

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Laboratory Services Division

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.]

Adopted by the Board of Health on December 19, 2018; effective February 14, 2019.

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 through 4 of these rules and regulations. All approved EBAT facilities and certified 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 postmortem samples operate under Parts 5 through 9 of these rules and regulations. All certified forensic toxicology laboratories performing testing in the categories of blood alcohol, blood drug, urine drug and postmortem 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.

“Approved Facility” – any location that meets the requirements of these regulations and which is approved by the Department to house the certified EBAT instrumentation.

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

“Certified EBAT Instructor” – an employee of a 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 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 Operator” – an employee of 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.

“Certified Laboratory” – a forensic toxicology laboratory certified by the Department to perform analytical testing of bodily fluids for alcohol or other drugs in the categories of blood alcohol, blood drug, urine drug or postmortem testing.

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

“Discovery 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.

“DUI” – refers to the term Driving Under the Influence of alcohol and/or other drugs as defined by Section 42-4-1301(1)(f), C.R.S.

“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.

“DWAI” – refers to the term Driving While Ability Impaired by alcohol and/or other drugs as defined by Section 42-4-1301(1)(g), C.R.S.

“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.

“Exception Message” – is the term used for a report generated by the certified EBAT instrument whenever an Evidential Breath Alcohol Test (EBAT) is unable to be successfully completed.

“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.

“Key Management” – refers to personnel designated as top management and additional personnel who do not have laboratory wide authority but are “key” to the laboratory providing testing services which may include the laboratory director, technical personnel or any other designated qualified individual who has supervisory responsibilities for the scientific aspects of the laboratory.

“Laboratory Director” – the individual meeting the qualification requirements specified in Part 5 and Part 9 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.

“Proficiency Testing (PT)” – The evaluation of unknown specimens which determines target alcohol or drug values for those unknown specimens that is manufactured by a provider accredited to the International Standards Organization (ISO/IEC 17043). A single evaluation is commonly referred to as a PT event.

“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.

“Satisfactory PT Performance” – results scored from an individual PT event that meet or exceed the minimum score allowable to be considered passing.

“Successful PT Performance” – ongoing satisfactory PT performance in multiple PT events that meet or exceed the minimum score allowable to be considered passing.

“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.

“Technical Personnel” - individuals who are engaged in any aspect of the testing of samples and reporting of results under the supervision of the laboratory director or the laboratory director’s designee.

“Unsatisfactory PT Performance” – results scored from an individual PT event that are scored below the minimum allowable to be considered passing.

“Unsuccessful PT Performance” – two consecutive unsatisfactory individual PT events or 2 out of 3 unsatisfactory individual PT events that are scored below the minimum allowable to be considered passing.

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

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- 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 Requirements for Evidential Breath Alcohol Testing (EBAT) Facilities

- 3.1 Standards for approval 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 approved by the Department.
 - 3.1.2 Department standards for approval of EBAT facilities are specified in Part 3 of this rule.
 - 3.1.3 EBAT facilities meeting the standards of performance as specified in Part 3 of this rule may be approved.
 - 3.1.4 Onsite Inspections of permanent, temporary and mobile EBAT facilities must be performed prior to initial approval 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 approval – permanent, temporary, and mobile EBAT facilities.

- 3.1.5.1 A facility representative must submit a written request to the Department for initial approval of an EBAT facility. The request will be in the form and manner required by the Department and must include:
 - 3.1.5.1.1 Acknowledgement from the facility representative that the requirements found in Part 3 have been reviewed prior to requesting approval.
 - 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 phone line are installed and available for communications by the certified EBAT instrument.
- 3.1.5.2 Upon receipt of the initial facility approval request, Department personnel will schedule an onsite inspection to verify compliance with the requirements found in Part 3 prior to approval.
- 3.1.6 The Department will perform an onsite inspection at an EBAT facility when any of the following occur:
 - 3.1.6.1 The EBAT facility is seeking initial approval, or
 - 3.1.6.2 The approved EBAT facility requests relocation of the certified EBAT instrument either temporarily or permanently within the facility, or
 - 3.1.6.3 A new EBAT facility is being constructed that will house the certified EBAT instrument, or
 - 3.1.6.4 A complaint is received by the Department that requires an onsite inspection to verify compliance.
- 3.2 Evidential Breath Alcohol Testing (EBAT) facility requirements
 - 3.2.1 Instrument power requirements
 - 3.2.1.1 Alternating current (AC) line voltage of 120 volts, 60 hertz (Hz) grounded outlet on a dedicated circuit.
 - 3.2.1.2 20 ampere maximum circuit breaker.
 - 3.2.1.3 Voltage 120 +/- 12v (108v – 132v).
 - 3.2.1.4 Grounded outlet.
 - 3.2.1.5 An adequate surge protection device must be placed between the EBAT instrumentation and the grounded outlet.
 - 3.2.2 Facility environmental requirements
 - 3.2.2.1 The temperature of the room where the EBAT instrumentation is operated must be maintained between (15.0 – 32.2) degrees Centigrade.

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- 3.2.2.2 The relative humidity of the room where the EBAT instrumentation is operated must be maintained between (5% - 70%).
 - 3.2.2.3 The EBAT instrumentation room must have adequate lighting.
 - 3.2.2.4 The area around and under the EBAT instrumentation must be free of dust, dirt and kept orderly.
 - 3.2.2.5 The EBAT instrumentation must be placed on a solid and adequate work surface.
 - 3.2.2.6 The room where the EBAT instrumentation is located must receive adequate ventilation.
 - 3.2.2.7 The ventilation to the room where the EBAT instrumentation is located must prevent automobile emissions from being introduced.
 - 3.2.2.8 The room where the EBAT instrumentation is located must not be used to store cleaning compounds or volatile chemicals.
 - 3.2.2.9 The room where the EBAT instrumentation is located must remain secure and not readily accessible to unauthorized personnel.
- 3.2.3 EBAT facility documents
- 3.2.3.1 The EBAT instrument calibration certificate must be posted next to the instrument.
 - 3.2.3.2 The EBAT instrument Exception Message guide must be posted next to the instrument.
 - 3.2.3.3 Corrective actions taken by the certified EBAT instructor or operator are appropriate and timely when Exception Messages are encountered.
 - 3.2.3.4 The EBAT instrumentation records applicable to the agency must be retained by the approved facility for a minimum of 5 years.
- 3.2.4 EBAT instrumentation
- 3.2.4.1 The approved facility must have available an adequate supply of mouth pieces.
 - 3.2.4.2 The approved facility must have available an adequate supply of standard simulator solution issued by the Department.
 - 3.2.4.3 The standard simulator solution is changed as needed and correctly by a certified EBAT instructor.
 - 3.2.4.4 EBAT instrumentation and supplies must be properly maintained, stored and available to authorized personnel.
 - 3.2.4.5 The EBAT instrumentation is being operated in the location it was approved for within the approved facility.

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 An approved 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 Message.
 - 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 Message.
 - 4.1.3.5.2 When a "No .02 Agreement" Exception Message 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 Message.

4.1.3.6.1 If an "Invalid Sample" Exception Message 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 "Not Ready" mode, wait until the instrument completes the warm-up period prior initiating any testing.
- 4.2.3 Completion of a 20-minute deprivation period must be conducted at the approved EBAT facility by a certified EBAT instructor or operator that is in an active status that must include;
 - 4.2.3.1 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
 - 4.2.3.2 Depriving the subject access to foreign material that may be introduced into the mouth cavity during the 20-minute deprivation period, and
 - 4.2.3.3 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 Message(s) (if applicable) that may have been encountered during the subject test attempt(s).
- 4.4.4 All printouts generated from the certified EBAT instrument for the subject must be included in the DUI packet as defined in Part 1.5.
- 4.4.5 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 either: successful onsite annual inspection for non-accredited labs, or, ongoing accreditation status for accredited labs, in addition to successful proficiency testing performance in the category or categories the laboratory is certified in and ongoing compliance with Parts 5 through 9 of this rule.
- 5.1.2 Laboratories seeking certification that are accredited by a nationally or internationally recognized accreditation organization that includes the scope of forensic toxicology may elect to forgo the annual onsite inspection as long as accreditation remains active, and, the biennial inspection performed by the accrediting organization includes review of the specialty of toxicology.
- 5.1.3 Accredited laboratories requesting certification from the Department must provide the Department a copy of the accrediting organizations most recent and final biennial inspection report within 30-days of receipt of accreditation in the scope of forensic toxicology in addition to, any accepted plan of correction submitted to the accrediting organization by the laboratory.
- 5.1.4 The Department will perform an onsite inspection of an accredited laboratory in the event that the specialty of toxicology is not reviewed by the accrediting organization during the biennial inspection.
- 5.1.5 Laboratories certified by the Department who send samples to a reference laboratory for testing, must send those samples to a forensic toxicology laboratory certified by the Department.
- 5.1.6 Laboratories may be certified to perform tests for one or more of the following categories: blood alcohol, blood drug, urine drug, and postmortem testing.

- 5.1.7 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 assurance, quality control, laboratory security, chain of custody, specimen retention, space, records, and result reporting.
- 5.1.8 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 requesting certification of their laboratory must submit to the Department a completed application. The application will be in the form and manner required by the Department and includes: laboratory name, laboratory director, facility address, laboratory correspondence information, and analytical categories for which the laboratory requests certification.
- 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 5 through 9 and participate in an initial onsite inspection. The onsite inspection may be waived for accredited laboratories so long as the requirements at 5.1.3 are satisfied as determined by the Department at its sole discretion.

5.3 Application for Continued Certification

- 5.3.1 Annually the Laboratory Director must request to be considered for continued certification by providing a completed application to the Department no later than June 1. The application will be in the form and manner required by the Department and will include: laboratory name, laboratory director, facility address, laboratory correspondence information, analytical categories for which the laboratory requests certification and case load totals.
- 5.3.2 Laboratories must be recertified annually starting July 1, and certification will be for a period of 1 year.
- 5.3.3 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.
- 5.3.4 To maintain certification, laboratories shall meet all applicable requirements found in Parts 5 through 9. Non-accredited laboratories or accredited laboratories identified in 5.1.4 must participate in an annual onsite inspection.

5.4 General Requirements

- 5.4.1 In addition to the laboratory's application, the laboratory must provide an updated listing of all technical personnel engaged in testing to the Department. The listing will be in the form and manner required by the Department.

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- 5.4.2 Prior to independently analyzing samples, technical 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 the competency of technical personnel as specified in Part 9.
 - 5.4.3 The laboratory must notify the Department in writing within thirty days of any changes pertaining to laboratory location and/or key management.
 - 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 use reference materials from a manufacturer accredited to the International Standards Organization (ISO) requirements for certified reference materials and certified reference standards, ISO/IEC 17034 when available.
 - 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 Part 9.
 - 5.4.7 The laboratory must demonstrate compliance with these regulations through a successful onsite 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 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, test results and test 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 investigate all analytical non-conformances. Whenever subject test results are impacted, further testing using the affected method(s) may not resume until the laboratory has performed a root cause analysis and corrected the non-conformance. All subject tests impacted by the non-conformance must be reviewed by the laboratory director and amended reports issued when necessary. Copies of the non-conformance, root cause analysis and corrective action plan must be provided to the Department upon request.
- 5.5 Proficiency Testing (PT) requirements for certified forensic toxicology laboratories.
- 5.5.1 Proficiency Testing (PT) is the evaluation of unknown specimens which determines target values for those unknown specimens and is required for each approved category the laboratory is certified in.
 - 5.5.2 PT material must be obtained from a PT provider that is accredited to the ISO/IEC 17043 standards and can provide appropriate biological specimens that are applicable to the testing the laboratory performs.

- 5.5.3 Prior to initial certification, the laboratory must at minimum, have successfully participated in one proficiency testing event(s) within the preceding 12 months in the category for which the laboratory seeks certification and must have received a satisfactory score(s) for each of those event(s) as defined in Part 5.
- 5.5.4 To maintain continued laboratory certification, a laboratory must demonstrate successful PT performance for each category in which the laboratory is certified.
- 5.5.5 For each approved category of testing, PT samples shall be:
- 5.5.5.1 Tested for all analytes reported by the laboratory that are present in the PT samples, and
 - 5.5.5.2 Tested by each technical personnel annually, and
 - 5.5.5.3 Tested using approved standard operating procedures, and
 - 5.5.5.4 Tested in the same manner as subject samples, and
 - 5.5.5.5 Reported to the PT provider, and
 - 5.5.5.6 The laboratory must request that the proficiency testing provider provide 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

- 5.5.6 Blood Alcohol Testing
- 5.5.6.1 A laboratory must demonstrate successful PT performance in a minimum of 3 alcohol PT testing events per year. Each event must consist of a minimum of 4 specimens each. The PT provider will evaluate the results and forward them to the laboratory as well as to the Department.
 - 5.5.6.2 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.
 - 5.5.6.3 Scoring Criteria for Blood Alcohol Proficiency Testing
 - 5.5.6.3.1 PT 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 scored and will be considered an unsatisfactory performance resulting in a score of 0 for the testing event. The laboratory must contact the PT provider and the Department if extenuating circumstances prevent timely response to a PT event.
 - 5.5.6.3.2 An acceptable blood alcohol PT result is one that falls within +/- 10% of the reported mean.

5.5.6.3.3 The laboratory must investigate any score less than 100% and undertake corrective action as needed. The investigation outcome and corrective action must be provided to the Department upon request.

5.5.5.3.4 The PT 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.

5.5.7 Urine, Blood and Postmortem Drug Testing

5.5.7.1 For blood drug, urine drug and postmortem screening and confirmation certification, the laboratory must demonstrate successful PT performance.

5.5.7.1.1 For blood drug certification the laboratory must participate in a minimum of two PT events annually that include blood samples.

5.5.7.1.2 For urine drug certification the laboratory must participate in a minimum of two PT events annually that include urine samples.

5.5.7.1.3 For laboratories performing only postmortem forensic toxicology testing the laboratory must participate in a minimum of two PT events annually that include a combination of blood and urine samples and other postmortem matrices when available.

5.5.7.2 Scoring criteria for drug proficiency testing

5.5.7.2.1 PT 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 scored and will be considered an "Unsatisfactory" performance resulting in a score of 0 for the testing event. The laboratory must contact the PT provider and the Department if extenuating circumstances prevent timely response to a PT event.

5.5.7.2.2 All analytes listed and reported (qualitatively and quantitatively) by the laboratory must be analytically tested in the PT challenges in the same manner as subject samples.

5.5.7.2.3 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.

5.5.7.2.3.1 Scoring is as follows: if a laboratory only reports an analyte qualitatively, the total possible points for that analyte will be 4 points.

Total points possible:

- A. Each possible positive identification is 4 points.
- B. Each quantitative result is worth a possible 2 points.

Note: quantitative results will be subject to further point restrictions when standard deviation (SD) values are given by the PT provider.

Laboratory's points:

- A. Each correctly identified analyte is 4 points.
- B. Each false negative is 0 points (i.e., no qualitative result given).
- C. Each quantitative result within 1 standard deviation (SD) is 2 points.
- D. Each quantitative result within 2 SD is 1 point.
- E. Each quantitative result outside 2 SD is 0 points.
- F. Each correctly identified negative specimen is 4 points.
- G. Each false positive is minus (-) 25 points and is automatically considered an unsatisfactory event.

Laboratory's Score = (laboratory's points / total possible points) * 100

5.5.7.2.4 Whenever a laboratory receives 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 provided to the Department upon request.

5.5.7.2.5 Whenever a quantitative result reported by the laboratory in a PT challenge is considered "Unacceptable" by the PT provider (outside $\pm 2SD$ 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.

5.5.7.2.6 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 one extra set of PT samples when suspension status occurs.

5.6 Onsite Laboratory Inspection

5.6.1 Onsite laboratory inspections must be performed prior to initial certification and annually thereafter for non-accredited labs by the Department in accordance with this rule.

5.6.2 The onsite inspection will include a review of the laboratory's practices to ensure compliance with these regulations. Laboratories must demonstrate compliance with all applicable requirements in Parts 5 through 9.

- 5.6.3 Laboratories will be contacted by the Department to schedule the annual onsite inspection after receipt of the application requesting certification. A letter confirming the inspection date will be sent to the laboratory.
- 5.6.4 The Department will evaluate compliance with the laboratory certification standards listed in Part 9 during the onsite inspection.
- 5.6.5 Following the onsite inspection, a written report will be prepared that will list any non-conformances identified. The report should be sent to the laboratory within 30-days of inspection.
- 5.6.6 Within 30-days of receipt of the inspection report, the laboratory must provide to the Department for review and approval a written plan of correction that addresses each non-conformance listed in the inspection report.
- 5.6.7 Any requested objective evidence must be provided to the Department within 60-days of receipt of the inspection report. Any items requiring clarification will be resolved by phone or written correspondence.
- 5.6.8 Identification of non-conformance practices that impact test results or, failure to provide an acceptable plan of correction or, failure to provide adequate objective evidence within the specified timelines, may result in limitation, suspension, revocation or denial of certification. Such action shall be governed by Section 24-4-104, C.R.S.
- 5.6.9 Upon the laboratory's successful completion of the annual inspection and certification process, the department will issue a certificate. The certificate will include the name and location of the laboratory, the categories the laboratory is certified to perform testing in and the certification period.
- 5.6.10 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.
 - 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. Ethyl alcohol or phenol solutions must not be used as a skin antiseptic.
- 6.1.1.6 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.
- 6.1.1.7 Properly mixed in accordance with the instructions provided in the forensic blood collection kit.
- 6.1.1.8 The blood collection tubes must be affixed with a unique identification label that includes the subject name and evidence seal.
- 6.1.1.9 The specimens must be placed in secured storage until shipped.
- 6.1.1.10 If shipping is delayed by more than 48-hours, samples must be refrigerated at or below 8 degrees centigrade and not frozen in order to prevent the container(s) from breaking.
- 6.1.1.11 Whenever possible, specimens should be shipped within 7-days of collection by the law enforcement agency.

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 In the event that not enough specimen is provided to complete the State's test(s) and the second sample must be used, the laboratory must obtain authorization from the appropriate authority prior to testing.
- 6.2.3 Any remaining blood specimen must be retained and stored by the certified laboratory at or below 8 degrees Centigrade or frozen in an appropriate container 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.
- 6.2.4 The second blood specimen must be analyzed by a Department certified laboratory when requested 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 a unique identification label that includes the subject name and evidence seal.
- 7.1.1.4 The specimens must be placed in secured storage until shipped.
- 7.1.1.5 If shipping is delayed by more than 48-hours, samples must be refrigerated at or below 8 degrees centigrade in an appropriate container.
- 7.1.1.6 Whenever possible, specimens should be shipped within 7-days of collection by the law enforcement agency.

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 at or below 8 degrees centigrade in an appropriate container 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 Department certified laboratory when requested 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. Postmortem Forensic Toxicology – Collection and Testing Requirements

8.1 Postmortem Specimen Collection

- 8.1.1 Collection of specimens from deceased persons conducted per Section 42-4-1304, C.R.S. will be performed by a person whose training and normal duties include the collection of blood or other bodily substances from deceased persons.
 - 8.1.1.1 Any person collecting specimens pursuant to Section 42-4-1304, C.R.S., must be certified by the Department.
 - 8.1.1.2 To become certified, any person collecting specimens pursuant to Section 42-4-1304, C.R.S., will demonstrate in the form and manner required by the Department that they satisfy Rule 8.1.2.
- 8.1.2 Individuals who collect specimens from deceased persons may be certified by the Department when any of the following requirements are met.

- 8.1.2.1 A medical provider as defined by Section 12-36-106, C.R.S., licensed to practice medicine in the state of Colorado whose scope of practice and normal duties include the collection of specimens from deceased persons.
 - 8.1.2.1.2 Individuals supervised by a medical provider, as defined in 8.1.2.1, whose scope of practice and normal duties include the collection of specimens from deceased persons.
- 8.1.2.2 An individual serving as a Colorado county coroner and whose normal duties include the collection of specimens from deceased persons.
 - 8.1.2.2.1 Individuals supervised by a Colorado county coroner, as defined in 8.1.2.2, whose normal duties include the collection of specimens from deceased persons.
- 8.1.2.3 Emergency medical service providers certified by the Department as defined by Section 25-3.5-203, C.R.S., whose normal duties include the collection of specimens from deceased persons.
- 8.1.3 No person having custody of the body of the deceased shall perform any internal embalming procedure until a blood and urine specimen to be tested for alcohol, drugs and carbon monoxide concentrations has been taken.
- 8.1.4 The laboratory must develop and provide detailed guidelines and instructions for the collection of postmortem specimens that include the date and time of collection, the time of the incident and the time of death.
- 8.1.5 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.
- 8.1.6 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 Postmortem Specimen Testing
 - 8.2.1 Postmortem 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 postmortem specimens must be retained and stored by the certified laboratory at or below 8 degrees centigrade in an appropriate container for a period of not less than 12-months from the date of collection unless requested and received by a representative from another certified laboratory for additional testing.

Part 9. DUI and DUID Forensic Toxicology Laboratory Certification Standards

- 9.1 Personnel
 - 9.1.1 The laboratory must have a Laboratory Director. The Laboratory Director is responsible for the overall operation and administration of the laboratory as well as for assuring compliance with these regulations and the accuracy of the results reported by the laboratory.

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- 9.1.2 The Laboratory Director must meet one of the following qualifications: board certified in clinical pathology by the American Board of Pathology; or 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.
 - 9.1.3 The Laboratory Director is ultimately responsible for the supervision of all laboratory operations and personnel and to ensure compliance with the requirements of this rule. The Laboratory Director may delegate supervisory responsibilities to a designee if those responsibilities are designated in writing.
 - 9.1.4 The Technical Personnel must have a minimum of an associate degree in a laboratory science or, one year training in an accredited laboratory sciences program and one year documented on-the-job laboratory experience.
 - 9.1.5 The Laboratory Director or designee must ensure policies and procedures to assess the competency of Technical Personnel engaged in testing are established, followed and documented.
 - 9.1.6 Competency assessments must be performed and documented on all new Technical Personnel prior to reporting results; on existing Technical Personnel on an annual basis; and on all Technical Personnel when a method or instrumentation is added or modified by the laboratory prior to reporting subject results. The competency assessments and documentation must be consistent with the laboratory's written training policies and procedures.
 - 9.1.7 The laboratory must maintain documentation of formal education, training, and experience for the Laboratory Director and Technical Personnel.
 - 9.1.8 The laboratory must have a written job description for each position in the laboratory.
- 9.2 Standard operating procedure manual
- 9.2.1 The laboratory must have a written procedure manual for the performance of all methods of analytes it reports available for Technical Personnel to follow at all times.
 - 9.2.2 The current Laboratory Director or designee must approve, sign and date each procedure.
 - 9.2.3 The Laboratory Director or designee must approve, initial, and date each change or revision to the procedure.
 - 9.2.4 The laboratory must maintain copies of previous standard operating procedures with effective dates of use for a minimum of 5-years from the date last used.
 - 9.2.5 The Standard Operating Procedure (SOP) manual must include the following criteria and processes for laboratory personnel to follow.
 - 9.2.5.1 Specimen receiving
 - 9.2.5.2 Specimen accessioning
 - 9.2.5.3 Specimen storage

- 9.2.5.4 Identifying and rejecting unacceptable specimens
- 9.2.5.5 Recording and reporting discrepancies
- 9.2.5.6 Security of specimens, aliquots and/or extracts and records
- 9.2.5.7 Validation of 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
- 9.2.5.8 Aliquoting specimens to avoid contamination and/or carry-over
- 9.2.5.9 Sample retention to assure stability for one year
- 9.2.5.10 Disposal of specimens
- 9.2.5.11 The theory and principles behind each assay
- 9.2.5.12 Preparation and identification of reagents, standards, calibrators and controls
- 9.2.5.13 Special requirements and safety precautions involved in performing assays
- 9.2.5.14 Frequency and number of control and calibration materials
- 9.2.5.15 Recording and reporting assay results
- 9.2.5.16 Protocol and criteria for accepting or rejecting analytical data
- 9.2.5.17 Procedure to verify the accuracy of the final report
- 9.2.5.18 Pertinent literature references for each method
- 9.2.5.19 Current step-by-step instructions with sufficient detail to perform the assay to include equipment operation and any abbreviated versions used by the Technical Personnel.
- 9.2.5.20 Acceptability criteria for the results of calibration standards and controls as well as for the comparison between two aliquots or columns.
- 9.2.5.21 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.
- 9.2.5.22 A documented system for the review, notification and implementation of corrective actions to include, when applicable, contacting the requesting agency.
- 9.2.5.23 Policies and procedures to follow when specimens are requested for referral and testing by another certified laboratory.

9.3 Proficiency Testing (PT)

9.3.1 The laboratory must have a documented system for timely review and evaluation of all PT results by the Laboratory Director and by all Technical Personnel who participated in the PT event.

9.3.2 The laboratory must maintain a copy of all records and documentation for a minimum of 5 years from the date of the proficiency testing event.

9.4 Quality Assurance and Quality Control

9.4.1 The laboratory must check and document the accuracy of automatic and/or adjustable pipettes and other measuring devices when placed into service and annually thereafter.

9.4.2 The laboratory must 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 measurements used by the laboratory.

9.4.3 The laboratory must annually verify and document the accuracy of thermometers using a reference thermometer.

9.4.4 The laboratory must 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.

9.4.5 The laboratory must 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 (when applicable).

9.4.6 The laboratory must avoid mixing different lots of reagents in the same analytical run.

9.4.7 For quantitative analysis, the laboratory must perform and document a calibration curve that has a correlation coefficient of 0.99 or greater using, at a minimum, four calibrators that encompass the reportable range.

9.4.8 If the laboratory uses historical calibration data for an assay, control materials must be included with each batch of specimens tested to verify the validity of the calibration including at or close to the reporting limits. Laboratories may use historical calibration curves only if they have demonstrated and documented the linearity and precision of the curve over time. Calibration must be validated by using control materials with each batch of specimens tested to cover the entire range of the calibration curve.

9.4.9 For qualitative analyses, the laboratory must analyze, at minimum, a negative control and a positive control with each analytical run of samples analyzed.

9.4.10 For quantitative analyses, the laboratory must analyze, at minimum, a negative control and two levels of positive controls that challenge the entire calibration curve.

9.4.11 The laboratory must use control material(s) (when possible) that differs in source, lot number, or concentration from the calibration material used with each analytical run. In instances where the same source must be utilized, separate weighing's or solutions must be used to prepare these controls.

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- 9.4.12 For multi-analyte assays, the laboratory must perform and document calibration curves and controls specific to each analyte, or at minimum, one with similar chemical properties as reported in the analytical run.
- 9.4.13 The laboratory must analyze at least one control that is made using reference material from an ISO/IEC 17034 accredited manufacturer when available. For quantitative purposes, the control must be within (10% for ethanol and 20% for blood and urine drugs) of the stated assayed value with each analytic run.
- 9.4.14 The laboratory must analyze an appropriate matrix matched negative and positive control with each analytical run, when available.
- 9.4.15 The laboratory must analyze calibrators and controls in the same manner as unknowns.
- 9.4.16 The laboratory must define acceptability criteria for calibration standards and controls for all assays, such that they are within 10% for ethanol and 20% for blood and urine drugs, of the target value.
- Note: a slightly wider acceptable value (e.g. +/-25% or +/-30%) for calibrators and controls that approach the Limit Of Quantitation (LOQ) of the assay is permitted.
- 9.4.17 The laboratory must 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.
- 9.4.18 The laboratory must have written criteria to follow when corrective action is required for any unacceptable calibration, control, and standard or instrument performance.
- 9.4.19 The laboratory must document the corrective actions taken when an unacceptable calibration, control, standard, or other reagent result exceeds the laboratory's criteria of acceptability.
- 9.4.20 Corrective actions must be documented and reviewed by the Laboratory Director or designee on an ongoing basis to ensure the effectiveness of the actions taken.
- 9.4.21 The laboratory must maintain records of validation data for any new or modified methods to include; accuracy, precision, analytical specificity (interferences), Limit Of Detection (LOD), LOQ and verification of the regression model.
- 9.4.22 Analytical methods must be developed by the laboratory such that screening and confirmation testing can be completed on no more than 5 ml of sample volume.
- 9.4.23 The analyst must follow the SOP for the tests performed.
- 9.5 Chain of Custody, Security, and Specimen Retention Facility Space
- 9.5.1 The laboratory must have a system to document the complete chain of custody of all forensic specimens to include receipt, storage, personnel handling the specimens, external transfers and disposal.
- 9.5.2 The laboratory must issue instructions to user agencies that include the requirements for specimen types(s), unique identification, and volume.
- 9.5.3 The laboratory must document the condition of the sample, external package and individual evidence seals.
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- 9.5.4 The laboratory must compare the evidence seals against the corresponding requisition and document any discrepancies. When discrepancies occur, documentation must state how the discrepancy was resolved.
 - 9.5.5 The laboratory must maintain a current list of authorized personnel.
 - 9.5.6 The laboratory must restrict entry into the laboratory only to authorized personnel.
 - 9.5.7 The laboratory must have provisions for securing the laboratory during non-working hours.
 - 9.5.8 The laboratory must secure short and long-term storage areas when not in use.
 - 9.5.9 The laboratory must log in and aliquot specimens in a secure area.
 - 9.5.10 There must be adequate space to perform the analyses in the laboratory.
- 9.6 Records and Reporting
- 9.6.1 All instrumentation and analysis records maintained by the testing laboratory must be retained for a period of not less than 5-years.
 - 9.6.2 Prior to reporting results, all specimens that have been identified as positive on an initial screening drug test must be confirmed using a second analytical procedure using a different chemical principle from the initial screening test when available or as applicable.
 - 9.6.3 The laboratory must confirm the identity of an analyte using a different extract of the same specimen than was used for the screening test.
 - 9.6.4 Prior to reporting results, all blood ethanol results must be confirmed using a second GC column where the results from the second column had a significant difference in retention time and a change in elution order of some of the common volatiles from the column utilized in the initial column.
 - 9.6.5 When blood samples are screened for ethanol by head space gas chromatography with flame ionization detection (if applicable), a separate aliquot from the original specimen must be used for confirmation. (e.g. two separate aliquots should be tested for blood alcohol).
 - 9.6.6 For postmortem testing (if applicable), the laboratory must confirm the identity of a drug analyte or alcohol concentration using a second column and a different extract from the same sample, or use a different sample matrix from the same subject when possible.
 - 9.6.7 The laboratory must only report quantitative results that are within the calibration curve.
 - 9.6.8 The laboratory must verify results that are outside the calibration curve in a manner consistent with the laboratory's SOPs.
 - 9.6.9 The laboratory must qualitatively report results below the lowest concentration of calibrator or standard and above the Limit Of Detection (LOD) as a semi-quantitative result. (e.g. less than or greater than X mg/L).

- 9.6.10 The laboratory must maintain records of testing for at least 5-years to include: accession numbers, specimen type, raw data from the analytical run, controls, subject results, final and/or amended reports, acceptable reference range parameters, identification of Technical Personnel who performed the testing, and date of analysis.
- 9.6.11 The laboratory's final report must contain the name and location of the laboratory where the testing was performed, 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.
- 9.6.12 The laboratory must develop an adequate discovery packet that meets the requirements specified in Part 1.5 of these rules and regulations.
- 9.7 Analytical Process
- 9.7.1 General Requirements
- 9.7.1.1 The laboratory must document the conditions of the instruments to include the detector response, tune and validation of new chromatography columns (when applicable).
- 9.7.1.2 The laboratory must perform and document preventative maintenance as required by the manufacturer.
- 9.7.1.3 The maintenance records must be readily available to the Technical Personnel.
- 9.7.1.4 The laboratory must use an internal standard for each qualitative and quantitative analysis that has similar chemical and physical properties to that of the compound identified and is isotopically labeled when available.
- 9.7.1.5 The laboratory must document the monitoring of the response (area or peak height) of the internal standard to ensure consistency over time of the analytical system.
- 9.7.1.6 The laboratory must monitor analyses to check for contamination and/or carry-over.
- 9.7.1.7 The laboratory must have written acceptability criteria for variance between the results when the same analyte is quantified in multiple analyses.
- 9.7.1.8 The laboratory must evaluate the performance of the instrument after routine and preventative maintenance prior to analyzing subject samples.
- 9.7.1.9 If the laboratory has written its own software, the laboratory must have documentation that the software's accuracy was verified.
- 9.7.2 Head Space-Gas Chromatography with Flame Ionization Detection (HS-GC-FID)
- 9.7.2.1 The laboratory must 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.
- 9.7.3 Gas Chromatography with Mass Spectrometry (GC-MS)

- 9.7.3.1 The laboratory must document the changes of septa as specified in the SOP.
- 9.7.3.2 The laboratory must document changes and/or replacements of liners as specified in the SOP.
- 9.7.3.3 The laboratory must have written criteria for an acceptable tune for the mass spectrometer. When the tune is unacceptable, corrective action to include additional maintenance must be documented (if applicable).
- 9.7.3.4 If the laboratory uses selected ion monitoring, the laboratory must compare ion ratios and retention times between calibrators, controls and samples for identification of an analyte within the same analytical run.
- 9.7.3.5 If the laboratory uses a library match to qualitatively identify an analyte, the laboratory must compare the relative retention time and mass spectra from a known standard or control run that has been tested on the same instrument before reporting the results.
- 9.7.4 Immunoassays
 - 9.7.4.1 If the laboratory tests specimens differently from what the manufacturer has approved for the assay, or if the laboratory has modified the test method from the manufacturer instructions, the laboratory must have documentation of the validation for the modified test method or test system.
- 9.7.5 Liquid Chromatography with Mass Spectrometry or with Tandem Mass Spectrometry (LCMS, LCMS/MS)
 - 9.7.5.1 The laboratory must maintain records of the mass spectrometer calibration.
 - 9.7.5.2 The laboratory must confirm the identity of an analyte by LC-MS/MS (screening or quantitation) with at least two transitions in addition to the laboratory's retention time criteria.
 - 9.7.5.3 If the laboratory recycles eluting solvents, it must maintain written acceptability standards for each type of eluting solvent it recycles.

Part 10. Violations and Remedies

10.1 Violations

- 10.1.1 It is a violation of these rules and regulations to perform EBAT testing without the appropriate certification for the EBAT instrument, operator or instructor.
- 10.1.2 Violation of these rules and regulations may result in denial, suspension or revocation of certification as described in 10.4.
- 10.1.3 Generally, a violation will not be cited if:
 - 10.1.3.1 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.

10.1.3.2 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.

10.2 Complaints

10.2.1 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.

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

10.3.1 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.

10.4 Denial, Suspension or Revocation of Certification:

10.4.1 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:

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

10.4.1.2 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.

10.4.1.3 Gross incompetence or negligent practice.

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

10.4.1.5 Inadequate space, equipment, personnel or methods utilized for testing.

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

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

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

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

10.5 Injunction

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

Editor's Notes

History

Entire rule eff. 10/01/2011.

Entire rule eff. 02/01/2013.

Parts 5.1, 5.3.3, 5.3.5 eff. 03/17/2018.

Entire rule eff. 02/14/2019.