.4 Injunction

8.4.1 The Department may seek an injunction against any entity for failure to comply with these rules and regulations.

APPENDIX 1A

TITLE: Checklist for Evidential Breath Alcohol Test(s).

1. The subject must remove foreign objects from the nose and mouth to include dentures. The subject must be closely and continuously observed for 20 minutes prior to testing to assure no belching, regurgitation or intake of any foreign material by nose or mouth has occurred. If such occurs, another 20 minutes of close and continuous observation must elapse under the same conditions.

2. Turn power switch on and/or observe the power switch has been activated.

3. Observe the simulator temperature is between 33.8 degrees centigrade and 34.2 degrees centigrade.

4. Activate the Start Test switch.

5. Follow the instructions and sequence of events as they appear on the device display.

6. After the sequence of events has been completed package and seal the Delayed Breath Alcohol specimen.

7. Record the evidential breath alcohol test information on the standard simulator log sheet.

APPENDIX 2A

Colorado Department of Public Health and Environment
Laboratory Services Division
Breath Alcohol Testing Program

Approved checklist for Evidential Breath Alcohol Test(s) after upgrade to Intoxilyzer 5000EN software revision 1358.XX, in compliance with the Colorado Board of Heath Rules and Regulations concerning testing for alcohol and other drugs, 5-CCR1005-2, as amended.

SUBJECT: _____

DATE:_____

Certified operator or instructor conducting the EBAT must initial inside the parentheses to the left of each step and sign in the space provided at the bottom.

( ) 1. Turn power switch on or observe the power switch has been activated. If the EBAT device is in the STANDBY mode, press the START TEST switch.

( ) 2. The subject must remove foreign objects from the nose and mouth includingdentures. The subject must be closely and continuously observed for 20 minutes prior to testing to assure no belching, regurgitation or intake of any foreign material by nose or mouth has occurred. If such occurs, another 20 minutes of close and continuous observation must elapse under the same conditions.

Start Time: _____ Stop Time: _____

( ) 3. Verify that the external breath tube and simulator vapor tube are both warm.

( ) 4. Observe the simulator temperature is between 33.8 degrees Centigrade and 34.2 degrees Centigrade.

( ) 5. Press the START TEST switch.

( ) 6. Follow the instructions and sequence of events as they appear on the EBATdevice display.

( ) 7. Retain all printouts generated by the EBAT device with the DUI packet. (ie. Error message printouts)

THIS EVIDENTIAL BREATH ALCOHOL TEST WAS CONDUCTED IN ACCORDANCE WITH THE COLORADO BOARD OF HEALTH RULES AND REGULATIONS, 5-CCR1005-2.

_____

Certified Operator or Instructor Conducting Test

APPENDIX 2B

DUI and DUID Laboratory Certification Application

Laboratories are certified by the Colorado Department of Public Health and Environment as authorized by the Colorado Board of Health Rules and Regulations 5 CCR 1005-2, Testing for Alcohol and Other Drugs

(for re-certification, complete the following and submit at least 30 days prior to the current expiration date)

LABORATORY NAME: _____

ADDRESS (LOCATION): _____

ADDRESS MAIL: _____
(if different from above)

CONTACT PERSON TO ADDRESS MAIL: _____
(name) **(title)**

E MAIL ADDRESS: _____

PHONE NUMBER: _____

FAX NUMBER: _____

ANALYTICAL CATEGORIES:

Screening or Initial Testing	method (list)	number of samples in past year		**Confirmation or Repeat Testing**	method (list)	number of samples in past year
Blood Alcohol				Blood Alcohol		
Blood drug				Blood Drug		
Urine Drug				Urine Drug		

For each director, supervisor and analyst, submit a current Curriculum Vitae with this application.

Return signed and completed application to:

Colorado Department of Public Health and Environment
Laboratory Services Division
Certification Program
8100 Lowry Blvd
Denver CO 80230-6928

This information is a true and accurate representation of the methods and personnel employed by this laboratory on the date of this application.

_____ _____ _____
(signature of director or designated responsible party) (Title) (Date)

APPENDIX 2C

DUI and DUID Laboratory Certification Onsite Evaluation Standards

Laboratory Name:

_____

Inspector(s) Name:_____**Date of inspection**:_____

Laboratory Staff interviewed:_____

A. PERSONNEL

1. Y N NA Does the laboratory have a director?

2. Y N NA Does the director have a Bachelor degree in chemical, physical or biological science or medical technology, forensic science, or equivalent, from an accredited institution, and 2 years of laboratory experience?

   (Answer NA if question #4 is Yes)

3. Y N NA Is the director responsible for the overall management and operation of the laboratory? How is this documented? What documented tasks does the director perform relating to management and operation of the laboratory?

4. Y N NA If the director does not supervise the daily function of the laboratory, has this responsibility been delegated to a qualified technical supervisor (TS)? (See question 2 in this section for qualifications) How is this documented? What documented tasks does the TS perform relating to management and operation of the laboratory?

5. Y N NA Do the analysts have at minimum an associate degree in a laboratory science or one year training in a nationally recognized accredited laboratory program or one year documented on the job laboratory training?

6. Y N NA Does the laboratory director or TS ensure laboratory personnel are adequately trained? What system is used to evaluate and ensure personnel competency? (Such as observation, written test, analysis of unknown samples or quality control materials)

7. Y N NA Does the laboratory maintain documentation for the director and all personnel's education, training and experience?

8. Does the laboratory maintain records of personnel training and annual competency checks in the following areas:

   Y N NA a) sample processing procedures

   Y N NA b) theory of instrument operation and software

   Y N NA c) analytical procedures

Y N NA d) quantitation and calculations

Y N NA e) reporting results

9. Y N NA Does each laboratory position have a written job description?

B. STANDARD OPERATING PROCEDURE MANUAL

1. Y N NA Does the laboratory have a written procedure manual for the performance of all methods of analytes it reports?

1.1 Y N NA Do the Standard Operating Procedures (SOP) contain the critical elements in this Appendix 2C, section B5 (a-t)?

2. Y N NA Has the current laboratory director or technical supervisor approved, signed and dated each procedure?

3. Y N NA Has the laboratory director or technical supervisor approved, initialed and dated each change in the procedure?

4. Y N NA Does the laboratory have a written procedure manual available to the laboratory analyst at the bench? What system is used to ensure all staff are familiar with the SOP, including any revisions?

5. Does the procedure manual include criteria and process for:

Y N NA a) specimen receiving?

Y N NA b) specimen accessioning?

Y N NA c) specimen storage?

Y N NA d) identifying and rejecting unacceptable specimens?

Y N NA e) recording discrepancies?

Y N NA f) security of specimens, aliquots or extracts?

Y N NA g) validating a new or revised method prior to testing specimens for accuracy, precision, specificity (interferences), detection limits and reporting range?

Y N NA h) aliquoting specimens to avoid contamination and/or carry-over?

Y N NA I) sample retention to assure stability for one year?

Y N NA j) disposal of specimens?

Y N NA k) the theory and principles behind each assay?

Y N NA l) preparation and identification of reagents, standards, calibrators and controls? How does the laboratory ensure all standards are traceable to NIST as specified in section D?

Y N NA m) special requirements and safety precautions involved in performing assays?

Y N NA n) frequency and number of control and calibration materials?

Y N NA o) recording and reporting assay results?

Y N NA p) protocol and criteria for accepting or rejecting analytical data?

Y N NA q) procedure to verify the accuracy of the final report?

Y N NA r) pertinent literature references for each method?

Y N NA s) current step by step instructions with sufficient detail to perform the assay to include equipment operation?

Y N NA t) a documented review system of control, standard, tests results, clerical errors, analytical errors and any unusual analytical results? How are corrective actions implemented and documented? What system does the laboratory use to contact affected clients?

6. Y N NA Does the laboratory maintain copies of previous standard operating procedures and the dates they were in effect and analytical results for a least 5 years from date last used?

C. PROFICIENCY TESTING

1. Y N NA Has the laboratory successfully participated in approved proficiency test (PT) programs for the categories in which they are seeking certification?

Identify programs and results:

_____
_____
_____
_____
_____
_____
_____

2. Y N NA Does the laboratory participate in additional proficiency testing programs other than those required under these standards?

3. Y N NA Does the laboratory analyze PT samples with the same number of replicates, standards, equipment and testing personnel as used for specimen testing?

4. Y N NA Does the laboratory maintain a copy of all records and documentation for a minimum of two years from the date of the proficiency testing event?

5. Y N NA Has the laboratory director reviewed and evaluated all PT results?

6. Y N NA Has the laboratory taken and documented remedial action for unacceptable PT and specimen results?

D. QUALITY ASSURANCE AND QUALITY CONTROL

1. Y N NA Are there records of preventive maintenance, repair and calibration of all instruments used to perform approved tests?

2. Y N NA Does the laboratory check and document the accuracy of automatic and/or adjustable pipettors and other measuring devices when placed into service and annually thereafter?

3. Y N NA Does the laboratory have the analytical balances cleaned, serviced and checked annually by qualified service personnel?

4. Y N NA Does the laboratory record temperatures daily on all equipment where temperature control is specified in SOP's, such as water baths, heating blocks, incubators, ovens, refrigerators, and freezers?

5. Y N NA Does the laboratory properly label reagents as to identity, concentration, date of preparation, storage conditions, expiration date and identity of the preparer?

6. Y N NA If the laboratory prepares its own calibrators and controls, are these made using independently prepared stock drug solutions? How does the laboratory ensure / document agreement with NIST traceable standards within 5%?

7. Y N NA Does the laboratory avoid mixing different lots of reagents in the same analytical run?

8. Y N NA Does the laboratory perform and document calibration curve for each assay performed using a blank and at least three calibrators throughout the reporting range to include the "detection limit" at least every six months or whenever there is a change in or to a procedure or equipment used?

9. Y N NA Does the laboratory analyze two levels of calibrators and/or controls with each batch of specimens?

10. Y N NA Does the laboratory analyze an appropriate matrix blank and control with each batch of specimens analyzed?

11. Y N NA Does the laboratory analyze calibrators and controls in the same manner as unknowns?

12. Y N NA Does the laboratory define control limits for all assays?

13. Y N NA Does the laboratory monitor and document the performance of calibrators and control specimens?

14. Y N NA Does the laboratory have written criteria for corrective action of unacceptable control, standard, or instrument performance?

15. Y N NA Does the laboratory take remedial action if control results exceed reference ranges?

16. Y N NA Is the remedial action documented?

17. Y N NA Does the laboratory maintain records of validation data for new and modified assays to include interferent studies?

18. Y N NA Does the analyst follow the SOP for the tests performed?

E. CHAIN OF CUSTODY-SECURITY-SPECIMEN RETENTION FACILITY SPACE

1. Y N NA Is there a system to document the complete chain of custody of all forensic specimens from receipt to disposal?

2. Y N NA Does the laboratory issue instructions to user agencies, including the types and amount of specimens required?

3. Y N NA Does the laboratory document the condition of the external package and individual evidence seals?

4. Y N NA Does the laboratory compare the evidence seals against requisition and document any discrepancies? How are discrepancies resolved?

5. Y N NA Does the laboratory document the condition of the specimens at the time of receipt?

6. Y N NA Does the laboratory document all persons handling the original specimens, aliquots, and extracts?

7. Y N NA Does the laboratory document all transfers of specimens, aliquots, and extracts when requested for by defendant's legal counsel and sent to another certified laboratory?

8. Y N NA Does the laboratory maintain a current list of authorized personnel?

9. Y N NA Does the laboratory restrict entry into the laboratory to only authorized personnel?

10. Y N NA Does the laboratory have provisions for securing the laboratory during non-working hours?

11. Y N NA Does the laboratory secure short and long term storage areas when not in use?

12. Y N NA Does the laboratory log-in and aliquot specimens in a secure area?

13. Y N NA Are urine specimens stored for at least 1 year at -20 degrees C. or less?

14. Y N NA Are blood specimens stored for at least 1 year at less than 8 degrees C.?

15. Y N NA Does the laboratory document the disposal of samples, aliquots, and extracts?

16. Y N NA Is there adequate space to perform the analyses?

17. Y N NA Is the lighting, ventilation and temperature control adequate?

F. RECORDS -- REPORTING

1. Y N NA Are records of analyses and instrumentation printouts maintained by the testing laboratory for a period of not less than 5 years?

2. Y N NA Are all specimens identified as positive on an initial drug test confirmed using a second analytical procedure utilizing different technique and chemical principle from the initial test?

3. Y N NA If blood samples are screened for ethanol by gas chromatography, is a separate aliquot from the original specimen used for confirmation? i.e. (two separate aliquots should be tested for blood alcohol)

4. Y N NA Does the laboratory maintain records, accession numbers, specimen type, QC results, acceptable reference range parameters, analyst and date of analysis for at least 5 years?

5. Y N NA Does the laboratory adequately document the available external chain of custody information?

G. ANALYTICAL PROCESS

G.1 Gas Chromatography

1. Y N NA Does the laboratory document the conditions of the gas chromatograph, including the detector response daily?

2. Y N NA Does the laboratory document changes of septa as specified in the SOP?

3. Y N NA Is there documentation of liners being cleaned or replaced as specified in the SOP?

4. Y N NA Does the laboratory document the performance of new columns before use?

6. Y N NA Does the laboratory use an internal standard for qualitative and quantitative analysis?

7. Y N NA For quantitative analysis does the internal standard have similar chemical and physical properties to that of the analyte?

8. Y N NA Does the laboratory monitor the response (area or peak height) for the internal standard to ensure consistency of the analytical system over time?

G2. Gas Chromatography Mass Spectrometry (GC-MS)

1. Y N NA Does the laboratory maintain records of mass spectrometric tuning?

2. Y N NA Does the laboratory have written criteria for an acceptable mass-spectrometric tune?

3. Y N NA If the tune is unacceptable, is corrective action documented?

4. Y N NA If the laboratory uses full scan mass spectral identification through library searching, are there documented criteria for acceptability?

5. Y N NA If the laboratory uses selected ion monitoring for identification does it compare ion ratios and retention times between calibrators, controls and specimens?

6. Y N NA If the laboratory has written its' own software, has it been documented and the accuracy verified?

G3. Immumoassays

1. Y N NA Do the calibrators give adequate separation or measurement units (absorbance intensity or counts per minute)?

2. Y N NA If the laboratory uses radioimmunoassay does it determine background counts before each run or daily, including the background in each well of a multi-well counter?

3. Y N NA Do the background counts meet the acceptable criteria?

G4. Thin Layer Chromatography

1. Y N NA Does the laboratory apply unextracted standards to each thin layer chromatographic plate?

2. Y N NA Does the laboratory evaluate new thin layer chromatographic plates before placing them into service? How does the laboratory establish and document acceptable performance?

3. Y N NA Does the spotting technique preclude the possibility of contamination and/or carry-over? How is this verified?

4. Y N NA Does the laboratory measure all appropriate RF values for qualitative identification purposes?

5. Y N NA If the laboratory uses sequential color reactions, are these recorded?

6. Y N NA Does the laboratory maintain records of thin layer chromatographic plates?

7. Y N NA Does the laboratory analyze an appropriate matrix blank with each batch of specimens analyzed?

G5. High Pressure Liquid Chromatography (HPLC)

1. Y N NA Does the laboratory evaluate the performance of new columns before use? How?

2. Y N NA If the laboratory recycles eluting solvents, are there standards for acceptability?

3. Y N NA Does the laboratory use an internal standard with each batch of specimens for qualitative and quantitative analysis?

4. Y N NA If an internal standard is used for quantitative analysis, are its chemical and physical properties similar to the analyte?

5. Y N NA Does the laboratory monitor the response (area or peak height) for the internal standard to ensure consistency of the analytical system over time?

COMMENTS SECTION: