



Colorado Department of Public Health and Environment

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Laboratory Services Division

5 CCR 1005-2

RULES PERTAINING TO TESTING FOR ALCOHOL AND OTHER DRUGS
(Promulgated by the State Board of Health)

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

Part 1: General

1.1 Purpose and Scope

This rule establishes minimum standards for certification and approval of entities and processes used for alcohol and drug testing. This rule is applicable to: samples taken from subjects 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 suspected of being impaired by alcohol and/or drugs 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 The Colorado department of public health and environment has determined that results obtained from the certified EBAT instrument are scientifically accurate, precise, and analytically reliable 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.

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

1.4 Testing of blood alcohol, blood drug, urine drug and post mortem samples operate under Parts 5-8 and Appendix 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.

1.5 Definitions

"Analytical Non-Conformance" – refers to a result that has been reported by the certified laboratory that exceeds its established criteria of acceptability resulting in repeat analysis requiring amended reporting.

"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) take 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. "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" – refers to the term driving under the influence of alcohol and/or other drugs as defined by Colorado revised statute 42-4-1301.

"DWAI" – refers to the term driving while ability impaired by alcohol and/or other drugs as defined by Colorado revised statute 42-4-1301.

"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, and any exception messages which may have been encountered during the subject test attempts.

"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 certified by the Department to house the certified EBAT instrumentation.

"Internal Standard" – refers to a reference material that has similar chemical and physical properties to the analyte being measured and is added at a known concentration to a sample prior to testing.

"Laboratory Director" – the individual meeting the qualification requirements specified in Part 5 and Appendix 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 analytical run.

"Litigation Packet" – refers to records requested for litigation purposes that include sufficient material to allow independent review by a qualified toxicologist. the records must include when applicable, but are not limited to; the request of analysis, chain of custody documents, test subject analytical data, calibration, standard, quality control data from the subject analytic run, limits of quantitation (LOQ), limits of detection (LOD), analyst curriculum vitae (CV), and the standard operating procedure used during the analysis.

"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.

"Supervisory Analyst" – the individual(s) that meet the qualification requirements specified in Part 5 and Appendix 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)

- 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 by the department that may only be used by the certified EBAT operator to whom it was issued.
 - 2.1.2 To maintain active certification status, a certified EBAT operator must complete the following recertification requirements:
 - 2.1.2.1 Successfully perform and complete a recertification EBAT within a 180-day period, and
 - 2.1.2.2 Annually – Successfully complete the Department's certified EBAT operator recertification refresher course.
 - 2.1.2.3 Upon successful completion of the Department's operator recertification requirements, the certified EBAT operator card's 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 serve as evidence of certification.
- 2.2 If the certified EBAT operator fails to meet the EBAT recertification requirements found in this part, the Department will:
 - 2.2.1 Decertify the EBAT operator, and
 - 2.2.2 Deactivate the EBAT operator certification card used to access the certified EBAT instrument, and
 - 2.2.3 Maintain the EBAT operator in an inactive status until the EBAT operator certification requirements found in Part 2.1 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 a currently 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 certification course, the certified EBAT instructor will be issued an instrument access card that may only be used by the certified EBAT instructor to 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 Biennially - 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 refresher 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 instructor card issued by the Department may also serve as evidence of certification.
- 2.4 For any certified EBAT instructor that does not meet the EBAT recertification requirements found in this part the Department will:
 - 2.4.1 Decertify the EBAT instructor, and
 - 2.4.2 Deactivate the EBAT instructor certification card, used to access to the certified EBAT instrument, and
 - 2.4.3 Maintain the EBAT instructor in an inactive status until one of the following three recertification criteria are met:
 - 2.4.3.1 Within 30-days after expiration of the EBAT instructor certification expiration date, the inactive instructor must successfully complete a recertification 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,
 - 2.4.3.2 After 30-days from expiration of the EBAT instructor certification expiration date, the inactive instructor must meet the EBAT operator certification requirements found at Part 2.1, or
 - 2.4.3.3 The EBAT instructor meets the requirements found at Part 2.3 of the rule.
- 2.5 EBAT instructors or operators returning from active military service may reactivate their certification status by completing the following:
 - 2.5.1 Provide documentation of active duty status to the department, (period of absence must not exceed 2 years), and
 - 2.5.2 Successfully pass the EBAT instructor or operator certification test with a score of 80% or greater, and
 - 2.5.3 Successfully perform and complete a recertification EBAT.
 - 2.5.4 Upon successful completion of the recertification requirements in this Part, the certified EBAT instructor or operator card will be updated to an active status and become available for use during the next certification period.
 - 2.5.5 The certified EBAT instructor or operator must meet the requirements found in this Part in order to maintain an active certification status.

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 only in facilities that have been certified by the Department.
- 3.1.2 Department standards for certification of EBAT facilities are specified in Part 3 and Appendix A of this rule.
- 3.1.3 EBAT facilities meeting the standards of performance as specified in Part 3 and Appendix A of this rule may 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 When deficiencies are cited in a facility inspection report, a plan of correction must be received by the Department for review and approval within 15 days of receipt of the facility inspection report by the agency.
- 3.1.5 Initial certification – permanent, temporary, and mobile EBAT facilities.
 - 3.1.5.1 A facility representative must submit a written request to the Department for initial certification of an EBAT facility that must include:
 - 3.1.5.1.1 Acknowledgement from the facility representative that the requirements found in Part 3 and Appendix A have been reviewed prior to requesting certification.
 - 3.1.5.1.2 Documentation from a certified electrician verifying the power to the certified EBAT instrument is on its own dedicated power circuit.
 - 3.1.5.1.3 Verification from the facility representative that a dedicated and active data, and when available, analog phone line are installed and available for communications by the certified EBAT instrument.
 - 3.1.5.2 Upon receipt of the initial facility certification request, Department personnel will schedule an onsite inspection to verify compliance with the requirements found in Part 3 and Appendix A prior to certification.
 - 3.1.5.3 The Department will perform and onsite inspection at a certified EBAT facility 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 requests relocation of the certified EBAT instrument either temporarily or permanently 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 is certified for without prior authorization from the Department.

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 A certified EBAT instructor or operator to perform the test that is in an active status meeting the requirements found in Part 2, and

- 4.1.2 A certified EBAT facility where the test is to be conducted meeting the requirement found in Part 3, and
- 4.1.3 A certified EBAT instrument used to perform the test.
 - 4.1.3.1 Evidential breath specimens must be analyzed using a certified EBAT instrument approved for use by the Department. Certification of the EBAT instrument will be based on scientific standards of performance established by the Department.
 - 4.1.3.2 The Department must certify each EBAT instrument initially and annually thereafter.
 - 4.1.3.3 The Department will issue a certificate for each certified EBAT instrument after initial certification and after each annual certification. The certificate will reflect the certified EBAT instrument serial number and the inclusive dates for the certification period.
 - 4.1.3.4 Every EBAT sequence must include an assayed reference standard(s) with a known ethanol concentration of 0.100 grams of alcohol/210 liters of breath that brackets the subject's breath samples. The assayed reference standard(s) target value(s) is 0.100 grams of alcohol/210 liters of breath and must fall within a range of (0.090 – 0.110 grams of alcohol/210 liters of breath).
 - 4.1.3.4.1 The results of the assayed reference standard(s) must agree with each other within $\pm 10\%$ during the calibration checks.
 - 4.1.3.4.2 If the correlation between calibration checks is not within $\pm 10\%$, the instrument will discontinue the test sequence and print a "No Calibration Correlation" exception report.
 - 4.1.3.5 For each EBAT, the results of the two subject samples must agree with each other within 0.020 grams of alcohol/210 liters of breath.
 - 4.1.3.5.1 If the 0.020 grams of alcohol/210 liters of breath correlation is not obtained with the subject samples, the instrument will discontinue the test sequence and print a "No .02 Agreement" exception report.
 - 4.1.3.5.2 When a "No .02 Agreement" exception report is obtained, the certified EBAT instructor or operator must repeat the 20-minute deprivation period prior to retesting the subject.
 - 4.1.3.6 The two subject breath samples must meet the minimum measurement requirements in order to obtain a result. Samples not meeting the minimum sample requirements may result in an "Invalid Sample" exception report.
 - 4.1.3.6.1 If an "Invalid Sample" exception report is obtained, the certified EBAT instructor or operator must repeat the 20-minute deprivation period prior to retesting the subject.

4.2 Pre-Analytic EBAT 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 (evidential breath or blood alcohol) they prefer to take to determine the alcohol concentration in their body, or the choice to refuse either evidential chemical test. Nothing in this rule is intended to exempt or exonerate an individual from the penalties proscribed in sections 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.
- 4.2.2 Ensure the certified EBAT instrument is in the "Ready" mode. If the certified EBAT instrument is in "Standby" mode, depress the start test button to initiate the warm-up period.
- 4.2.3 Completion of a 20-minute deprivation period conducted at the certified EBAT facility by a certified EBAT instructor or operator that is in an active status that must include;
 - 4.2.2.1 Removal of any foreign material from the subject's mouth cavity that is not permanent in nature, prior to starting the 20-minute deprivation period, and

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

4.2.2.3 Observing the subject for signs of belching, regurgitation, or intake of any foreign material into the mouth cavity during the 20-minute deprivation period. If such observations occur, the 20-minute deprivation period must be repeated under the same conditions prior to testing.

4.2.4 Entry of the certified EBAT instructor or operator information into the certified EBAT instrument.

4.2.5 Entry of the arresting officer information into the certified EBAT instrument.

4.2.6 Entry of the subject information into the certified EBAT instrument to include the start time of the 20-minute deprivation period.

4.3 Analytic EBAT requirements include;

4.3.1 Providing the subject instruction for delivery of a breath sample that contains end-expiratory air from the lungs.

4.3.2 Starting the test sequence and following the test instructions displayed by the certified EBAT instrument.

4.3.3 Providing a clean mouthpiece with each breath sample provided by the subject.

4.3.4 Observing the subject through completion of the second breath sample to look for signs of belching, regurgitation, or intake of any foreign material into the mouth cavity. If such observations occur, the test sequence must be discontinued by the certified EBAT instructor or operator and another 20-minute deprivation period must be repeated under the same conditions prior to retesting.

4.3.5 Removal of the subject from the area in close proximity to the certified EBAT instrument during the two-minute period between breath samples in order to prevent tampering of the instrument during the test sequence.

4.4 Post-Analytic EBAT requirements include:

4.4.1 The certified EBAT instructor or operator must sign the completed EBAT report attestation statement indicating the test was performed in compliance with the procedures set forth by the Department and as prescribed by this rule.

4.4.2 The certified EBAT instructor or operator must review the final report(s) for completeness.

4.4.3 The certified EBAT instructor or operator must include all printouts generated by the certified EBAT instrument to include any associated exception reports (if applicable) that may have been encountered during the subject test attempt(s).

4.4.3 All printouts generated from the certified EBAT instrument for the subject must be included in the DUI packet as defined in Part 1.5.

4.4.4 All certified EBAT instrumentation records must be retained for a minimum of 5-years by either the certified EBAT facility or the Department as applicable.

Part 5: Certification Requirements for Forensic Toxicology Laboratories

5.1 Laboratory Analysis of Blood, Urine and Post Mortem Specimens

5.1.1 Laboratories must be certified by the Department to provide analysis. Participation in the Forensic Toxicology Laboratory certification program is based upon successful on-site inspection, successful participation in proficiency testing and ongoing compliance with the applicable requirements in this rule.

5.1.2 Laboratories accredited by the American Board of Forensic Toxicology (ABFT) may be granted reciprocity on a biennial basis as long as accreditation remains active. Laboratories certified by the department will be inspected on the alternating accreditation years.

- 5.1.3 Laboratories certified by the Department who send samples to a reference laboratory for testing, must send those samples to either another Department certified lab, or a forensic toxicology laboratory accredited by ABFT.
- 5.1.4 Laboratories may be certified to perform tests for one or more of the following categories: blood alcohol, blood drug, urine drug, and post mortem testing.
- 5.1.5 Laboratories must meet standards of performance as established by these regulations. Standards of performance include; personnel qualifications, standard operating procedure manual, analytical process, proficiency testing, quality control, laboratory security, chain of custody, specimen retention, space, records, and result reporting.
- 5.1.6 Laboratory inspections must be performed prior to initial certification and annually thereafter by Department personnel as established by this rule. A laboratory meeting the certification requirements of these regulations will be issued a certificate. Recertification shall be required annually and will be effective each July 1.

5.2 Initial Application

- 5.2.1 Laboratory Directors must submit to the Department a completed application (Appendix B) for certification of their laboratory.
- 5.2.2 The Department will acknowledge the request and provide a copy of this rule to the laboratory.
- 5.2.3 To be certified, laboratories must demonstrate compliance with all applicable requirements in Parts 6,7,8,9 and Appendix C and participate in an initial on-site inspection.

5.3 Application for Continued Certification

- 5.3.1 Annually the Laboratory Director must provide a completed application (Appendix B), no later than June 1, to the Department to be considered for continued certification.
- 5.3.2 Laboratories must be recertified annually starting July 1, and certification will be for a period of 1 year.
- 5.3.3 Certified laboratories referring specimens to ABFT accredited laboratories must include documentation with the application (Appendix B) that the reference laboratory is ABFT accredited.
- 5.3.4 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.
- 5.3.5 To maintain certification, laboratories shall meet all applicable requirements found in Parts 5-8, and Appendix C and participate in an annual on-site inspection.

5.4 General Requirements

- 5.4.1 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 all personnel performing the testing.
- 5.4.2 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 C.
- 5.4.3 The laboratory must notify the Department in writing within thirty days of any changes pertaining to laboratory location and/or personnel.
- 5.4.4 The Laboratory Director is directly responsible for the accuracy of the tests performed, the accuracy of the reports issued, and adherence to the applicable requirements in this rule.

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

5.4.5.1 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.

5.4.6 The laboratory must establish and adhere to written methods of analysis (Standard Operating Procedure (SOP)) used to perform the tests reported. Critical elements that must be addressed in the SOP are in Appendix C, Section B (a-u).

5.4.7 The laboratory must demonstrate compliance with these regulations through a successful on-site inspection conducted by Department personnel 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.

5.4.8 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, calibration, quality control and quality assurance documentation for 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 made available for review by Department personnel.

5.4.9 The laboratory must provide an acceptable plan of correction to the department within 15 days of identification of an analytical Non-Conformance. Subject testing in the affected method may not resume until the laboratory's plan of correction is accepted by the Department and the source of the Non-Conformance has been identified and resolved. All subject tests impacted by the Non-Conformance must be reviewed by the Laboratory Director and amended reports issued if necessary.

5.5 Proficiency Testing requirements for Blood, Urine and Post Mortem Samples

5.5.1 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.

5.5.2 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 preceding 12 months.

5.5.3 To maintain continued laboratory certification, a laboratory must participate in the designated PT program and maintain satisfactory performance as determined by the Department.

5.5.4 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.

5.5.4.1 The laboratory must request that the proficiency testing provider mail a consultant copy of their PT survey results to:

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

5.5.5 Blood Alcohol Testing

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

5.5.5.2 A laboratory must participate in PT testing through 3 events per year, consisting of 5 specimens each. The laboratory MUST 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.

5.5.5.3 Other forensically significant volatiles, such as acetone, methanol and isopropanol, may be included in one or more PT samples IN each of the 3 events. 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.

5.5.5.4 Grading Criteria for Blood Alcohol Proficiency Testing

5.5.5.4.1 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.

5.5.5.4.2 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 for approval within 15 days of receipt of the results.

5.5.5.4.3 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 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.

5.5.6 Urine, Blood and Post Mortem Drug Testing

5.5.6.1 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.

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

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

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

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

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 (qualitatively and quantitatively) by the laboratory must be tested in the PT challenges when provided in the same manner as subject samples.

5.5.6.2.3 A satisfactory event score is the positive identification and when applicable, quantitation 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 for approval within 15 calendar days of receipt of the results.

5.5.6.2.5 Whenever a quantitative result reported by the laboratory in a PT challenge is considered "Unacceptable" by the PT provider ($\pm 2sd$ or 30% from the mean, whichever is greater), 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 for "Unsuccessful" PT performance if consecutive "Unsatisfactory" PT events occur, or two out of three consecutive "Unsatisfactory" PT events occur a laboratory may be reinstated to active status after successful participation in the next PT challenge. Failure to achieve a "Satisfactory" score 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.

5.6 On-Site Laboratory Inspection

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

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

5.6.3 Laboratories will be contacted by the Department 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.

5.6.4 The inspection checklist (Appendix C) will be used onsite to evaluate and assess the laboratory's compliance with the 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 included in a report to describe the noncompliant practice, the source of information, the scope and extent of the noncompliant practice.

5.6.5 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 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".

5.6.7 The written plan of correction will be reviewed by the Department, and if acceptable, will be approved. Any items requiring clarification will be resolved by phone or written correspondence.

5.6.8 Documents must be provided to the Department by the laboratory within 90 days of the inspection for verification and proof of implementation of the 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 as determined by the Department.

5.6.9 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 the inspector's recommendation to deny initial certification or limit, deny, suspend or revoke the laboratory certificate. Such action shall be governed by section 24-4-104, C.R.S.

5.6.10 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 approved categories and the effective dates of the certification period. The certification period will not exceed twelve months.

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

Part 6: Blood Forensic Toxicology – Collection and Testing Requirements

6.1 Blood Specimen Collection

6.1.1 Blood Specimen(s) must be:

- 6.1.1.1 Collected in the presence of the arresting officer or other responsible person who can authenticate the specimens.
- 6.1.1.2 Collected and labeled following the instruction provided in the forensic blood collection kit.
- 6.1.1.3 Collected by venipuncture by a physician, nurse, paramedic, emergency medical technician, medical technologist, or a person who's training and normal duties include collecting blood specimens under the supervision of a physician or nurse.
- 6.1.1.4 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 to the subject or the ready availability of emergency medical services to the public.
- 6.1.1.5 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 phenol solutions must not be used as a skin antiseptic.

6.1.2 After Collection, Blood Specimens must be:

- 6.1.2.1 Dispensed or collected directly into two 10ml sterile tubes set to draw a (Nominal 10 ml) volume containing Sodium Fluoride (Nominal 100mg) and Potassium Oxalate (Nominal 20mg) preservative.
- 6.1.2.2 Properly mixed in accordance with the instructions provided in the forensic blood collection kit.
- 6.1.2.3 Affixed with an identification label and evidence seal.
- 6.1.2.4 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.

6.2 Blood Specimen Testing

- 6.2.1 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 using a different chemical principle from the initial screening test when available, prior to reporting the results.
- 6.2.2 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 received by a representative of another certified laboratory, acting on behalf of the defendant.
- 6.2.3 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 using a different chemical principle from the initial screening test when available, prior to reporting the results to a court of law.

Part 7: Urine Forensic Toxicology – Collection and Testing Requirements

7.1 Urine Specimen Collection

7.1.1 Urine specimen(s) must be:

- 7.1.1.1 Collected in the presence of collection personnel who can authenticate the specimen(s).
- 7.1.1.2 Collected in a clean, sterile container.
- 7.1.1.3 Affixed with an identification label and evidence seal.
- 7.1.1.4 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.

7.2 Urine Specimen Testing

- 7.2.1 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 using a different chemical principle from the initial screening test when available, prior to reporting the results.
- 7.2.2 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 by a representative from another certified laboratory acting on behalf of the defendant.
- 7.2.3 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 using a different chemical principle from the initial screening test when available, prior to reporting the results to a court of law.

Part 8: Post Mortem Forensic Toxicology – Collection and Testing Requirements

8.1 Post Mortem Specimen Collection

- 8.1.1 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.
- 8.1.2 The laboratory must develop and provide detailed guidelines and instructions for the collection of post mortem specimens.
- 8.1.3 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.
- 8.1.4 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.

8.2 Post Mortem Specimen Testing

- 8.2.1 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.
- 8.2.2 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 by a representative from another certified laboratory acting on behalf of the defendant.

Part 9: Violations and Remedies

9.1 Violations

- 9.1.1 It is a violation of these rules and regulations to perform EBAT testing without the appropriate certification for the EBAT instrument, operator or instructor.
- 9.1.2 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.
- 9.1.3 Generally, a violation will not be cited if:
 - 9.1.3.1 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.
 - 9.1.3.2 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.

9.2 Complaints

- 9.2.1 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 requested by the Department from the laboratory, unannounced onsite survey, limitation, suspension, or revocation of the laboratory's certification.

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

- 9.3.1 Any 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.

9.4 Denial, Suspension or Revocation of Certification:

- 9.4.1 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:
 - 9.4.1.1 Falsification of data or other deceptive practices including false statements by omission or commission relevant to the certification process.
 - 9.4.1.2 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.
 - 9.4.1.3 Gross incompetence or negligent practice.
 - 9.4.1.4 Willful or repeated violation of any lawful rule, regulation or order of the Department or the Board of Health and its officers.
 - 9.4.1.5 Inadequate space, equipment, or methods utilized for testing.
 - 9.4.1.6 Submission of any test results of another person as those of the subject being evaluated.
 - 9.4.1.7 For a laboratory, failure to successfully participate in proficiency testing.
 - 9.4.1.8 For a laboratory, the receipt of consecutive "Unsatisfactory" evaluations, or achievement of an "Unsatisfactory" score in 2 of any 3 consecutive proficiency testing events.

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

9.5 Injunction

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

APPENDIX A - Evidential Breath Alcohol Testing (EBAT) Annual Facility Inspection (AFI) Report

**Evidential Breath Alcohol Testing (EBAT)
Annual Facility Inspection (AFI) Report**

Date: _____

Agency: _____

Instructor(s): _____

Phone: () _____ **Fax:** () _____

E-Mail: _____ **Type Of Inspection:** _____

EBAT Instrument Serial Number: _____

A. Initial EBAT Facility Certification

- 1. Facilities must submit a formal request to the Department requesting certification on official agency letterhead.**

- Not Applicable
 Acceptable
 Not Acceptable/correction required

Comments:

Date Received:

- 2. Verification from a certified electrician confirming the certified EBAT instrument is on a dedicated power circuit of no more than 20 amps.**

- Not Applicable
 Acceptable
 Not Acceptable/correction required

Comments:

Date Received:

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

- Not Applicable
 Acceptable
 Not Acceptable/Correction Required

Comments:

Date Received:

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

- Not Applicable
 Acceptable
 Not Acceptable/Correction Required

Comments:

Date Received:

B. Power Requirements – EBAT Permanent Location

1. AC line voltage of 120 volts, 60 Hz grounded outlet on a dedicated circuit.

1a. 20 ampere maximum circuit breaker

Acceptable

Not Acceptable/Correction Required

Comments:

1b. Voltage 120 ± 12 v (108-132)

Acceptable

Not Acceptable/Correction Required

Comments:

1c. Grounded outlet

Acceptable

Not Acceptable/Correction Required

Comments:

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

Acceptable

Not Acceptable/Correction Required

Comments:

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

Acceptable

Not Acceptable/Correction Required

Comments:

C. Power Requirements – EBAT Mobile Location

1. **Sine wave power inverter capable of providing a steady 120 volts AC output from a DC input.**

- Not Applicable
 Acceptable
 Not Acceptable/Correction Required

Comments:

2. **The power line to the EBAT instrumentation must be on a dedicated circuit.**

- Not Applicable
 Acceptable
 Not Acceptable/Correction Required

Comments:

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

- Not Applicable
 Acceptable
 Not Acceptable/Correction Required

Comments:

D. EBAT INSTRUMENTATION ENVIRONMENT

- 1. The temperature of the EBAT instrumentation room must be maintained between 60 and 90 degrees Fahrenheit.**

- Acceptable
 Not Acceptable/Correction Required

Comments:

- 2. The EBAT instrumentation room must have adequate lighting.**

- Acceptable
 Not Acceptable/Correction Required

Comments:

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

- Acceptable
 Not Acceptable/Correction Required

Comments:

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

- Acceptable
 Not Acceptable/Correction Required

Comments:

- 5. The EBAT instrumentation room receives adequate ventilation.**

- Acceptable
 Not Acceptable/Correction Required

Comments:

- 6. Automobile emissions are not allowed in the EBAT instrumentation room.**

- Acceptable
 Not Acceptable/Correction Required

Comments:

- 7. The 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 instrumentation room 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/Correction Required

Comments:

2e. EBAT instrument exception report reference table

- Acceptable
 Not Acceptable/Correction Required

Comments:

- 2. EBAT instrumentation records applicable to the agency 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/Correction Required

Comments:

- 2. The EBAT facility must have available an adequate supply of standard simulator solution**

- Acceptable
 Not Acceptable/Correction Required

Comments:

Lot #:

G. EBAT Instrumentation

1. EBAT instrument test sequence

- Acceptable
 Not Acceptable/Correction Required

Comments:

2. EBAT instrument time and date

- Acceptable
 Not Acceptable/Correction Required

Comments:

3. EBAT instrument certification date

- Acceptable
 Not Acceptable/Correction Required

Comments:

Certification Date:

Posted Certification Date:

4. EBAT instrument external breath tube heating

- Acceptable
 Not Acceptable/Correction Required

Comments:

Temperature:

5. EBAT instrument dedicated data line

- Not Applicable
 Acceptable
 Not Acceptable/Correction Required

Comments:

6. EBAT instrument dedicated analog phone line

- Not Applicable
 Acceptable
 Not Acceptable/Correction Required

Comments:

Analog phone #:

7. The EBAT instrumentation must not be moved from the location it was certified for without prior authorization from the Department.

- Acceptable
 Not Acceptable/Correction Required

Comments:

8. The EBAT instrumentation must be operated in a smoke-free environment.

- Acceptable
- Not Acceptable/Correction Required

Comments:

H. EBAT Instrumentation Simulators

1. Active Simulator

Serial Number:

Display Reading: (33.8°C - 34.2°C) °C

Digital Thermometer Reading: Minimum°C

Digital Thermometer Reading: Maximum°C

Comments:

2. Back-Up Simulator

Serial Number:

Display Reading: (33.8°C - 34.2°C) °C

Digital Thermometer Reading: Minimum°C

Digital Thermometer Reading: Maximum°C

Comments:

3. Back-Up Simulator

Serial Number:

Display Reading: (33.8°C - 34.2°C) °C

Digital Thermometer Reading: Minimum°C

Digital Thermometer Reading: Maximum°C

Comments:

Calibrated Thermometer Information:

Thermometer: _____

Serial Number: _____

Last Certification: _____

Next Certification: _____

Correction Factor: _____

I. Record Review

1. 0.100 g/210 liters Standard Simulator Solution in use.

- 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. Standard Simulator Solution is changed as necessary and when required.

- Acceptable
 Not Acceptable/Correction Required

Comments:

4. Automated 7-Day calibration checks performed.

- Acceptable
 Not Acceptable/Correction Required

Comments:

5. Average number of tests per month:

EBAT:

Training:

Exception Reports:

APPENDIX B – DUI and DUID Forensic Toxicology Laboratory Certification Application

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 received by June 1)

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		
Reference Lab Samples				Reference Lab Samples		

- Laboratories referring specimens to ABFT accredited laboratories must include documentation to show proof of accreditation status with this application, or must send samples to laboratories certified by the Department.
- For each new director, supervisor and analyst, a current Curriculum Vitae (CV) must be submitted 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)

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 supervise and maintain documentation that the established protocols of the laboratory are being followed and monitored on an ongoing basis to ensure compliance, 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 functions 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 ensures 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.

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 initialed and dated each change or revision to the procedure?
4. Does the Standard Operating Procedure (SOP) manual include the following criteria and processes for laboratory personnel to follow?
 - 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 and reporting 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) Acceptability criteria for the results of calibration standards and controls as well as between two aliquots or columns.
 - Y N NA u) A documented system for reviewing the results of testing calibrators, controls, standards, and subject tests results, as well as reviewing for clerical errors, analytical errors and any unusual analytical results? Are corrective actions implemented and documented, and does the laboratory contact the requesting entity?
 - Y N NA v) 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 for a minimum of 5 years from the 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?
2. Y N NA Does the laboratory participate in additional proficiency testing programs other than those required under these standards?

Identify PT Program(s) and Results:

-
-
-
3. Y N NA Does the laboratory analyze PT samples using the same procedures 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 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)?
 8. Y N NA Has the laboratory taken and documented remedial action when a score of less than 100% is achieved during a drug PT event to include any false negative results and quantitative results scored "Unacceptable" by the PT provider ($\pm 2SD$ or 30% from the mean, whichever is greater)?
 9. Y N NA Does the laboratory only report those analytes that are included on the master list of analytes for each PT program in which they participate? If the laboratory reports analytes other than those included in the PT program, do they have documented activities performed to ensure the accuracy of those analytes?

D. QUALITY ASSURANCE AND QUALITY CONTROL

1. Y N NA Are there records of instrument preventive maintenance, repair, troubleshooting and corrective actions?
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 on all equipment when in use 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, the 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?
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, analyzed 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, at minimum, a negative and two levels of controls that challenge the linearity of the entire curve?
13. Y N NA Does the laboratory use control material(s) that differs in either source or, lot number, or 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 NISTtraceable and within (10% for ethanol and 20% for blood and urine drugs) 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 ACCEPTABILITY criteria for calibration standards and controls for all assays?
19. Y N NA Does the laboratory monitor and document the performance of calibrator and control materials 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 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?

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 that include the requirements for specimen types(s), identification 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 the 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 only to authorized personnel?
10. Y N NA Does the laboratory have provisions for securing the laboratory during non-working hours?
11. Y N NA Does the laboratory secure short and long-term storage areas when not in use?
12. Y N NA Does the laboratory log in and aliquot specimens in a secure area?
13. Y N NA Are urine specimens stored for at least 1 year at -20 degrees C or 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 Are equipment and instrument operating conditions consistent with manufacturer requirements?

F. RECORDS – REPORTING

1. Y N NA Are all instrumentation and analysis records 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 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 than was used for the screening test?
4. Y N NA Prior to reporting results, are all blood ethanol results confirmed using a second GC column where the results 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?
5. 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)

6. Y N NA For post mortem testing, does the laboratory confirm the identity of a drug analyte or alcohol concentration using a second column and a different extract from the same sample, or using a different sample matrix from the same subject when possible?
7. Y N NA Does the laboratory only report quantitative results that are above the lowest concentration of calibrator or standard used in the analytical run?
8. Y N NA Does the laboratory verify results that are below the lowest concentration of calibrator or standard and above the Limit Of Quantitation (LOQ) 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 and above the Limit Of Detection (LOD) 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, raw data of calibration standards and curves, controls and subject results, final and amended reports, 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, to include any identified and documented discrepancies.
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 (GC)

1. Y N NA Does the laboratory document the conditions of the gas chromatograph, including the detector response?
2. Y N NA Does the laboratory perform and document preventive maintenance as required by the manufacturer?
3. Y N NA Are the maintenance records readily available to the staff operating the equipment?
4. Y N NA Does the laboratory document the performance of new columns before use? How?
5. 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?
6. Y N NA Does the laboratory have established criteria of acceptability not to exceed 10% for variances between the results of the blood ethanol analysis using different aliquots and between different columns?
7. Y N NA Does the laboratory document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system?

G.2 Gas Chromatography Mass Spectrometry (GC/MS)

1. Y N NA Does the laboratory perform and document preventive maintenance as required by the manufacturer?
2. Y N NA Does the laboratory document the 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 Are the maintenance records readily available to the staff operating the equipment?
5. Y N NA Does the laboratory maintain records of mass spectrometric tuning?
6. Y N NA Does the laboratory have written criteria for an acceptable mass-spectrometric tune?
7. Y N NA If the tune is unacceptable, is corrective action documented?
8. Y N NA Does the laboratory monitor analytic analyses to check for contamination and/or carry-over?
9. Y N NA If the laboratory uses selected ion monitoring within each run does the laboratory compare ion ratios and retention times between calibrators, controls and specimens for identification of an analyte?
10. 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 and is isotopically labeled when available or appropriate for the assay?
11. Y N NA Does the laboratory document the monitoring of the response (area or peak height) for the internal standard to ensure consistency overtime of the analytical system?
12. Y N NA Does the laboratory define the criteria for designating qualitative results as positive?
13. Y N NA If the laboratory has written its own software, has it been documented and the accuracy verified?
14. Y N NA If the laboratory uses GC/MS for both screening and confirmation, does the laboratory analyze two aliquots where the second aliquot is tested in a different batch than the original aliquot? if sample volume prohibits the testing of two aliquots, is it noted on the final report that only one aliquot was tested?
15. Y N NA Does the laboratory have written acceptability criteria for variance between the results when the same analyte is quantitated in multiple analyses?
16. Y N NA If the laboratory uses a library match to qualitatively identify an analyte, does the laboratory compare the relative retention time and mass spectra from a known standard or control run on the same system before reporting the results?
17. Y N NA After routine and preventive maintenance (e.g. clipping or replacing the column or cleaning the source) does the laboratory evaluate the performance of the instrument prior to analyzing subject samples? How?

G.3 Immunoassays

1. Y N NA Does the laboratory perform and document preventive maintenance as required by the manufacturer?
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, if they exist?

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 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 thin layer chromatographic 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 carryover? 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?

G.5 High Pressure Liquid Chromatography (HPLC)

1. Y N NA Does the laboratory perform and document preventive maintenance as required by the manufacturer?
2. Y N NA Are the maintenance records readily available to the staff operating the equipment?
3. Y N NA Does the laboratory monitor and document the performance of the HPLC instrument each day of testing?
4. Y N NA Does the laboratory evaluate the performance of new columns before use? How?
5. Y N NA If the laboratory recycles eluting solvents, are there written standards for acceptability?
6. 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 when available or appropriate for the assay?
7. Y N NA Does the laboratory document the monitoring of the response (area or peak height) of the internal standard to ensure consistency overtime of the analytical system?

G.6 Liquid Chromatography Mass Spectrometry (LCMS) (LCMS/MS)

1. Y N NA Does the laboratory perform and document preventive maintenance as required by the manufacturer?
2. Y N NA Are the maintenance records readily available to the staff operating the equipment?
3. Y N NA Does the laboratory maintain records of mass spectrometric tuning?
4. Y N NA Does the laboratory have written criteria for an acceptable mass-spectrometric tune?
5. Y N NA If the tune is unacceptable, is corrective action documented?
6. 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?
7. Y N NA Does the laboratory use an internal standard with each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available or appropriate for the assay?

