DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Laboratory Services Division

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

5 CCR 1005-2

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

Part 1: General ~~[Eff. 03/02/2009]~~

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 certified EBAT instrument used to perform evidential breath alcohol testing is scientifically accurate, precise and reliable, when the certified EBAT instrument is properly operated as described in these rules and regulations.~~

The Colorado Department of Public Health and Environment have determined that the results obtained from the certified EBAT instrument is scientifically accurate, precise, reliable and of evidentiary quality when the certified EBAT instrument is properly operated as described in this rule. Recommendations made to the State Board of Health are evidence based through analytic testing and evaluation conducted by the Department

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1.3 Evidential Breath Alcohol Testing (EBAT) facilities will operate under Parts 2, 3, 4 and Appendix ~~2~~A of these rules and regulations. All EBAT facilities performing direct evidential breath alcohol tests must comply with all applicable requirements in this rule. ~~Parts 2, 3, 4 and Appendix 2A of these rules and regulations.~~

1.4 Testing of blood alcohol, blood drug, urine drug and post mortem samples operate under Parts ~~6, 7, 8, 9~~ 5-8 and Appendix ~~2~~B and C of these rules and regulations. All certified laboratories performing blood alcohol, blood drug, urine drug and post mortem testing must comply with all applicable requirements in this rule. ~~Parts 6, 7, 8, 9 and Appendix 2C 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 disinfection of the blood collection area.

"Certification" – the official approval by the Department of an Evidential Breath Alcohol Test (EBAT) instrument, instructor, operator, facility or laboratory to function under these rules and regulations.

"Certified EBAT Instrument" – the instrumentation approved for use by the Department for performing evidential breath alcohol testing in approved facilities by certified instructors and operators in order to determine the alcohol content in a subject's breath for evidentiary purposes as identified in section 42-4-1301, C.R.S. ~~The approved EBAT instrument for the state of Colorado is the Intoxilyzer 5000EN.~~

"Certified EBAT 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 EBAT 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.

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

~~"DUI Packet" – refers to the EBAT documentation provided by the law enforcement agency that must include, but is not limited to the following; a completed error-free EBAT and any error messages printed by the certified EBAT instrument, and all Appendix 2A checklists initiated by the certified EBAT operator or instructor.~~

"DUI Packet" -refers to the documentation produced by the certified EBAT instrument that must be included by the certified EBAT instructor or operator. This must include but is not limited to the following; the completed subject EBAT, the instrument quality assurance performance report, and any exception messages encountered during the subject test.

"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 testing instrument approved by the Department as described by Section 42-4-1301, C.R.S.

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

"Laboratory Director" – the individual meeting the qualification requirements specified in Part 5~~6~~ and Appendix ~~2~~C of these rules who is responsible for the overall operation and results reported by the laboratory.

"Limit of Detection (LOD)" – the lowest concentration or amount of an analyte that can be reliably shown to be present or measured under defined conditions and is derived by adding three standard deviations to the true value of the blank.

"Limit of Quantitation (LOQ)" – the concentration at which quantitative results can be reported with a high degree of confidence and is derived by adding ten standard deviations to the true value of the blank or administratively defined in terms of the lowest concentration of the lowest calibrator used in the analytic run.

"Litigation Packet" – records requested for litigation purposes must include sufficient material to allow independent review by a qualified toxicologist. These records should include the request for analysis, chain of custody documents, all analytical data which supports identification, and if applicable, quantitation of the analyte(s) to include the limits of quantitation (LOQ). Where appropriate, it should include not just the raw data and reports, but worksheets, sequence tables, quality control data including target ranges. The material in the litigation packet should be complete and properly organized.

"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.

~~"Standard Simulator Solution Logs" – the certified EBAT instrument printout containing all testing records for a period of 28 days or 96 tests, whichever comes first.~~

"Supervisory Analyst" – the individual(s) that meet the qualification requirements specified in Part 5~~6~~ and Appendix ~~2~~C of these rules and who is responsible for the day to day operation and reporting of results by the laboratory as delegated in writing by the laboratory director.

"Tampering" – to meddle with the certified EBAT instrument especially for the purpose of altering test results, damaging or misusing the instrument either by intentional or unintentional means.

~~**Part 2: Certification Requirements for Operators and Instructors Performing Evidential Breath Alcohol Testing (EBAT) [Eff. 03/02/2009]**~~

~~2.1 Certification of Operators of EBAT Instruments 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 one error-free EBAT test 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 error-free 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 from 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 Documented proof of active duty, documented proof of last operator certification prior to going on active duty, operator test material and a copy of the error-free EBAT test 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 to be signed by the certified instructor indicating the operator name, 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 Instructors of Certified EBAT Instruments 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 instruments.~~

~~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 in order to be recertified as an instructor.~~

~~2.2.5.1 An instructor who fails to certify within the 365-day period may recertify as an operator after performing one error-free EBAT test in the presence of a certified instructor, following the procedure specified in Appendix 2A of this regulation prior to performing subject testing.~~

~~2.2.6 EBAT Instructors who return from 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 a copy of the error-free 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 to be signed by the certified instructor or the Department's program manager or designee, stating the instructor's name, 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.~~

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Part 2: Certification Requirements for Operators and Instructors Performing Evidential Breath Alcohol Testing (EBAT)

2.1 Operators seeking initial EBAT certification or EBAT recertification by the department must meet the following criteria:

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, and

2.1.1.2 Attend and successfully complete the department's eight (8) hour EBAT operator certification course, and

2.1.1.3 Successfully complete the department's EBAT operator comprehensive practical, and

2.1.1.4 Successfully pass the department's EBAT operator exam with a score of 80% or greater.

2.1.1.5 Upon successful completion of the department's operator certification course, the certified EBAT operator will be issued an instrument access card that may only be used by the certified EBAT operator for whom it was issued.

2.1.2 To maintain active status, a certified EBAT operator must complete the following recertification requirements:

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2.1.2.1 Semi-annually - successfully perform and complete an Evidential Breath Alcohol Test, and

2.1.2.2 Annually - successfully complete the department's certified EBAT operator recertification course.

2.1.2.3 Upon successful completion of the department's operator recertification requirements, the certified EBAT operator card active status will be updated and available for use during the next certification period.

2.1.3 The certified EBAT operator card issued by the department may also serve as evidence of certification.

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2.2 The certified EBAT operator not meeting the EBAT recertification requirements found in this Part, the department will:

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2.2.1 Deactivate the EBAT operator certification card, used to access to the certified EBAT instrument, and

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2.2.2 Maintain the EBAT operator in an inactive status until the EBAT operator certification requirements found in this Part are met.

2.3 Instructors seeking initial EBAT certification or EBAT recertification by the department must meet the following criteria:

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

2.3.1.1 Be currently employed by a law enforcement agency or the department, and

2.3.1.2 Be currently a certified EBAT operator in active status, and

2.3.1.3 Attend and successfully complete the department's sixteen (16) hour EBAT instructor certification course, and

2.3.1.4 Successfully complete the department's EBAT instructor comprehensive practical, and

2.3.1.5 Successfully pass the department's EBAT instructor exam with a score of 80% or greater.

2.3.1.6 Upon successful completion of the department's instructor training course, the certified EBAT instructor will be issued an instrument access card that may only be used by the certified EBAT instructor for whom it was issued.

2.3.2 To maintain active status, a certified EBAT instructor must complete the following recertification requirements:

2.3.2.1 Annually - Participate in teaching, at minimum, one EBAT operator certification course, and

2.3.2.2 Annually - Successfully complete the department's certified EBAT Instructor recertification course.

2.3.3 A certified EBAT instructor in active status is also recognized as a certified EBAT operator and may perform testing.

2.3.4 The certified EBAT operator card issued by the department may also serve as evidence of certification.

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2.3.5 The certified EBAT instructor not meeting the EBAT recertification requirements found in this Part, the department will:

2.3.5.1 Deactivate the EBAT instructor certification card, used to access to the certified EBAT instrument, and

2.3.5.2 Maintain the EBAT instructor in an inactive status until one of the three certification criteria is met:

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2.3.5.2.1 Within 30-days after the EBAT instructor certification expiration date, the inactive instructor may perform and complete a successful Evidential Breath Alcohol Test to regain an active status as a certified EBAT operator. The certified EBAT operator must meet the requirements found at Part 2.1.2 in order to maintain certification, or

2.3.5.2.2 After 30-days from the EBAT instructor certification expiration date, the inactive instructor must meet the EBAT operator certification requirements found at Part 2.1, or

2.3.5.2.3 The EBAT instructor meets the requirements found at Part 2.4 of the rule.

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2.4 EBAT instructors or operators returning from active military service may reactivate their certification status by completing the following:

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2.4.1 Provide documentation of active duty status to the Department, (Period of absence must not exceed 2 years), and

2.4.2 Successfully pass the EBAT instructor or operator certification test with a score of 80% or greater, and

2.4.3 Successfully perform and complete an Evidential Breath Alcohol Test.

2.4.4 Upon successful completion of the recertification requirements in this part, the certified EBAT instructor or operator card active status will be updated and available for use during the next certification period.

2.4.5 The certified EBAT instructor or operator must meet the requirements found in this Part in order to maintain certification.

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~~**Part 3: Certification Requirements for Approved Evidential Breath Alcohol Testing (EBAT) Facilities [Eff. 03/02/2009]**~~

~~3.1 Standards for approved permanent, temporary and mobile Evidential Breath Alcohol Testing (EBAT) facilities~~

~~3.1.1 Evidential Breath Alcohol Test(s) must be conducted only in facilities that have been approved by the Department.~~

~~3.1.2 Department standards for all approved EBAT facilities are specified in these regulations.~~

~~3.1.3 All approved EBAT facilities must meet standards of performance as established by this section of these regulations.~~

~~3.1.4 Inspections of permanent, temporary and mobile facilities must be performed prior to initial approval and once in a calendar year thereafter by Department staff.~~

~~3.1.4.1 Facility inspection reports will be sent to the facility within 15 days of the inspection date.~~

~~3.1.4.2 When applicable, facilities must send a plan of correction to the Department for review and approval within 15 days of receipt of the facility inspection report.~~

~~3.1.5 Initial inspections of permanent and temporary EBAT facilities must be conducted by Department staff using sections 3.1.12.1 *et seq.* to 3.1.12.7 *et seq.* of these regulations.~~

~~3.1.6 Annual, complaint and follow-up inspections of permanent and temporary EBAT facilities must be conducted by Department staff using sections 3.1.12.2 *et seq.* to 3.1.12.8 *et seq.* of these regulations.~~

~~3.1.7 Initial inspections of mobile EBAT facilities must be conducted by Department staff using sections 3.1.12.1 *et seq.* ; 3.1.12.3 *et seq.* to 3.1.12.7 *et seq.* ; and 3.1.12.9 *et seq.* of these regulations.~~

~~3.1.8 Annual, complaint and follow-up inspections of mobile EBAT facilities must be conducted by Department staff using sections 3.1.12.3 *et seq.* to 3.1.12.9 *et seq.* of these regulations.~~

~~3.1.9 Mobile EBAT facilities, the certified EBAT instrument and its associated equipment must be brought to the Department each time a facility inspection is required.~~

3.1.10 A certified EBAT instrument that is used in an approved mobile EBAT facility must not be used at a permanent or temporary facility unless approved by the Department.

3.1.11 A certified EBAT instrument that is used in an approved permanent or temporary facility must not be used at a mobile facility unless approved by the Department

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

3.1.12.1 Initial approval – permanent, temporary and mobile EBAT facilities

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

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

3.1.12.1.3 The facility's certified instructor or DUI enforcement officer is responsible for monitoring the construction of the EBAT facility and verifying compliance with the requirements of this section.

3.1.12.1.4 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 certified EBAT instrument is an isolated line.

3.1.12.1.5 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.

3.1.12.1.5.1 The certified EBAT instrument must not be moved from its approved location within the approved facility without authorization from the Department.

3.1.12.2 Power requirements – permanent and temporary facilities

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

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

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

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

3.1.12.3 Environment – permanent, temporary and mobile EBAT facilities

3.1.12.3.1 The temperature of the approved facility must be maintained between 70 and 80 degrees Fahrenheit.

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

3.1.12.3.3 The area around and under the certified EBAT instrument must be free of dust and dirt.

3.1.12.3.4 The approved facility must be kept orderly.

3.1.12.3.5 The certified EBAT instrument and breath alcohol simulator must be located on the organizer stand.

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

3.1.12.3.7 The certified EBAT instrument must be in a smoke-free environment.

3.1.12.3.8 The approved facility must have adequate ventilation to prevent vapor build-up around the certified EBAT instrument.

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

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

3.1.12.3.11 Automobile emissions must not be allowed in the approved EBAT facility.

3.1.12.4 Documents – Permanent, temporary and mobile EBAT facilities

3.1.12.4.1 The following documents must be maintained at the approved EBAT facility with the certified EBAT instrument.

3.1.12.4.1.1 Current, original certificate for the certified EBAT instrument.

3.1.12.4.1.2 Checklist, Appendix 2A

3.1.12.4.1.3 Error message sheet

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

3.1.12.4.1.5 Current Standard Simulator Solution Log Sheet.

3.1.12.5 Supplies – permanent, temporary and mobile EBAT facilities

3.1.12.5.1 The following supplies must be maintained at the certified EBAT facility with the certified EBAT instrument.

3.1.12.5.1.1 Mouthpieces;

3.1.12.5.1.2 Standard simulator solution;

~~3.1.12.5.1.3 Printer paper~~

~~3.1.12.6 Certified Evidential Breath Alcohol Testing instrument functions – permanent, temporary and mobile EBAT facilities~~

~~3.1.12.6.1 The certified EBAT instrument time and date must be correct, or synchronized with the facility dispatch clock when the facility dispatch clock is used instead of the certified EBAT instrument clock.~~

~~3.1.12.6.2 The external breath tube must be heated.~~

~~3.1.12.6.3 The simulator vapor tube must be heated.~~

~~3.1.12.6.4 The certified EBAT instrument certification date on the printout must be the same as the certification date on the posted certification certificate – Permanent locations only.~~

~~3.1.12.6.5 The certified EBAT instrument must be connected to an active analog telephone line at all times – Permanent locations only.~~

~~3.1.12.7 Simulator functions – Permanent, temporary and mobile EBAT facilities~~

~~3.1.12.7.1 Active simulator~~

~~3.1.12.7.1.1 Record serial number~~

~~3.1.12.7.1.2 Display must read between 33.8°C and 34.2°C.~~

~~3.1.12.7.1.3 Simulator solution temperature must be between 33.8°C and 34.2°C measured by a calibrated, NIST-traceable, digital thermometer.~~

~~3.1.12.7.1.4 Simulator must be functioning properly.~~

~~3.1.12.7.2 Backup simulator(s)~~

~~3.1.12.7.2.1 Record serial number(s).~~

~~3.1.12.7.2.2 Display(s) must read between 33.8°C and 34.2°C.~~

~~3.1.12.7.2.3 Simulator solution temperature must be between 33.8°C and 34.2°C measured by a calibrated, NIST-traceable, digital thermometer.~~

~~3.1.12.7.2.4 Simulator must be functioning properly.~~

~~3.1.12.8 Records review – Permanent, temporary and mobile EBAT facilities.~~

~~3.1.12.8.1 Review of the Standard Simulator Solution Log Sheets must show precise standard results within ±10% of the target value.~~

~~3.1.12.8.2 Review of the Standard Simulator Solution Log Sheet must not indicate an unacceptable number of error messages.~~

~~3.1.12.8.3 A new Standard Simulator Solution Log Sheet must be created every 28 days or 96 tests, whichever comes first.~~

~~3.1.12.8.4 Diagnostic checks must be performed every 28 days.~~

~~3.1.12.8.5 Calibration checks must be performed with each new Standard Simulator Solution Log and every 7 days thereafter.~~

~~3.1.12.8.6 A breath sample check must be performed every 28 days or 96 tests, whichever comes first.~~

~~3.1.12.8.7 Effective April 1, 2009, all EBAT Standard Simulator Solution Logs, and solution records must be retained by the approved EBAT facility for a minimum of 5 years.~~

~~3.1.12.9 Additional requirements for mobile EBAT facilities~~

~~3.1.12.9.1 Power~~

~~3.1.12.9.1.1 Acceptable power sources are:~~

~~3.1.12.9.1.1.1 Square wave power inverter capable of generating an AC line voltage of 140 volts RMS± 10%.~~

~~3.1.12.9.1.1.2 Power inverter/sine wave converter combination that generates 120 volts AC ± 10% from 14 VOLTS DC.~~

~~3.1.12.9.1.1.3 Electric motor/generator combinations that use a 12 volt AC ± 10% 60 HZ generator.~~

~~3.1.12.9.1.1.4 The isolated power line to the certified EBAT instrument must be verified by Department staff.~~

~~3.1.12.9.1.1.5 A surge protection device approved by the Department must be placed between the certified EBAT instrument and the isolated power outlet.~~

~~3.1.12.9.1.1.6 Only the certified EBAT instrument and its associated equipment shall be connected to the surge protection device or the isolated power outlet.~~

Part 3: Certification Requirements for Evidential Breath Alcohol Testing (EBAT) Facilities

3.1 Standards for certification of permanent, temporary, and mobile Evidential Breath Alcohol Testing (EBAT) facilities.

3.1.1 Evidential Breath Alcohol Test(s) must be conducted in facilities that are certified by the department.

3.1.2 Department standards for certification of EBAT facilities are specified in Part 3 and Appendix 2B of the Rule.

3.1.3 EBAT facilities meeting the standards of performance as specified in Part 3 and Appendix 2B of the Rule may be receive certification.

3.1.4 Onsite inspections of permanent, temporary, and mobile EBAT facilities must be performed prior to initial certification and once per calendar year thereafter by department personnel.

3.1.4.1 Facility inspection reports will be sent by the department to the facility within 15 days of the inspection date.

3.1.4.2 Facility inspection reports that require a plan of correction must be received by the department within 15 days of receipt of the inspection report for review and approval.

3.1.5 Initial certification – permanent, temporary, and mobile EBAT facilities

3.1.5.1 A facility representative must submit a formal request to the department for initial certification of an EBAT facility that includes;

3.1.5.1.1 Acknowledgement from the facility representative that the requirements found in Part 3 and Appendix B has been reviewed prior to requesting certification.

3.1.5.1.2 Verification from a certified electrician confirming the power to the certified EBAT instrument is on its own isolated power circuit.

3.1.5.1.3 Verification from the facility representative confirming the dedicated communication lines (data and/or analog phone line) to the certified EBAT instrument are installed and active.

3.1.5.2 Upon receipt of the facility certification request, department personnel will coordinate with the agency representative to schedule an onsite inspection to verify compliance with requirements found in this Part and Appendix 2B prior to certification.

3.1.5.3 The department will perform an onsite inspection at certified EBAT facilities when any of the following occur;

3.1.5.3.1 The EBAT facility is seeking initial certification, or

3.1.5.3.2 The certified EBAT facility needs to temporarily or permanently relocate the certified EBAT instrument within the agency, or

3.1.5.3.3 A new EBAT facility is being constructed that will house the certified EBAT instrument, or

3.1.5.3.4 A complaint is received by the department that requires an onsite inspection to verify compliance.

3.1.6 The certified EBAT instrument must not be moved from the location it was certified for without prior authorization from the department.

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~~**Part 4: Evidential Breath Alcohol Testing (EBAT) - Collection and Testing Procedures [Eff. 03/02/2009]**~~

4.1 Purpose and Scope

4.1.1 Part 4 establishes minimum standards for certification and approval of entities and processes used for breath alcohol testing using the certified EBAT instrument approved by the Department.

4.2 Evidential Specimen Collection

4.2.1 Breath

4.2.1.1 Evidential breath specimens must be analyzed using a certified EBAT instrument approved by the Department. Approval or disapproval of EBAT instruments will be based on scientific standards of performance established by the Department and approved by the Colorado Board of Health.

4.2.1.2 The Department must certify each EBAT instrument initially and annually thereafter.

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

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

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

4.2.1.6 Unless otherwise provided by law, at the request of the subject, 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.

4.3 Methods of Analysis

4.3.1 Alcohol in Evidential Breath Specimens

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

4.3.1.2 The certified 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.

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

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

4.3.1.2.3 A completed evidential breath alcohol test (EBAT) is one in which the checklist (Appendix 2A) is followed and a printout without error messages is obtained.

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

4.3.1.4 Step 1. "Turn power button on or observe the power button has been activated. If the certified EBAT instrument is in the standby mode, press the start test button."

4.3.1.4.1 Certified EBAT instrument(s) at approved EBAT facilities must always be powered on. This is indicated by the small red light below the power button being illuminated.

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

4.3.1.4.3 If the certified EBAT instrument is in the standby mode, press the START TEST button.

4.3.1.4.4 If the certified EBAT instrument is in the ready mode, (when the instrument display is scrolling or flashing and the simulator display is lit), proceed to Step 2.

4.3.1.5 Step 2. "The subject must remove foreign objects from the nose and mouth including removable dentures. The subject must be closely and continuously observed for 20 minutes prior to testing to ensure 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."

4.3.1.5.1 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.

4.3.1.5.2 During the 20-minute observation period the certified EBAT operator or instructor must be close enough to the subject to detect any belching, regurgitation or intake of foreign material.

4.3.1.5.3 When belching, regurgitation or intake of foreign material is detected during the 20-minute observation period, the certified EBAT operator or instructor must start the observation period over again. A new checklist (Appendix 2A) must be filled out for this test.

4.3.1.5.4 The observation period must be conducted at the approved EBAT facility by a certified EBAT operator or instructor .

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

4.3.1.5.6 Start and stop times for the observation period must be recorded from the certified EBAT instrument clock or the facility dispatch clock, when the EBAT instrument has been synchronized with the facility dispatch clock.

4.3.1.6 Step 3. "Verify that the external breath tube and simulator vapor tube are both warm."

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

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

4.3.1.6.3 If either tube is cold to the touch, stop the test and call a certified EBAT instructor for assistance.

4.3.1.7 Step 4. "Observe the simulator temperature is between 33.8 degrees Centigrade and 34.2 degrees Centigrade."

4.3.1.7.1 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.

4.3.1.8 Step 5. "Press the start test button."

4.3.1.8.1 Press the green start test button to initiate the automated test sequence.

4.3.1.9 Step 6. "Follow the instructions and sequence of events as they appear on the certified EBAT instrument display."

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

4.3.1.9.2 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).

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

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

4.3.1.9.5 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.

4.3.1.9.5.1 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.

4.3.1.9.5.1.1 When a "NO .02 Agreement" error message is obtained, the certified EBAT operator or instructor 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.

~~4.3.1.9.6 The certified EBAT operator or instructor must be close enough to the subject to detect any belching, regurgitation or foreign material in the mouth or nose from the time the EBAT is started through the completion of the second breath sample.~~

~~4.3.1.9.6.1 Whenever belching, regurgitation or foreign material is detected in the mouth or nose from the start of the EBAT through completion of the second breath sample, the certified operator or instructor must choose the Non-Compliance option to abort the test. The certified EBAT operator or instructor must perform the test procedure over again after another 20-minute observation period. A new checklist (Appendix 2A) must be filled out for this test.~~

~~4.3.1.9.7 In order to prevent tampering of the certified EBAT instrument during the testing procedure, the subject must be removed from the area in close proximity to the instrument during the two-minute period between subject breath tests.~~

~~4.3.1.9.8 A clean mouthpiece will be used each time the subject blows into the certified EBAT instrument.~~

~~4.3.1.10 Step 7. Retain all printouts generated by the certified EBAT instrument to include any error messages, and any checklist(s) initiated (Appendix 2A) with the DUI packet.~~

~~4.3.1.10.1 The certified EBAT operator or instructor conducting the EBAT must sign the checklist(s) and completed EBAT printout(s) and retain all initiated checklist(s) (Appendix 2A) with the DUI packet.~~

~~4.3.1.10.2 All printouts generated by the certified EBAT instrument must be retained with the DUI packet, including error message printouts.~~

~~4.3.1.10.3 Effective April 1, 2009, all certified EBAT instrument Standard Simulator Solution Logs and solution records must be retained by the facility for a minimum of 5 years.~~

Part 4: Evidential Breath Alcohol Testing (EBAT) - Collection and Testing Procedures

4.1 This Part establishes the minimum standards for collection and testing of evidential breath alcohol samples that include;

4.1.1 An active, certified EBAT instructor or EBAT operator to perform the test following the protocols established by the department, and

4.1.2 A certified EBAT facility to conduct the test at, and

4.1.3 A certified EBAT instrument to measure the breath alcohol content.

4.2 Pre-Analytic testing requirements include;

4.2.1 Unless otherwise provided by law, at the request of the subject, 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.

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4.2.2 Completion of a 20-minute depravation period conducted at the certified EBAT facility by the certified EBAT instructor or operator includes;

4.2.2.1 Verifying the subject information by the certified EBAT instructor or operator, and

4.2.2.2 Removal of foreign material from the subject's mouth cavity that is not permanent in nature, prior to starting the 20-minute depravation period, and

4.2.2.3 Depriving the subject access to foreign material that may be introduced into the mouth cavity during the 20-minute depravation period, and

4.2.2.4 Observing the subject throughout the depravation and EBAT sequence, and

Note: The subject must be observed by the certified EBAT instructor or operator to look for signs of belching, regurgitation or intake of any foreign material into the mouth cavity by the subject. If such observations occur, the 20-minute depravation period must be repeated under the same conditions prior to retesting the subject.

4.2.2.5 Providing instruction to the subject on providing a breath sample into the certified EBAT instrument.

4.3 Analytic testing requirements include;

4.3.1 The subject breath sample must be tested using a certified EBAT instrument, and

4.3.2 The subject breath sample is tested by an active certified EBAT instructor or operator following the protocols approved by the department, and

4.3.3 The certified EBAT instrumentation successfully completes the test sequence and results are reported.

4.4 Post-Analytic testing requirement include:

4.4.1 Review of the subject EBAT report includes;

4.4.1.1 Verification of subject information, and

4.4.1.2 Verification of certified EBAT instructor or operator information, and

4.4.1.2 Verification of the certified EBAT instrument results.

4.4.2 The certified EBAT instructor or operator must include the certified EBAT instrument's current Quality Assurance Performance Report as part of the EBAT DUI Packet as defined in Part 1.5, and

4.4.3 Inclusion of all subject test attempts as part of the EBAT DUI Packet as defined in Part 1.5.

~~**Part 5: Reserved [Eff. 03/02/2009]**~~

Part 5~~6~~: Certification Requirements for Forensic Toxicology Laboratories ~~[Eff. 03/02/2009]~~

5~~6~~.1 Laboratory Analysis of Blood, Urine and Post Mortem Specimens

5~~6~~.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 with Part 5.5~~.~~

5~~6~~.1.2 Laboratories accredited by the American Board of Forensic Toxicology (ABFT) will be granted reciprocity on an annual basis as long as accreditation remains active. However, laboratories certified by these rules are subject to inspection by the department regardless of accreditation status~~.~~

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5~~6~~.1.3 Laboratories will be certified to perform tests for one or more of the following categories: blood alcohol, blood drug~~s~~, urine drug~~,s~~ and post mortem testing.

5~~6~~.1.4 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, laboratory security, chain of custody, specimen retention, space, records, and results reporting.

5~~6~~.1.5 Laboratory inspections must be performed prior to initial certification and annually thereafter by Department staff as established by these regulations. A laboratory meeting the requirements of these regulations will be issued a certificate. Recertification shall be required each July 1.

5~~6~~.2 Initial Application

5~~6~~.2.1 Laboratory directors must submit to the Department a ~~written request~~ completed application (Appendix B) for certification of their laboratory.

5~~6~~.2.2 The Department will acknowledge the request and provide a copy of thi~~s~~e rule~~s and regulations~~ to the laboratory.

5~~6~~.2.3 To be certified, laboratories ~~shall meet~~must be compliant with all applicable requirements in Parts 6,7,8,9 and Appendix 2C ~~of these rules~~ and ~~pass~~ participate in an initial on-site inspection.

5~~6~~.3 Application for Continued Certification

5~~6~~.3.1 Annually the laboratory director must provide a completed application (Appendix ~~2~~B), no later than June 1, to the Department to be considered for continued certification.

5~~6~~.3.2 Laboratories must be recertified annually starting ~~every~~ July 1, and certification will be for a period of 1 year.

5~~6~~.3.3 Certified laboratories referring specimens to ABFT accredited laboratories must include documentation with the application (Appendix 2B) that the reference laboratory is ABFT accredited.

5~~6~~.3.4 Laboratories must maintain a listing of all analytical methods used by the laboratory and all analytes tested and reported by the laboratory. The laboratory must provide this listing to the Department upon request.

5~~6~~.3.5 To maintain certification, laboratories shall meet all applicable requirements found in Parts 5-8, ~~6,7,8,9~~, and Appendix ~~2~~C of the~~se~~ rules and ~~pass~~ participate in an annual on-site inspection.

5~~6~~.4 General Requirements

5~~6~~.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.

5~~6~~.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 and document employee competency as specified in Appendix ~~2~~C.

5~~6~~.4.3 The laboratory must notify the Department in writing within thirty days of any changes pertaining to laboratory location or personnel.

5~~6~~.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.

5~~6~~.4.5 The laboratory must have adequate space, equipment, materials, and controls available to perform the tests reported.

5~~6~~.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.

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5~~6~~.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 ~~2~~C, Section B5 (a-u).

5~~6~~.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 may be inspected on an unannounced basis to evaluate complaints.

5~~6~~.4.8 Effective April 1, 2009, the laboratory must maintain all records related to analysis for a minimum of 5 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.

5~~6~~.5 Proficiency Testing requirements for Blood, Urine and Post Mortem Samples

5~~6~~.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.

5~~6~~.5.2 Prior to initial certification, the laboratory must have successfully participated in one of the designated proficiency testing events in the category for which the laboratory seeks certification, within the past 12 months.

5~~6~~.5.3 To maintain continued laboratory certification, a laboratory must participate in the designated PT program and maintain satisfactory performance as determined by the department.

5~~6~~.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.

5~~6~~.5.4.1 The laboratory must request that the proficiency testing provider mail a consultant copy of their PT survey results to:

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Colorado Department of Public Health and Environment

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Laboratory Services Division

Certification Program

8100 Lowry Boulevard

Denver, CO 80230-6828

56.5.5 Blood Alcohol Testing

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

56.5.5.2 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 to the Department.

56.5.5.3 Other forensically significant volatiles, such as acetone, methanol and isopropanol, may be included in one or more PT samples. The laboratory must be able to detect any volatile included in the PT samples and must retain documentation of this detection with the PT results.

56.5.5.4 Grading Criteria for Blood Alcohol Proficiency Testing

56.5.5.4.1 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.

56.5.5.4.2 The laboratory must investigate any score less than 100% and undertake corrective action as needed. The investigation outcome and corrective action must be submitted to the Department within 15 days of receipt of the results for approval.

56.5.5.4.3 The PT provider will score each event as "satisfactory or "unsatisfactory" and the results will be reviewed by the Department to determine if successful PT performance has been achieved. 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.

56.5.6 Urine, Blood and Post Mortem Drug Testing

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

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

56.5.6.1.2 For urine-drug certification the required program is the Urine Toxicology (UT) survey.

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56.5.6.1.3 For laboratories performing only post mortem forensic toxicology testing the required programs are the Toxicology (T) and the Urine Toxicology (UT) surveys.

56.5.6.1.4 Laboratories certified for both blood and urine drug testing are eligible to apply for post mortem certification without participating in the Toxicology (T) survey.

~~6.5.6.2 A satisfactory event score is the identification of 80% of the target analytes present with no false positives. Any false positive will result in an unsatisfactory score for the PT event.~~

~~6.5.6.3 All analytes listed and reported by the laboratory to the Department must be tested for in the proficiency testing challenges when provided.~~

~~6.5.6.4 Whenever a laboratory has an unsatisfactory PT event, the laboratory must investigate and undertake corrective action as needed. The investigation outcome and corrective action documentation must be submitted to the Department within 15 calendar days of receipt of the results for approval.~~

~~6.5.6.5 Whenever a quantitative result reported by the laboratory in a PT challenge exceeds 20% from the target concentration, the laboratory must undertake and document corrective action. The corrective action documentation must be retained with the PT results.~~

~~6.5.6.6 A laboratory will be suspended from a category if two consecutive unsatisfactory PT events occur, or two out of three consecutive unsatisfactory PT events occur for unsuccessful PT performance. 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 revocation of the certificate and require two successful PT events before the laboratory may be eligible to reapply for certification. The laboratory may request the PT provider send, at the expense of the laboratory, one extra set of the designated PT samples when suspension status occurs.~~

5.5.6.2 Grading Criteria for Drug Proficiency Testing

5.5.6.2.1 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.

5.5.6.2.2 All analytes listed and reported by the laboratory to the Department must be tested for in the proficiency testing challenges when provided.

5.5.6.2.3 A satisfactory event score is the identification of 80% of the target analytes present with no false positives. Any false positive will result in an unsatisfactory score for the PT event.

5.5.6.2.4 Whenever a laboratory has an unsatisfactory PT event (less than 80%), the laboratory must investigate and undertake corrective action as needed. The investigation outcome and corrective

action documentation must be submitted to the Department within 15 calendar days of receipt of the results for approval.

5.5.6.2.5 Whenever a quantitative result reported by the laboratory in a PT challenge exceeds 20% from the target concentration, or is considered "unacceptable" by the PT provider, the laboratory must undertake and document corrective action. The corrective action documentation must be retained with the PT results.

5.5.6.2.6 A laboratory will be suspended from a category if two consecutive unsatisfactory PT events occur, or two out of three consecutive unsatisfactory PT events occur for unsuccessful PT performance. 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 revocation of the certificate and require two successful PT events before the laboratory may be eligible to reapply for certification. The laboratory may request the PT provider send, at the expense of the laboratory, one extra set of the designated PT samples when suspension status occurs.

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~~6~~.6 On-Site Laboratory Inspection

~~5~~6.6.1 On-site laboratory inspections must be performed prior to initial certification and annually thereafter by the Department.

~~5~~6.6.2 The on-site inspection will include a review of the laboratory's practices to ~~assure~~ ensure compliance with these regulations. The requirements are in checklist format in Appendix 2C.

~~5~~6.6.3 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.

~~5~~6.6.4 The ~~on-site inspection's~~ inspection checklist (Appendix 2C) will be used ~~systematically~~ onsite to evaluate and assess the ~~a~~ laboratory's compliance with these certification requirements. 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~~ included in a report to ~~include~~describe the noncompliant practice, the source of information and the scope and extent of the noncompliant practice.

~~5~~6.6.5 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 sent to the laboratory within 15 days of inspection.

~~5~~6.6.6 ~~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.~~ When noncompliant practices are identified in an inspection report, the laboratory must provide a written response to the report within 15 days of receipt. The laboratory's written plan of correction must address each noncompliant item cited as 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" .

5~~6~~.6.7 The written plan of correction will be reviewed by the inspector, and if acceptable, will be approved. Any items requiring clarification will be resolved by phone or written correspondence.

5~~6~~.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~~ changes 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 is difficult to verify by documentation, or if practices subject to correction have significant potential for direct impact on the quality of laboratory results when determined by the department.

5~~6~~.6.9 Identification of noncompliant practices directly resulting in inaccurate laboratory reports, failure to provide a plan of correction or failure to adequately correct 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.

5~~6~~.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.

5~~6~~.6.11 The Department will annually publish a list of certified laboratories.

Part 6~~7~~: Blood Forensic Toxicology – Collection and Testing Requirements ~~[Eff. 03/02/2009]~~

6~~7~~.1 Blood Specimen Collection

6~~7~~.1.1 Blood Specimen(s) must be:

6~~7~~.1.1.1 Collected in the presence of the arresting officer or other responsible person who can authenticate the specimens.

6~~7~~.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 collecting blood specimens under the supervision of a physician or nurse.

6~~7~~.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.

6~~7~~.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~~phenol solutions must not be used as a skin antiseptic.

6~~7~~.1.2 After Collection, Blood Specimens must be:

6~~7~~.1.2.1 ~~Dispensed or collected directly into two sterile tubes resulting in a sodium fluoride concentration greater than 0.90 percent weight.~~Dispensed or collected directly into two sterile tubes containing 1.0 percent sodium fluoride preservative as labeled by the manufacturer.

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67.1.2.2 Inverted several times to properly mix the blood with the sodium fluoride.

67.1.2.3 Affixed with an identification label and evidence seal.

67.1.2.4 The specimens must be placed in secured temporary refrigerated storage at less than 8 degrees Centigrade or frozen until shipped. Specimens must be shipped within 7 days of collection.

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67.2 Blood Specimen Testing

67.2.1 One tube of blood must be analyzed for the State's test(s). The State's test(s) must be performed and completed in a reasonable period of time as not to affect the validity of the test(s). Specimens found to be positive on the initial test(s) must be confirmed prior to reporting the results.

67.2.2 Any remaining blood specimens must be retained and stored by the certified laboratory at less than 8 degrees Centigrade or frozen for a period of not less than 12 months from the date of collection unless requested and receipted by a representative of another certified laboratory, acting on behalf of the defendant.

67.2.3 The second blood specimen must be analyzed by a certified laboratory designated by the defendant or defendant's legal counsel. The test(s) must be performed and completed in a reasonable period of time as not to affect the validity of the test(s). Specimens found to be positive on the initial test(s) must be confirmed prior to reporting the results to a court of law.

Part 78: Urine Forensic Toxicology – Collection and Testing Requirements ~~[Eff. 03/02/2009]~~

78.1 Urine Specimen Collection

78.1.1 Urine specimen(s) must be:

78.1.1.1 Collected in the presence of collection personnel who can authenticate the specimen(s).

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78.1.1.2 Collected in a clean, sterile container.

78.1.1.3 Affixed with an identification label and evidence seal.

78.1.1.4 The specimens must be placed in secured temporary refrigerated storage at less than 8 degrees Centigrade or frozen until shipped. Specimens must be shipped within 7 days of collection.

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78.2 Urine Specimen Testing

78.2.1 The State's test(s) must be performed and completed in a reasonable period of time as not to affect the validity of the test(s). Specimens found to be positive on the initial test(s) must be confirmed prior to reporting the results.

78.2.2 Any remaining urine specimen(s) must be retained by the certified laboratory in frozen storage for a period of not less than 12 months unless requested and receipted ~~for~~ by a representative ~~of~~ from another certified laboratory acting on behalf of the defendant.

78.2.3 Any remaining urine specimen(s) must be analyzed by a certified laboratory designated by the defendant or defendant's legal counsel. The test(s) must be performed and completed in a reasonable period of time as not to affect the validity of the test(s). Specimens found to be positive on the initial test(s) must be confirmed prior to reporting the results to a court of law.

PART 89: Post Mortem Forensic Toxicology – Collection and Testing Requirements ~~[Eff. 03/02/2009]~~

89.1 Post Mortem Specimen Collection

89.1.1 Collection of specimens from deceased persons is conducted as per Section 42-4-1304, C.R.S. by a person who's training and normal duties include the collection of blood specimens from deceased persons.

89.1.2 The laboratory must develop and provide detailed guidelines and instructions for the collection of post mortem specimens.

89.1.3 Each specimen should be labeled with the name of the subject from whom the specimens were collected together with other appropriate identification; for example, the medical examiner's case number and/or a unique identification number.

9.1.4 Whenever possible, the amount of specimen collected should be sufficient to allow for analysis of one or more analytes if needed at a later date.

89.2 Post Mortem Specimen Testing

89.2.1 Post mortem test(s) must be performed and completed within a reasonable period of time as to not affect the validity of the test(s). Specimens found to be positive on the initial test(s) must be confirmed prior to reporting the results.

89.2.2 Any remaining post mortem specimens must be retained by the certified laboratory for a period of not less than 12 months unless requested and receipted ~~for~~ by a representative ~~of~~ from another certified laboratory acting on behalf of the defendant.

PART 910: Violations and Remedies ~~[Eff. 03/02/2009]~~

910.1 Violations

910.1.1 It is a violation of these rules and regulations to perform EBAT testing without the appropriate certification for the EBAT instrument, operator or instructor.

910.1.2 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.

910.1.3 Generally, a violation will not be cited if:

910.1.3.1 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.

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910.1.3.2 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.

910.2 Complaints

910.2.1 Complaints received by the department will be investigated to determine if the claim is substantiated or unsubstantiated. Complaints received will be documented and an investigation may include and result in, but is not limited to, the following actions: desk review of documentation request by the Department from the laboratory, unannounced onsite survey, limitation, suspension, or revocation of the laboratory's certification.

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

910.3.1 Any ~~approved~~ certified facility, certified laboratory, operator or 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.

910.4 Denial, Suspension or Revocation of Certification:

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

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

910.4.1.2 Refusing authorized department personnel access to the laboratory or facility, or failure to provide requested records to the Department for the purpose of determining compliance with these rules and regulations.

910.4.1.3 Gross incompetence or negligent practice.

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

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

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

910.4.1.7 For a laboratory, failure to successfully participate in proficiency testing.

910.4.1.8 For a laboratory, the receipt of two consecutive "unsatisfactory" evaluations, or achievement of an "unsatisfactory" score in 2 of any 3 consecutive proficiency testing events.

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

910.5 Injunction

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

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~~APPENDIX 1A Reserved [Eff. 03/02/2009]~~

APPENDIX A - Evidential Breath Alcohol Testing Facility Inspection Report

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EVIDENTIAL BREATH ALCOHOL TESTING (EBAT) FACILITY INSPECTION REPORT

To: **Date:**
Agency: **From:**

Phone:
E-mail:

Type of Inspection: **Serial Number:**

On an on-site Evidential Breath Alcohol Test device Facility Inspection was performed for the location of Intoxilyzer S.N. at the .

Thank you,

A. INITIAL EBAT FACILITY CERTIFICATION

1. Facilities must submit a formal request to the Department requesting certification.

☐ Not Applicable
☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:
Date Received:

2. Verification from a certified electrician confirming the certified EBAT instrument is on an isolated power circuit.

☐ Not Applicable
☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:
Date Received:

3. Verification of review by the facility of Part 3 and Appendix 1A prior to requesting certification.

☐ Not Applicable
☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:
Date Received:

4. Verification from the facility that the certified EBAT instrument has dedicated communication lines installed and active.

☐ Not Applicable
☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:
Date Received:

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B. POWER REQUIREMENTS—EBAT PERMANENT LOCATION

1. AC line voltage of 120 volts, 60 Hz with grounded, 3-prong outlets and a 20 ampere or less circuit breaker must be provided.

1a. 20 ampere or less circuit breaker

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

1b. Voltage 120 ± 12 (=108-132)

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

1c. Grounded Outlet

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

1d. 3-prong Outlet

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

2. The power line to the certified EBAT instrumentation must be on a dedicated and isolated circuit.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

3. An adequate surge protection device must be placed between the certified EBAT instrumentation and the power source.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

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C. POWER REQUIREMENTS—EBAT MOBILE LOCATION

1. Power inverter/sine wave converter combinations that generate 120 volts AC from 14 volts DC.

☐ Not Applicable
☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

2. Electric motor/generator combinations that use a 12 volt DC motor to run a 120 volt AC 60 Hz generator.

☐ Not Applicable
☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

3. The power line to the certified EBAT instrumentation must be on a dedicated and isolated circuit.

☐ Not Applicable
☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

4. An adequate surge protection device must be placed between the certified EBAT instrumentation and the power source.

☐ Not Applicable
☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

D. EBAT ENVIRONMENT

1. The temperature of the EBAT facility must be maintained between 60 and 90 degrees Fahrenheit.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

2. The EBAT facility must have adequate lighting.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

3. The area around and under the certified EBAT instrumentation must be free of dust, dirt, and kept orderly.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

4. The certified EBAT instrumentation must be placed on a solid and adequate work surface.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

5. The certified EBAT instrumentation receives adequate ventilation.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

6. Automobile emissions are not allowed in the EBAT facility.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

7. The certified EBAT instrumentation must not have cleaning compounds or volatile organics (gasoline and petroleum products) used or stored around it.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

8. The EBAT facility must remain secure and not readily accessible to unauthorized personnel.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

E. EBAT DOCUMENTS

1. The following certified EBAT instrumentation documents must be posted at the EBAT facility:

1e. EBAT instrument Certification Certificate

☐ Acceptable
☐ Not Acceptable

2e. EBAT Instrument Exception Message Sheet

☐ Acceptable
☐ Not Acceptable

2. Certified EBAT instrumentation records must be retained by the certified EBAT facility for a minimum of 5 years.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

F. EBAT SUPPLIES

1. The EBAT facility must have available an adequate supply of mouth pieces:

☐ Acceptable
☐ Not Acceptable

2. The EBAT facility must have available an adequate supply of Simulator Quality Control Solution

☐ Acceptable
☐ Not Acceptable
Comments:

Lot #:

G. EBAT INSTRUMENTATION

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1. EBAT Test Sequence
☐ Acceptable
☐ Not Acceptable

2. EBAT Instrument Time and Date
☐ Acceptable
☐ Not Acceptable

3. EBAT Instrument Certification Date
☐ Acceptable
☐ Not Acceptable
Certification date:
Posted Certification Date:

4. EBAT Instrument External Breath Tube Heating
☐ Acceptable
☐ Not Acceptable

5. EBAT Instrument Dedicated Data Line
☐ Acceptable
☐ Not Acceptable
Comments:

6. EBAT Instrument Dedicated Analog Phone Line
☐ Acceptable
☐ Not Acceptable
Comments:
Analog Phone #:

7. The certified EBAT instrumentation must not be moved from the location it was certified for without prior authorization from the department.
☐ Not Applicable
☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

H. EBAT INSTRUMENTATION SIMULATORS

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1. Active Simulator

Serial Number: .....

Display Reading: (33.8°C and 34.2°C) ..... °C

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Digital thermometer reading: ..... °C

Comments:

2. Back-up Simulator

Serial Number: .....

Display Reading: (33.8°C and 34.2°C) ..... °C

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Digital thermometer reading: ..... °C

Comments:

3. Back-up Simulator

Serial Number: .....

Display Reading: (33.8°C and 34.2°C) ..... °C

Digital thermometer reading: ..... °C

Comments:

NIST Traceable Thermometer Information:

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Thermometer:

Serial Number:

Last Certification:

Next Certification:

Correction Factor:

I. RECORD REVIEW

1. 0.100 g/210L Simulator Quality Control Solution.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:
Standard Trend:

2. Corrective actions taken by the certified EBAT instructor or operator are appropriate and timely when exception messages are encountered.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

3. Simulator Quality Control Solution is changed as necessary and when required.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

4. Automated 7-Day calibration checks performed and reviewed.

☐ Acceptable
☐ Not Acceptable/Correction Required
Comments:

5. Average number of tests per month:

EBAT:

Training:

Active EBAT instructors:

Active EBAT operators:

~~APPENDIX 2A [Eff. 03/02/2009]~~

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~~APPENDIX 2A~~
~~Colorado Department of Public Health and Environment~~
~~Laboratory Services Division~~
~~Breath Alcohol Testing Program~~

~~Approved checklist for Evidential Breath Alcohol Test(s), using the certified EBAT instrument, in compliance with the Colorado Board of Heath Rules and Regulations concerning testing for alcohol and other drugs, 5 CCR 1005-2, as amended.~~

~~SUBJECT:~~~~_____~~

~~DATE:~~~~_____~~

~~Certified EBAT 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 button on or observe the power button has been activated. If the certified EBAT instrument is in the standby mode, press the START TEST button.~~

~~( ) 2. The subject must remove foreign objects from the nose and mouth including removable dentures. The subject must be closely and continuously observed for 20 minutes prior to testing to ensure 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 button.~~

~~( ) 6. Follow the instructions and sequence of events as they appear on the certified EBAT instrument display.~~

~~( ) 7. Retain all printouts generated by the certified EBAT instrument to include error messages and all Appendix 2A checklists initiated with the DUI packet.~~

~~THIS EVIDENTIAL BREATH ALCOHOL TEST WAS CONDUCTED IN ACCORDANCE WITH THE COLORADO BOARD OF HEALTH RULES AND REGULATIONS, 5 CCR 1005-2.~~

~~_____~~
~~Certified EBAT Operator or Instructor Conducting Test~~

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~~APPENDIX 2B [Eff. 03/02/2009]~~

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~~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~~

~~APPLICATION TYPE~~

~~☐ INITIAL ☐ UPDATE (Include any required documentation)~~

~~☐ RE-CERTIFICATION (Must be submitted 30 days prior certification expiration date)~~

~~LABORATORY NAME: _____~~

~~LABORATORY DIRECTOR: _____~~

~~FACILITY ADDRESS: _____~~

~~MAILING ADDRESS: _____~~

~~(If different from facility address)~~

~~CITY: _____ STATE: _____ ZIP: CODE: _____~~

~~PHONE NUMBER: (____) _____ FAX NUMBER: (____) _____~~

~~CONTACT PERSON: _____~~

~~EMAIL ADDRESS: _____~~

~~ANALYTICAL CATEGORIES:~~

~~Screening or Initial Testing~~	~~Method (list)~~	~~Number of samples in past year~~		**~~Confirmation Testing~~**	~~Method (list)~~	~~Number of samples in past year~~
~~Blood Alcohol~~				~~Blood Alcohol~~		
~~Blood drug~~				~~Blood Drug~~		
~~Urine Drug~~				~~Urine Drug~~		
~~Post Mortem~~				~~Post Mortem~~		

~~Laboratories referring specimens to ABFT accredited laboratories must include documentation to show proof of accreditation status with this application.~~

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

~~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 Laboratory Director)~~ ~~(Date)~~

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APPENDIX B

DUI and DUID Forensic Toxicology 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

APPLICATION TYPE

☐ **INITIAL** ☐ **UPDATE (Include any required documentation)**

☐ **RE-CERTIFICATION (Must be submitted 30 days prior certification expiration date)**

LABORATORY NAME: _____

LABORATORY DIRECTOR: _____

FACILITY ADDRESS: _____

MAILING ADDRESS: _____

(If different from facility address)

CITY: _____ STATE: _____ ZIP: CODE: _____

PHONE NUMBER: (____) FAX NUMBER: (____)

CONTACT PERSON: _____

EMAIL ADDRESS: _____

ANALYTICAL CATEGORIES:

Screening or Initial Testing	Method (list)	Number of samples in past year		**Confirmation Testing**	Method (list)	Number of samples in past year
Blood Alcohol				Blood Alcohol		
Blood drug				Blood Drug		
Urine Drug				Urine Drug		
Post Mortem				Post Mortem		
ABFT Reference Lab Samples				ABFT Reference Lab Samples		

Laboratories referring specimens to ABFT accredited laboratories must include documentation to show proof of accreditation status with this application.

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

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 Laboratory Director) **(Date)**

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APPENDIX 2C [Eff. 03/02/2009]

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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 Is the laboratory director: board certified in clinical pathology by the American Board of Pathology; certified as a diplomat by the American Board of Forensic Toxicology (ABFT); or alternatively, have a doctoral degree in one of the natural sciences and at least three years of full-time laboratory experience in forensic toxicology; or a master's degree in one of the natural sciences and at least four years of full-time experience in forensic toxicology; or a bachelor's degree in one of the natural sciences and at least five years full-time experience in forensic toxicology?
3. Y N NA Does the laboratory director supervise and maintain documentation that the daily functions of the laboratory are meeting the requirements specified in these rules?
4. Y N NA If the laboratory director does not supervise the daily functions of the laboratory, has this responsibility been delegated in writing to a qualified supervisory analyst?
5. Y N NA Does the supervisory analyst have at minimum, a bachelor's degree in one of the natural sciences and either three years full-time experience performing forensic toxicology testing or 3 years experience in analytic toxicology and 1 year experience in forensic toxicology?

6. Y N NA Does the supervisory analyst supervise the testing analyst(s) and maintain documentation that the daily functions of the laboratory are meeting the requirement specified in these rules and regulations?

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

8. Y N NA Does the laboratory director or designated supervisory analyst ensure policies and procedures to assess the testing analyst(s) competency is established, followed and documented?

9. Y N NA Is competency assessment performed and documented on new analysts prior to reporting results; on existing analysts on an ongoing basis; and on all analysts when a method or instrumentation is added or modified by the laboratory prior to reporting subject results? Is the competency assessment and documentation consistent with the laboratory's training policies and procedures?

10. Y N NA Does the laboratory maintain documentation for the director and all analysts' education, training and experience?

11. 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 available to testing analysts at all times?

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

3. Y N NA Has the current laboratory director approved, signed and dated each procedure?

4. Y N NA Has the laboratory director approved, initialed and dated each change or revision to the procedure?

5. Does the procedure manual include criteria and processes 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 to include TO accuracy, precision, analytical sensitivity, analytical specificity (interferences), limit of detection (LOD), limit of quantitation (LOQ) and verification of the reportable 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?

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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 to include any abbreviated versions used by the testing analyst(s)?

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?

Y N NA u) Policies and procedures to follow when specimens are requested for referral and testing by another certified laboratory?

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 analysts as used for subject testing?

4. Y N NA Has the laboratory director and all testing analysts participating in the PT challenge signed the attestation statements?

5. Y N NA Effective April 1, 2009, does the laboratory maintain a copy of all records and documentation in a litigation packet format as defined in part 1.5 of these rules, for a minimum of 5 years from the date of the proficiency testing event?

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

7. Y N NA Has the laboratory taken and documented remedial action when a score of less than 100% is achieved during a PT event to include any results greater than 20% from any quantitative target value for that analyte?

8. Y N NA Has the laboratory notified and provided corrective action documentation to the department within 15 calendar days of receipt of unsatisfactory PT results (less than 100% for blood alcohol and less than 80% for urine and blood drugs) for approval?

D. QUALITY ASSURANCE AND QUALITY CONTROL

1. Y N NA Are there records of preventive maintenance, repair, troubleshooting logs and corrective actions present?

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

3. Y N NA Does the laboratory clean, maintain and calibrate as needed the analytical balances and in addition, verify the performance of the balance annually using certified weights to include three or more weights bracketing the ranges of measurement used by the laboratory?

4. Y N NA Does the laboratory annually verify and document the accuracy of thermometers using a reference thermometer?

5. 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?

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

7. 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 and document agreement with NIST-traceable standards within 5%?

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

9. Y N NA Does the laboratory perform and document a calibration curve with each analysis (that has a correlation coefficient of 0.99 or greater for blood alcohol and 0.98 or greater for blood and urine drugs) using at least three calibrators throughout the reporting range to include the limit of quantitation (LOQ) and at minimum performed every six months or whenever there is a change in a procedure or equipment used?

10. Y N NA If the laboratory uses historical calibration data for an assay, has the linearity and precision of the curve been demonstrated and documented over time? Are controls used with each analytic run that validates the calibration over the entire range of the curve?

11. Y N NA Does the laboratory analyze a negative and at minimum two levels of controls, when available, differing in concentration and differing from the calibration material with each analytical run?

12. Y N NA Does the laboratory analyze at least one commercially prepared control that is NIST-traceable and within (10% for ethanol and 20% for blood and urine drugs) of the stated assayed value with each analytic run?

13. Y N NA Does the laboratory analyze an appropriate matrix blank and control with each analytical run, when available?

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

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

16.Y N NA Does the laboratory monitor and document the performance of calibrator and control material on an ongoing basis to ensure variance in performance does not exceed the laboratory's established criteria of acceptability?

17.Y N NA Does the laboratory have written criteria to follow when corrective action is required for unacceptable calibration, control, standard or instrument performance?

18.Y N NA Does the laboratory document the corrective actions taken when an unacceptable calibration, control, standard, or other reagent result exceeds the laboratory's criteria of acceptability?

19.Y N NA Are corrective actions documented and reviewed for effectiveness by the laboratory director or designated supervisory analyst on an ongoing basis to ensure the effectiveness of the actions taken?

20.Y N NA Does the laboratory maintain records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), limit of detection (LOD), limits of quantitation (LOQ) and verification of the linear range?

21. Y N NA Are analytical methods developed by the laboratory such that screening and confirmation drug testing can be completed on no more than 5 mL of sample volume?

22.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 login 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 colder?

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

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 Prior to reporting results, are all specimens that have been identified as positive on an initial screening drug test confirmed using a second quantitative analytical procedure utilizing a different technique and chemical principle from the initial screening test when available or as applicable?

3. Y N NA Does the laboratory confirm the identity of an analyte using a different extract of the same specimen that was used for the screening test?

4. Y N N A For post mortem testing, does the laboratory confirm the identity of a drug analyte or alcohol concentration using a different extract from the same sample or using a different sample extract from the same source when possible?

5. Y N NA Does the laboratory report quantitative results below the lowest concentration of calibrator or standard used in the analytical run?

6. Y N NA Does the laboratory verify results below the lowest concentration of calibrator or standard and above the limit of detection (LOD) by using a blank and a standard that falls below the expected value of the analyte in the sample in duplicate prior to reporting a quantitative result?

7. Y N NA Does the laboratory qualitatively report results below the lowest concentration of calibrator or standard as either trace or using a non-specific numerical designation? (e.g. positive but less than 0.5mg/L)

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

9. 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?

10. Y N NADoes the laboratory adequately document the available external chain of custody information?

11. Y N NADoes the laboratory's final report contain the name and location of the laboratory, name and unique identifier of subject, date and time of sample collection, sample received date, sample analysis date, identification of the testing analyst, test result, units of measure, and any other information or qualifiers needed for interpretation when applicable to the test method and results being reported.

12. Y N NA Has the laboratory developed an adequate litigation packet that meets the requirements specified in Part 1.5 of these rules and regulations?

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?

G.2 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, is 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?
7. Y N NA If the laboratory uses GC/MS for both screening and confirmation, does the laboratory use the sample library match for the screening portion and additionally run a known standard or control and include the retention time and mass spectra from the known standard or control and sample library for the confirmation?
8. Y N NA When GC/MS is used for both screening and confirmation, does the laboratory use a second sample aliquot extraction when available?

G.3 Immunoassays

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 the 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?

G.4 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?

G.5 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?

G.6 LIQUID CHROMATOGRAPHY MASS SPECTROSCOPY (LCMS) (LCMS/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 has written its own software, has the accuracy been verified prior to use and has the verification been documented?
5. Y N NA If the laboratory recycles eluting solvents, are there standards for acceptability?
6. Y N NA Does the laboratory use an internal standard with each batch of specimens for qualitative and quantitative analysis?
7. Y N NA If an internal standard is used for quantitative analysis, are its chemical and physical properties similar to 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?

9. Y N NA Does the laboratory analyze commercially prepared, isotopically labeled, internal standards for each compound identified in the method?

10. Y N NA Does the laboratory use an internal standard with a similar molecular structure when commercially prepared, isotopically labeled, internal standards are not available?

11. Y N NA Does the laboratory report results qualitatively or with any qualifying statements when commercially prepared, isotopically labeled, internal standards are not tested in the analytical run?

12. Y N NA Does the laboratory document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument.

13. Y N NA Does the laboratory document that method validation procedures are followed when changes in source, source conditions, eluent, or column are made prior to reporting test results?

COMMENTS SECTION:

APPENDIX C

DUI and DUID Forensic Toxicology Laboratory Certification 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 Is the laboratory director: board certified in clinical pathology by the American Board of Pathology; certified as a diplomate by the American Board of Forensic Toxicology (ABFT); or alternatively, have a doctoral degree in one of the natural sciences and at least three years of full-time laboratory experience in forensic toxicology; or a master's degree in one of the natural sciences and at least four years of full-time experience in forensic toxicology; or a bachelor's degree in one of the natural sciences and at least five years full-time experience in forensic toxicology?
3. Y N NA Does the laboratory director supervise and maintain documentation that the established protocols of the laboratory are being followed and monitored on an ongoing basis to ensure compliance?
4. Y N NA If the laboratory director does not provide direct supervision over daily operations of the laboratory, has this responsibility been delegated in writing to a qualified supervisory analyst?
5. Y N NA Does the supervisory analyst have at minimum, a bachelor's degree in one of the natural sciences and either three years full-time experience performing forensic toxicology testing or 3 years experience in analytical toxicology and 1 year experience in forensic toxicology?
6. Y N NA Does the supervisory analyst supervise the testing analyst(s) and maintain documentation that the established protocols of the laboratory are being followed and monitored on an ongoing basis to ensure compliance?
7. Y N NA Do the testing analysts have at minimum an associate degree in a laboratory science or one year training in a nationally recognized accredited laboratory program and one year documented on the job laboratory experience?
8. Y N NA Does the laboratory director or designated supervisory analyst ensure policies and procedures to assess the competency of testing analyst(s) are established, followed and documented?
9. Y N NA Is competency assessment performed and documented on new analysts prior to reporting results; on existing analysts on an ongoing basis; and on all analysts when a method or instrumentation is added or modified by the laboratory prior to reporting subject results? Is the competency assessment and documentation consistent with the laboratory's written training policies and procedures?
10. Y N NA Does the laboratory maintain documentation of education, training and experience for the director and all analysts'?
11. Y N NA Does each laboratory position have a written job description?

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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 available for testing analysts to follow at all times?
2. Y N NA Has the current laboratory director approved, signed and dated each procedure?
3. Y N NA Has the laboratory director approved, signed and dated each change or revision to the procedure?
4 (a-u) Does the Standard Operating Procedure (SOP) manual include criteria and processes for to following:

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 and/or extracts and records?
Y N NA g) Validating a new or revised method prior to testing specimens to include: accuracy, precision, analytical sensitivity, analytical specificity (interferences), limit of detection (LOD), limit of quantitation (LOQ) and verification of the reportable 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 and any abbreviated versions used by the testing analyst(s)?
Y N NA t) A documented system for review of the results of controls, standards, 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?
Y N NA u) Policies and procedures to follow when specimens are requested for referral and testing by another certified laboratory?
5. Y N NA Does the laboratory maintain copies of previous standard operating procedures and the dates they were in effect and the analytical results of testing for a least 5 years from the date last used?

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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 PT program(s) 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 using the same procedure with the same number of replicate analyses, standards, testing analysts and equipment as used for subject testing?
4. Y N NA Has the laboratory director and all testing analysts participating in the PT challenge signed the corresponding attestation statements?
5. Y N NA Effective April 1, 2009, does the laboratory maintain a copy of all records and documentation in a litigation packet format as defined in part 1.5 of these rules, for a minimum of 5 years from the date of the proficiency testing event?
6. Y N NA Has the laboratory director reviewed and evaluated all PT results?
7. Y N NA Has the laboratory taken and documented remedial action when a score of less than 100% is achieved during a Blood Alcohol PT event or 80% during a Drug PT event to include any quantitative results greater than 20% from the target value or graded as unacceptable by the PT agency for that analyte?
8. Y N NA Has the laboratory notified and provided corrective action documentation to the Department for approval within 15 calendar days of receipt of unsatisfactory PT results (less than 100% for blood alcohol and less than 80% for urine and blood drugs)?
9. Y N NA Does the laboratory only report those analytes that are included on the master list of drugs for each PT program in which they participate? If the laboratory does report other analytes than those included in the PT program, do they have documented activities performed to ensure the accuracy of those analytes?
10. Y N NA Has the laboratory documented corrective actions taken when the reported PT results exceeded 20% from the listed target concentration, and when the laboratory result is scored as unacceptable by the PT provider.

D. QUALITY ASSURANCE AND QUALITY CONTROL

1. Y N NA Are there records of instrument preventive maintenance, repair, troubleshooting and corrective actions present?

2. Y N NA Does the laboratory check and document the accuracy of automatic and/or adjustable pipettes and other measuring devices when placed into service and annually thereafter?
3. Y N NA Does the laboratory clean, maintain and calibrate as needed the analytical balances and in addition, verify the performance of the balance annually using certified weights to include three or more weights bracketing the ranges of measurement used by the laboratory?
4. Y N NA Does the laboratory annually verify and document the accuracy of thermometers using a reference thermometer?

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5. 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?

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

7. 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 and document agreement with NIST-traceable standards within 5%?

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

9. Y N NA Does the laboratory perform and document a calibration curve with each analysis (that has a correlation coefficient of 0.99 or greater for blood alcohol and 0.98 or greater for blood and urine drugs) using at least three calibrators throughout the reporting range to include the limit of quantitation (LOQ) and whenever there is a change in the procedure or equipment used?

10. Y N NA If the laboratory uses historical calibration data for an assay, has the linearity and precision of the curve been demonstrated and documented over time? In addition to a negative control, are 3 levels of controls at minimum used with each analytical run to verify the entire calibration curve with two controls bracketing all results reported?

11. Y N NA For qualitative analyses, does the laboratory analyze, at minimum, a negative and a positive control with each batch of samples analyzed?

12. Y N NA For quantitative analyses, does the laboratory analyze a negative and at minimum two levels of controls that challenges the linearity of the entire curve, and brackets the subject reported results. linear range or bracket the concentration of results reported ,

13. Y N NA Does the laboratory use control material that differs in either; source or, lot number or, differs in concentration from the calibration material used with each analytical run?

14. Y N NA For multi-analyte assays, does the laboratory perform and document calibration curves and controls specific to each analyte, or at minimum, one with similar chemical properties as reported in the batch?

15. Y N NA Does the laboratory analyze at least one commercially prepared control that is NIST-traceable and within (10% for ethanol and 20% for blood and urine drugs) of the stated assayed value with each analytic run?

16. Y N NA Does the laboratory analyze an appropriate matrix blank and control with each analytical run, when available?

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

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

19. Y N NA Does the laboratory monitor and document the performance of calibrator and control material on an ongoing basis to ensure performance does not exceed the laboratory's established criteria of acceptability?

20. Y N NA Does the laboratory have written criteria to follow when corrective action is required for unacceptable calibration, control, and standard or instrument performance?

21. Y N NA Does the laboratory document the corrective actions taken when an unacceptable calibration, control, standard, or other reagent result exceeds the laboratory's criteria of acceptability?

22. Y N NA Are corrective actions documented and reviewed for effectiveness by the laboratory director or designated supervisory analyst on an ongoing basis to ensure the effectiveness of the actions taken?

23. Y N NA Does the laboratory maintain records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), limit of detection (LOD), limits of quantitation (LOQ) and verification of the linear range?

24. Y N NA Are analytical methods developed by the laboratory such that screening and confirmation testing can be completed on no more than 5 mL of sample volume?

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

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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, which includes the requirements for specimen type(s) and volume?
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 the corresponding 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 sent to another certified laboratory whenever requested by defendant's legal counsel?
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 login 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 colder?
14. Y N NA Are blood specimens stored for at least 1 year at less than 8 degrees C or frozen?
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 and humidity control adequate? Are the room temperature and humidity conditions consistent with manufacturer requirements?

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 Prior to reporting results, are all specimens that have been identified as positive on an initial screening drug test confirmed using a second analytical procedure using a different technique and chemical principle from the initial screening test, when available or as applicable?
3. Y N NA Prior to reporting results, are all ethanol results confirmed using a second GC column where the result from the second column had significant difference in retention time and a change in elution order of some of the common volatiles from the column utilized in the initial test?
4. Y N NA If blood samples are screened for ethanol by gas chromatography, is a separate aliquot from the original specimen used for confirmation? (e.g. two separate aliquots should be tested for blood alcohol)
5. Y N NA Does the laboratory confirm the identity of an analyte using a different extract of the same specimen that was used for the screening test?
6. Y N NA For post mortem testing, does the laboratory confirm the identity of a drug analyte or alcohol concentration using a different extract from the same sample or using a different sample extract from the same source when possible?
7. Y N NA Does the laboratory only report quantitative results above the lowest concentration of calibrator or standard used in the analytical run?

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8. Y N NA Does the laboratory verify results below the lowest concentration of calibrator or standard and above the limit of detection (LOD) by using a blank and a standard that falls below the expected value of the analyte in the sample in duplicate prior to reporting a quantitative result?

9. Y N NA Does the laboratory qualitatively report results below the lowest concentration of calibrator or standard as either trace or using a non-specific numerical designation? (e.g. positive but less than 0.5mg/L)

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

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

12. Y N NA Does the laboratory's final report contain the name and location of the laboratory, name and unique identifier of subject, , submitting agency, sample received date, , date of report, type of specimen tested, test result, units of measure, and any other information or qualifiers needed for interpretation when applicable to the test method and results being reported.

13. Y N NA Has the laboratory developed an adequate litigation packet that meets the requirements specified in Part 1.5 of these rules and regulations?

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 each day of use?
2. Y N NA Does the laboratory document the performance of new columns before use? How?
3. Y N NA Does the laboratory use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified?
4. Y N NA Does the laboratory monitor the response (area or peak height) of the internal standard to ensure consistency over time of the analytical system?

G.2 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 Does the laboratory document changes of septa as specified in the SOP?
5. Y N NA Is there documentation of liners being cleaned or replaced as specified in the SOP?
6. Y N NA If the laboratory uses full scan mass spectral identification through library searching, is there documented criteria for acceptability?
7. Y N NA If the laboratory uses Selected Ion Monitoring (SIM) for identification does it compare ion ratios and retention times between calibrators, controls and specimens?
8. Y N NA Does the laboratory use an internal standard for qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified?
9. 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?
10. Y N NA Within each run, does the laboratory compare ion ratios and retention times between calibrators, controls and specimens?

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11. Y N NA Does the laboratory define the criteria for designating qualitative results as positive?
12. Y N NA If the laboratory has written its' own software, has it been documented and the accuracy verified?
13. Y N NA If the laboratory uses GC/MS for both screening and confirmation, does the laboratory analyze two aliquots at minimum, tested on a different day and in a different batch than the original aliquot?
14. Y N NA If the laboratory uses a sample library match to qualitatively identify an analyte, does the laboratory compare the retention time and mass spectra from a known standard or control before reporting the results?
15. Y N NA When GC/MS is used for both screening and confirmation, does the laboratory use a second sample aliquot extraction when available?
16. Y N NA Does the laboratory check for carry-over and contamination?
17. Y N NA Is the internal standard isotopic ally labeled?

G.3 Immunoassays

1. Y N NA Does the laboratory follow the manufacturer's instructions for maintenance and service of the instrument?
2. Y N NA Are the maintenance records readily available to the staff operating the equipment?
3. Y N NA If the laboratory tests specimens different from what the manufacturer has approved for the assay, or if the laboratory modified the test method from the manufacturer instructions, has the laboratory validated these changes?
4. Y N NA Does the laboratory define acceptable separation or measurement units (absorbance intensity or counts per minute) for each assay? Is this consistent with manufacturer instructions
5. Y N NA How does the laboratory ensure that it is meeting the minimum separation requirements?

G.4 Thin Layer Chromatography

1. Y N NA Does the laboratory apply un-extracted standards to each thin layer chromatographic plate?
2. Y N NA Does the laboratory include in their written procedure the preparation of mixed solvent systems, spray reagents and designation of lifetime?
3. Y N NA Does the laboratory include in their written procedure the storage of unused TLC plates? Are desiccators necessary?
4. 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?
5. Y N NA Does the spotting technique preclude the possibility of contamination and/or carry-over? How is this verified?
6. Y N NA Does the laboratory measure all appropriate RF values for qualitative identification purposes?
7. Y N NA If the laboratory uses sequential color reactions, are these recorded?
8. Y N NA Does the laboratory maintain records of thin layer chromatographic plates?
9. Y N NA Does the laboratory analyze an appropriate matrix blank with each batch of specimens analyzed?

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G.5 High Pressure Liquid Chromatography (HPLC)

1. Y N NA Does the laboratory monitor and document the performance of the HPLC instrument each day of testing?
2. Y N NA Does the laboratory evaluate the performance of new columns before use? How?
3. Y N NA If the laboratory recycles eluting solvents, are there standards for acceptability?
4. Y N NA Does the laboratory use an internal standard with each batch of specimens for qualitative and quantitative analysis and are its chemical and physical properties similar to the analyte reported?
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?

G.6 Liquid Chromatography Mass Spectroscopy (LCMS) (LCMS/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 has written its own software, has the accuracy been verified prior to use and has the verification been documented?
5. Y N NA Does the laboratory use an internal standard with each batch of specimens for qualitative and quantitative analysis and are its chemical and physical properties similar to the analyte?
6. Y N NA Is the internal standard isotopic ally labeled?
7. 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?
8. Y N NA Within each run, does the laboratory compare the two transitions and retention times between calibrators, controls and specimens?
9. Y N NA Does the laboratory report results qualitatively or with any qualifying statements when commercially prepared, isotopic ally labeled, internal standards are not tested in the analytical run?
10. Y N NA Does the laboratory document and maintain records when changes in source, source conditions, eluent, or column are made to the instrument.
11. Y N NA Does the laboratory evaluate the performance of the instrument when changes in source, source conditions, eluent, or column are made prior to reporting test results? How?

COMMENTS SECTION:

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Editor's Notes

History

Entire Rule eff. 03/02/2009.