COLORADO
Department of Public Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

To: Members of the State Board of Health

From: Jeff Groff, Manager, Evidential Breath Alcohol Testing (EBAT) Program.

Through: Randy Kuykendall, Director, Laboratory Services Division - DRK

Date: December 1, 2018

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to 5CCR 1005-2 – Testing for Alcohol and Other Drugs with a request for a rulemaking hearing to be set for December 19, 2018.

The department is requesting approval from the Colorado Board of Health of the proposed changes to 5CCR 1005-2. The purpose of the proposed changes are as follows;

- Alignment of the rule with current statute;
- Alignment of the Forensic Toxicology Laboratory certification requirements with current industry best practices to include International Standards Organization (ISO/IEC 17025) and the American Board of Forensic Toxicologists (ABFT) standards;
- Removal of the current appendices (A,B,C) and include those requirements in the body of the rule; and,
- Removal of redundant requirements and make minor grammatical and technical corrections.

The department has initiated robust stakeholder engagement to include face-to-face meetings and has received many valuable comments and feedback throughout that process. The department received additional suggestions from stakeholders (certified laboratories, the legal community, and other stakeholders) between the request for rule making hearing and the rule making hearing. Changes were made in response to this feedback. The changes maintain the current standard, or provide additional clarity to the language and are not substantive in nature. The department also reviewed the terminology as encouraged by the Board during the request for rulemaking presentation. Some of the clarifying edits respond to the Board's feedback. Changes to the proposed rule have been incorporated and are highlighted in yellow. The department has received positive feedback from stakeholders that the rule effectively communicates scientific and technical laboratory standards.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
5CCR 1005-2
Testing for Alcohol and Other Drugs

Basis and Purpose.

- In January 2018, the Board of Health adopted rules that waived specific laboratory certification requirements for laboratories that are accredited. At the time of the rulemaking, a technical deficiency was acknowledged as the statute only allowed waiver when accreditation was conferred by the American Board of Forensic Toxicology or the International Standards Organization (ISO). The Department and stakeholders acknowledged that under the plain language of the law, entities accredited through the ANSI-ASQ National Accreditation Board (who applies the ISO requirements) were not eligible for waiver of the certification requirements. HB 18-1302 corrected this by authorizing the Board to waive certification requirements when an entity is accredited by "a nationally or internationally recognized accreditation organization that includes the scope of forensic toxicology." This change aligns the rule to the statute. The substantive standards as to which requirements are waived and the Department's ability to respond to complaints remains unchanged.
- The proposed rule changes incorporate rules of the Department's rule review. The proposed changes align the rule with current industry best practices to include; defining laboratory key personnel, personnel competency assessment practices, providing the laboratories additional flexibility in selecting a proficiency testing provider, and specifying manufacturer criteria that provide quality control materials to the labs. The proposed rule changes are consistent with ISO/IEC 17025 and the American Board of Forensic Toxicologists (ABFT) accreditation requirements. These updates ensure that there is consistency in the quality standards between the accredited and non-accredited labs participating in the program.
- The proposed changes remove rule appendixes A, B, and C. Appendix A was moved into Part 3. Appendix B was moved into Part 5. Appendix C was moved into Part 5 and the new Part 9. The requirements are being incorporated into the body of the rule in the applicable parts. This change removes forms from the rule, consolidates redundant requirements and removes outdated historical requirements that are no longer applicable to the technologies and instrumentation.
- The proposed changes communicate the standards required by Section 42-4-1304(1) C.R.S. for the Department to certify individuals who collect samples from the deceased for testing of alcohol, drug and carbon monoxide concentrations "by and appropriately trained person certified by the department of public health and environment".
- The proposed changes remove references to NIST at 5.4.5.1 as NIST does not certify reference materials. Instead, clarification of what types of manufacturers the laboratories may purchase certified reference materials from is defined at 5.4.5.
- The proposed changes remove the term "Certified" to "Approved" for law enforcement facilities that house the certified EBAT instrumentation as part of the technical clean-up and clarification of the rule language. Section 42-4-1301.1 C.R.S does not require the department to certify law enforcement facilities and by aligning

the rule language with the department's statutory obligations removes unnecessary layering of additional approvals and certifications and does not alter current process.

- The proposed changes remove redundant and outdated language and make minor grammatical edits.

Specific Statutory Authority.
Statutes that require or authorize rulemaking: Sections 42-1-1301.1 and 42-4-1304, C.R.S.

Statutes that inform or direct the rule content:

Section 42-4-1304, C.R.S. Samples of blood or other bodily substance - duties of department of public health and environment.

> (1) The department of public health and environment shall establish a system for obtaining samples of blood or other bodily substance from the bodies of all pilots in command, vessel operators in command, or drivers and pedestrians fifteen years of age or older who die within four hours after involvement in a crash involving a motor vehicle, a vessel, or an aircraft. For purposes of this section, "vessel" has the meaning set forth in Section 33-13-102, C.R.S. 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, drug, and carbon monoxide concentrations has been taken by an appropriately trained person certified by the department of public health and environment. Whenever the driver of the vehicle cannot be immediately determined, the samples shall be obtained from all deceased occupants of the vehicle.
>
> (4)(a) as revised by HB14-1340:
> The certification of laboratories to ensure that the collection and testing of samples is performed in a competent manner, which may include waiving specific certification requirements for laboratories that are accredited by the American board of forensic toxicology, the international standards organization, or a successor to either organization; and
>
> (4)(a) as revised by HB18-1302:
> The certification of laboratories to ensure that the collection and testing of samples is performed in a competent manner, which may include waiving specific certification requirements for laboratories that are accredited by a nationally or internationally recognized accreditation organization that includes the scope of forensic toxicology; and

Is this rulemaking due to a change in state statute?

___X___ Yes, the bill number is HB 18-1302. Rules are ___ authorized _X__ required.

_____ No

Does this rulemaking incorporate materials by reference?

_____ Yes ___ URL or ___ Sent to State Publications Library

___X___ No

Does this rulemaking create or modify fines or fees?

_____ Yes
___X___ No

Does the proposed rule create (or increase) a state mandate on local government?

_X_ No. This rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed. Though the rule does not contain a state mandate, the rule may apply to a local government if the local government has opted to perform an activity, or local government may be engaged as a stakeholder because the rule is important to other local government activities.

___ No. This rulemaking reduces or eliminates a state mandate on local government.

___ Yes. This rule includes a new state mandate or increases the level of service required to comply with an existing state mandate, and local government will not be reimbursed for the costs associated with the new mandate or increase in service.

The state mandate is categorized as:

___ Necessitated by federal law, state law, or a court order
___ Caused by the State's participation in an optional federal program
___ Imposed by the sole discretion of a Department
___ Other: _____

Has an elected official or other representatives of local governments disagreed with this categorization of the mandate? ___Yes _X__No

If yes, please explain why there is disagreement in the categorization.

Please elaborate as to why a rule that contains a state mandate on local government is necessary.

N/A

REGULATORY ANALYSIS
for Amendments to
5CCR 1005-2
State Board of Health Rules Pertaining to the Testing for Alcohol and Other Drugs

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

   The classes of persons affected are:
   Forensic Toxicology Laboratories that are certified by the Department. These include both private and public laboratories.
   - Colorado Bureau of Investigation (CBI)*
   - El Paso County Coroner's Office*
   - Denver Police Department Crime Laboratory*
   - Colorado State University Toxicology Laboratory*
   - Chematox Labs, Inc.
   - Rocky Mountain Instrumental Labs (RMIL)
   - NMS Labs

   Individuals who collect samples from the deceased involved in a motor vehicle crash that are used for testing of alcohol, drugs and carbon monoxide concentrations. These include;
   - Colorado Coroners*
   - Forensic Pathologists*
   - Coroner Investigators*
   - Coroner Assistants*
   - Emergency Medical Service (EMS) First Responders*
   - Emergency Room and Hospital Personnel*

   A. <u>Identify each group of individuals/entities that rely on the rule to maintain their own businesses, agencies or operation, and the size of the group:</u>

      - CBI* (12-15 personnel)
      - El Paso County Coroner's Office* (5-6 personnel)
      - Denver Police Department Crime Laboratory* (3-4 personnel)
      - Colorado State University Toxicology Laboratory* (1-2 personnel)
      - Chematox Labs, Inc (9-10 personnel)
      - Rocky Mountain Instrumental Labs (RMIL) (6-8 personnel)
      - NMS Labs (175-180 personnel)
      - Colorado Coroners* (64 coroners)
      - Forensic Pathologists* (15 doctors)
      - Coroner Investigators* (90-100 personnel)
      - Coroner Assistants* (40-50 personnel)

   B. <u>Identify each group of individuals/entities interested in the outcomes the rule and those identified in #1.A achieve, and if applicable, the size of the group</u>

- 6 - Forensic Toxicology Laboratories
- 64 - Coroners and staff
- 15 - Forensic Pathologists
- Colorado Law Enforcement (Colorado State Patrol, Colorado County Sheriff's Organization , Colorado Chiefs of Police Association)*
- Colorado District Attorneys Counsel*
- Colorado Bar Association
- Colorado Public Defenders Association*

C. Identify each group of individuals/Entities that benefit from, may be harmed by or at-risk because of the rule, and if applicable, the size of the group:
The following groups benefit from the rule changes as they help to ensure that alcohol and drug results reported by the forensic toxicology labs certified by the department are accurate, precise and reliable.
- Both Colorado residents and non-residents.
- Colorado Law Enforcement*
- Colorado Legal Community (District Attorneys, DUI Defense Attorneys, Public Defenders)*
- Colorado Department of Revenue, Drivers' License Hearing Officers*
- Colorado Courts*

* Local government, local elected officials or organizations connected to local government.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

Quantitative Impact:
The proposed changes will have the following quantitative impact:
- The proposed changes to the rules have no impact on accredited forensic toxicology laboratories certified by the department. Currently there are 9 forensic toxicology laboratories certified by the department to perform testing on samples for DUI/DWAI purposes. Of the 9 Department certified laboratories, 5 (CBI-3, NMS-1, DPD-1) are currently accredited by either the American Board of Forensic Toxicologists (ABFT) or by an internationally recognized accrediting organization.
- Revisions to the forensic toxicology certification standards will have minimal to no impact on non-accredited forensic toxicology laboratories certified by the department.
- Individuals who collect samples from the deceased will be required to be certified by the department in order to be compliant with Section 42-4-1304, C.R.S.

Qualitative Impact:
The proposed changes will have the following qualitative impact:
- Alignment with current statutory requirements.
- Consistency in industry best practices for forensic toxicology laboratories.

A. <u>For those that rely on the rule to maintain their own businesses, agencies or operations:</u>

Describe the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

Favorable non-economic outcomes:

- Alignment with current statutory requirements and language.
- The long-term effect is comparable quality standards for accredited and non-accredited laboratories. Non-accredited labs that choose to become accredited in the future will have their processes and procedures in alignment with nationally and internationally recognized standards, thus making the transition to accreditation much easier and cost effective.

Unfavorable non-economic outcomes:
None identified

Anticipated financial impact:

Anticipated Costs:	Anticipated Benefits:
Description of costs that must be incurred. Forensic Toxicology Labs will be required to purchase their own blood alcohol Proficiency Testing (PT) material annually at a nominal cost instead of the Department purchasing them. Most of the labs in the program already do this. Description of costs that may be incurred. • None	Description of financial benefit. Laboratories will be able to decide on what PT material they wish to purchase and for some labs may actual reduce the number of PT samples requiring purchase annually.
Cost or cost range. $200 - $300 annually	Savings or range of savings. • None
Dollar amounts that have not been captured and why: • None	Dollar amounts that have not been captured and why: • None

Local Government Impact: N/A. To the extent a certified laboratory is operated by local government, this has occurred because the local government has opted to obtain certification and perform these services.

Fiscal Note: Other than the workload costs to update the rule, HB 18-1302 had no fiscal impact.

B. For those that are affected by or interested in the outcomes the rule and those identified in #1.A achieve.

Describe the favorable or unfavorable outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

Favorable non-economic outcomes:

DUI/DUID test results reported by department certified forensic toxicology laboratories and used for criminal and administrative purposes will continue to be current and have the same quality standards of performance regardless of whether the laboratory is accredited.

Unfavorable non-economic outcomes:

None identified.

Any anticipated financial costs monitored by these individuals/entities?

None identified.

Any anticipated financial benefits monitored by these individuals/entities?

None identified.

C. For those that benefit from, are harmed by or are at risk because of the rule, the services provided by individuals identified in #1.A, and if applicable, the stakeholders or partners identified in #1.B.

Describe the favorable or unfavorable outcomes (short-term and long-term), and if known, the likelihood of the outcomes:

Long-term benefit to those identified in #1.B and #1.C is continued confidence in the test results reported by the department-certified forensic toxicology laboratories. The test results are relied upon by law enforcement and the legal communities statewide for criminal and administrative procedures. Residents and non-residents who are charged with a DUI/DUID offense will have their samples tested by laboratories that are operating to industry best practices and high quality standards.

Financial costs to these individuals/entities:

None identified.

Financial benefits to or cost avoidance for these individuals/entities:

None identified.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

A. Anticipated CDPHE personal services, operating costs or other expenditures:

None identified.

Anticipated CDPHE Revenues: N/A

This rulemaking modifies fees: N/A

B. Anticipated personal services, operating costs or other expenditures by another state agency:
None identified.

Anticipated Revenues for another state agency:
None identified.

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Check mark all that apply:
___ Inaction is not an option because the statute requires rules be promulgated.

X__ The proposed revisions are necessary to comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.

X__ The proposed revisions appropriately maintain alignment with other states or national standards.

X__ The proposed revisions implement a Regulatory Efficiency Review (rule review) result, or improve public and environmental health practice.

X__ The proposed revisions implement stakeholder feedback.

___ The proposed revisions advance the following CDPHE Strategic Plan priorities:

Goal 1, Implement public health and environmental priorities
Goal 2, Increase Efficiency, Effectiveness and Elegance
Goal 3, Improve Employee Engagement
Goal 4, Promote health equity and environmental justice
Goal 5, Prepare and respond to emerging issues, and
Comply with statutory mandates and funding obligations

Strategies to support these goals:
___ Substance Abuse (Goal 1)
___ Mental Health (Goal 1, 2, 3 and 4)
___ Obesity (Goal 1)
___ Immunization (Goal 1)
___ Air Quality (Goal 1)
___ Water Quality (Goal 1)
X__ Data collection and dissemination (Goal 1, 2, 3, 4 and 5)
___ Implements quality improvement or a quality improvement project (Goal 1, 2, 3 and 5)
___ Employee Engagement (career growth, recognition, worksite wellness) (Goal 1, 2 and 3)
___ Incorporate health equity and environmental justice into decision-making (Goal 1, 3 and 4)

___ Establish infrastructure to detect, prepare and respond to emerging issues (Goal 1, 2, 3, 4, and 5)

___ Other favorable and unfavorable consequences of inaction:

- None identified

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

   Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The specific revisions proposed in this rulemaking were developed in conjunctions with stakeholders. The benefits, risks and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary or are the most feasible manner to achieve compliance with statute.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

   See response #4 and #5.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

   - Stakeholder Feedback from Forensic Toxicologists and Forensic Toxicology Laboratory Directors
   - ISO/IEC 17025 standards
   - ABFT accreditation standards
   - Current Colorado Revised Statutes (C.R.S.)

STAKEHOLDER ENGAGEMENT
for Amendments to
5CCR 1005-2
State Board of Health Rules Pertaining to the Testing of Alcohol and Other Drugs

State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The following individuals and/or entities were identified as the primary stakeholders and invited to provide input and included in the development of these proposed rules:

Organization	**Representative**
Colorado Coroner's Association	Randy Gorton – Vice President
Colorado Coroners Standards and Training Board (CCTSB)	Anne Strawbridge - Secretary
Colorado Bureau of Investigation (CBI)	Dan Anderson – Lab Director
El Paso County Coroner's Office	Dr. Robert Bux – Lab Director
Denver Police Department Crime Lab	Dr. Greg LaBerge – Lab Director
Colorado State University Toxicology Lab	Dr. Greg Dooley – Lab Director
Chematox Labs, Inc	Sarah Urfer – Lab Director
NMS Labs, Inc	Margaret Beamer – Lab Director
Rocky Mountain Instrumental Labs (RMIL)	Dr. Robert Lantz – Lab Director

Stakeholder engagement was initiated in late May 2018. Requests for feedback and comments were made by the department to the primary stakeholders listed in #1A and feedback was provided. Proposed changes were made to the existing language and sent back to the identified primary stakeholders for additional comments and feedback which was also provided. Department staff have also met with the Colorado Coroner's Association (CCA) Board of Directors during their annual meeting in June 2018. An onsite meeting to further discuss the proposed changes was held at the Laboratory Services Division on July 26th where additional comments and suggestions were received and incorporated. The revised draft was sent out again in September to the primary stakeholders for review and to offer opportunity to make any further comments.

The stakeholders identified in #1B were also notified of the rule revisions and provided the link to the draft document on the department's website. The secondary stakeholders identified in #1B were also provided opportunity to offer any comments.

All comments and feedback received from stakeholders and partners have been reviewed and when applicable, incorporated into the draft rule revision. The Department continued to collect feedback. Feedback from the legal community, laboratories, the Board of Health and other stakeholders was reviewed and incorporated as appropriate. Overall, stakeholders and partners are pleased with the stakeholder engagement process and the resulting rules. The consensus is positive and agreement on the proposed changes has been achieved.

Stakeholder Group Notification
The primary stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice

was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

___ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

_X_ Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The major policy issued encountered concerned the statutory language found at Section 42-4-1304(1), C.R.S. In discussions with the CCA and the CCSTB, stakeholders questioned whether a health or safety concern was being met through the statute requiring the department to certify the individuals obtaining the specimens to be tested for alcohol, drug, and carbon monoxide concentrations. Individuals who collect samples from the deceased are either currently licensed by the state to practice medicine, perform emergency services, are elected officials who are trained and certified, or are individuals who perform this work under the supervision of licensed and/or certified individuals listed above where their scope of work includes the collection of samples from the deceased. There is no parallel requirement for individuals who collect specimens from living individuals for the same forensic application. Stakeholders opined that this statutory requirement is unnecessary. Stakeholders appreciated the Department's need to comply with statute and the Department appreciated that stakeholders may reach out to their legislative representatives and pursue a repeal of this statutory requirement.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

None identified.

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.		Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.		Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.		Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.
	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.		Ensures a competent public and environmental health workforce or health care workforce.
X	Other:____This rule ensures forensic toxicology laboratories certified by the Department operate in alignment with the current industry standards. Quality laboratory services benefit those involved in criminal or administrative matters.		Other:_____ _____

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Laboratory Services Division

TESTING FOR ALCOHOL AND OTHER DRUGS

5 CCR 1005-2

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 ~~, 3,~~ 4 ~~and Appendix A~~ of these rules and regulations. All APPROVED EBAT FACILITES AND 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 THROUGH ~~-9~~8 ~~and Appendix B and C~~ of these rules and regulations. All certified FORENSIC TOXICOLOGY laboratories performing TESTING IN THE CATEGORIES OF blood alcohol, blood drug, urine drug and post~~t-~~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.

"APPROVED Facility" – any location that meets the requirements of these regulations and which is APPROVED ~~certified~~ 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, ~~facility~~ or FORENSIC TOXICOLOGY 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~~ Section 42-4-1301, C.R.S.

"Certified EBAT Instructor" – an employee of a~~ny 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 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.

"Certified EBAT Operator" – an employee of a~~ny 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 D~~d~~riving U~~u~~nder the ~~-~~I~~i~~nfluence of alcohol and/or other drugs as defined by ~~Colorado revised statute~~ SECTION 42-4-1301(1)(f), C.R.S.

"DWAI" – refers to the term D~~d~~riving W~~w~~hile A~~a~~bility I~~i~~mpaired by alcohol and/or other drugs as defined by ~~Colorado revised statute~~ SECTION 42-4-1301(1)(g), 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. T~~t~~his must include but is not limited to the following; the completed subject EBAT, and any E~~e~~xception M~~m~~essages 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.

"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.

~~"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.

"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 ~~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 analytic run.

"DISCOVERY~~Litigation~~ Packet" – refers to records requested for litigation purposes that include sufficient material to allow independent review by a qualified toxicologist. T~~t~~he 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 (PT)" – The evaluation of unknown specimens ~~supplied by a provider~~ 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.

~~"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.~~

"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:

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2.1.3 Tthe certified EBAT operator card issued by the Department may serve as evidence of certification.

*****

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

3.1 Standards for APPROVAL ~~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 APPROVED~~certified~~ by the Department.

3.1.2 Department standards for APPROVAL ~~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 BE APPROVED.~~receive certification.~~

3.1.4 Onsite Inspections of permanent, temporary and mobile EBAT facilities must be performed prior to initial APPROVAL ~~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 APPROVAL~~CERTIFICATION~~ – 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 ~~certification that~~AND 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 APPROVAL ~~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 APPROVAL ~~certification~~request, Department personnel will schedule an onsite inspection to verify compliance with the requirements found in Part 3 ~~and Appendix A~~ prior to APPROVAL ~~certification~~.

3.1.6~~5.3~~ The Department will perform an~~d~~ onsite inspection at an ~~certified~~EBAT facility when any of the following occur:

3.1.6.1~~5.3.1~~ The EBAT facility is seeking initial APPROVAL ~~certification~~, or

3.1.6.2~~5.3.2~~ The APPROVED ~~certified~~ EBAT facility requests relocation of the certified EBAT instrument either temporarily or permanently within the FACILITY ~~agency~~, or

3.1.6.3~~5.3.3~~ A new EBAT facility is being constructed that will house the certified EBAT instrument, or

3.1.6.4~~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.~~

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

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 ~~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 ±10% during the calibration checks.

4.1.3.4.2 If the correlation between calibration checks is not within ±10%, the instrument will discontinue the test sequence and print a "No Calibration Correlation" Eexception MESSAGE.~~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” Eexception MESSAGE.report.

4.1.3.5.2 When a “No .02 Agreement” Eexception MESSAGE 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” Eexception MESSAGE report.

4.1.3.6.1 If an “Invalid Sample” Eexception MESSAGE 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~~ 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~~Standby~~” mode, WAIT UNTIL THE INSTRUMENT COMPLETES THE WARM-UP PERIOD PRIOR INITIATING ANY TESTING.~~depress the start test button to initiate the warm-up period.~~

4.2.3 Completion of a 20-minute deprivation period MUST BE conducted at the certified EBAT facility by a certified EBAT instructor or operator that is in an active status that must include;

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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 Eexception MESSAGE(s) ~~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 either: successful on-site annual inspection for non-accredited labs, or, ongoing accreditation status for accredited labs, ~~and,~~ IN ADDITION TO successful PROFICIENCY TESTING PERFORMANCE IN THE CATEGORY OR CATEGORIES THE LABORATORY IS CERTIFIED IN ~~participation in the designated proficiency testing~~ and ongoing compliance with PARTS 5~~,~~ THROUGH 9 OF THIS RULE.~~the applicable requirements in 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 ~~the American Board of Forensic Toxicology (ABFT), the International Standards Organization (ISO), or a successor to the either organization~~ 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 organization's MOST RECENT AND final biennial inspection report within 30 days of receipt OF ACCREDITATION IN THE SCOPE OF FORENSIC TOXICOLOGY ~~for the specialty of 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.

~~either another Department certified lab, or a forensic toxicology laboratory accredited by the American Board of Forensic Toxicology (ABFT), the International Standards Organization (ISO), or a successor to the either organization.~~

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 post-mortem 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 ~~(Appendix B) for certification of their~~

~~laboratory.~~ ~~,~~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 ~~6,7,8,~~9 ~~and Appendix C~~ and participate in an initial on~~-~~site inspection. THE ONSITE INSPECTION MAY BE~~IS~~ 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 PROVID~~provide~~ING a completed application ~~(Appendix B)~~ 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 ~~Certified laboratories referring specimens to another accredited laboratory must include documentation with the application (Appendix B) that the reference laboratory is accredited by the American Board of Forensic Toxicology (ABFT), the International Standards Organization (ISO), or a successor to the either organization.~~

5.3.~~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.~~4~~5 To maintain certification, laboratories shall meet all applicable requirements found in Parts 5 ~~,~~THROUGH 9 ~~8, and Appendix C~~. Non-accredited laboratories or accredited laboratories identified in 5.1.4 must 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 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.~~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, TECHNICAL ~~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 THE COMPETENCY OF TECHNICAL PERSONNEL ~~employee competency~~ as specified in PART 9. ~~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 KEY MANAGEMENT. ~~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 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.~~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 PART 9. ~~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, t~~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. ~~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 (PT) requirements for CERTIFIED FORENSIC TOXICOLOGY LABORATORIES. ~~Blood, Urine and Post Mortem Samples~~

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. ~~supplied by a provider that determines target values for those unknown specimens. PT is required for each approved category.~~

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~~2 Prior to initial certification, the laboratory must AT MINIMUM, have successfully participated in one ~~of the designated~~ 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 ~~THE~~ PART 5.~~,~~ ~~within the preceding 12 months.~~

5.5.~~4~~3 To maintain continued laboratory certification, a laboratory must DEMONSTRATE SUCCESSFUL PT PERFORMANCE FOR EACH CATEGORY IN WHICH THE LABORATORY IS CERTIFIED.

~~participate in the designated PT program and maintain satisfactory performance as determined by the Department.~~

5.5.~~5~~4 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 ~~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.~~5~~6~~4~~.1 The laboratory must request that the proficiency testing provider PROVIDE ~~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.~~6~~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.~~

5.5.65.12 A laboratory must DEMONSTRATE SUCCESSFUL PT PERFORMANCE ~~participate~~ in A MINIMUM OF 3 ALCOHOL PT TESTING ~~PT testing through 3~~ events per year. EACH EVENT MUST CONSIST OF A MINIMUM~~, consisting~~ of 45 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.

5.5.65.23 Other forensically significant volatiles, such as acetone, methanol and isopropanol, may be included in one or more PT samples IN~~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.

5.5.65.34 SCORING ~~Grading~~Criteria for Blood Alcohol Proficiency Testing

5.5.65.34.1 PT~~roficiency 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 SCORED ~~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 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.

5.5.65.34.32 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. ~~submitted to the Department for approval within 15 days of receipt of the results.~~

5.5.5.34.43 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~~ OF Correction" specified by the Department, or suspension/limitation of certification for the failed analyte.

5.5.76 Urine, Blood and Postm ~~M~~ortem Drug Testing

5.5.76.1 For blood drug, urine drug and post-mortem screening and confirmation certification, THE ~~a~~ laboratory must DEMONSTRATE SUCCESSFUL PT PERFORMANCE. ~~successfully participate in the appropriate College of American Pathologists (CAP) proficiency test programs.~~

5.5.76.1.1 For blood -drug certification the LABORATORY MUST PARTICIPATE IN A MINIMUM OF TWO PT EVENTS ANNUALLY THAT INCLUDE BLOOD SAMPLES. ~~required program is the Forensic Toxicology (Criminalistics) (FTC) survey.~~

5.5.76.1.2 For urine -drug certification the LABORATORY MUST PARTICIPATE IN A MINIMUM OF TWO PT EVENTS ANNUALLY THAT INCLUDE URINE SAMPLES.

~~required program is the Urine Toxicology (UT) survey.~~

5.5.76.1.3 For laboratories performing only post-mortem 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 MATRICIES WHEN AVAILABLE. ~~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.~~

5.5.76.2 SCORING ~~Grading~~ criteria for drug proficiency testing

5.5.76.2.1 PT~~roficiency test~~ results must be returned to the PT~~pt~~ provider within the time specified by the PT~~pt~~ provider. Results received after the due date will not be SCORED ~~graded~~ and will be considered an “Unsatisfactory” performance resulting in a score of 0 for the testing event. T~~t~~he laboratory must contact the PT provider AND THE DEPARTMENT if extenuating circumstances prevent timely response to a PT event.

5.5.76.2.2 All analytes listed and reported (qualitatively and quantitatively) by the laboratory must be ANALYTICALLY tested in the PT challenges ~~when provided~~ in the same manner as subject samples.

5.5.76.2.3 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.

5.5.76.2.3.1 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 UNSATIFACTORY EVENT.

—LABORATORY'S SCORE = (LABORATORY'S POINTS / TOTAL POSSIBLE POINTS) * 100

5.5.76.2.4 Whenever a laboratory RECEIVES ~~has~~ an unsatisfactory PT~~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. ~~submitted to the Department for approval within 15 calendar days of receipt of the results.~~

5.5.76.2.5 Whenever a quantitative result reported by the laboratory in a PT challenge is considered "Unacceptable" by the PT provider (OUTSIDE ±~~2sd~~ 2SD or 30% from the mean, whichever is greater), the laboratory must undertake and document corrective action. T~~t~~he corrective action documentation must be retained with the PT results.

5.5.76.2.6 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~~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~~sS~~-~~S~~ite Laboratory Inspection

5.6.1 On-site 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 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~~LABORATORIES MUST DEMONSTRATE COMPLIANCE WITH ALL APPLICABLE REQUIREMENTS IN PARTS 5 THROUGH 9. ~~Appendix C.~~

5.6.3 Laboratories will be contacted by the Department to SCHEDULE THE ANNUAL ONSITE INSPECTION AFTER RECEIPT OF THE APPLICATION REQUESTING CERTIFICATION. ~~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 DEPARTMENT WILL EVALUATE COMPLIANCE WITH THE LABORATORY CERTIFICATION STANDARDS LISTED IN PART 9 DURING THE ONSITE INSPECTION. ~~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 THAT WILL LIST ANY NON-CONFORMANCES IDENTIFIED. ~~and reviewed by a peer inspector or supervisor prior to mailing.~~ The report should be sent to the laboratory within ~~15~~ 30 days of inspection.

5.6.6 ~~When noncompliant practices are identified in an inspection report,~~ 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.

~~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 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 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.~~8~~9 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. ~~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~~ Section 24-4-104, C.R.S.

5.6.~~9~~10 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.

~~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.~~

5.6.10~~1~~ 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. ETHYL ~~A~~alcohol or phenol solutions must not be used as a skin antiseptic.

~~6.1.2 After Collection, Blood Specimens must be:~~

6.1.1.6~~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.

6.1.1.7~~2.2~~ Properly mixed in accordance with the instructions provided in the forensic blood collection kit.

6.1.1.8~~2.3~~ THE BLOOD COLLECTION TUBES MUST BE a~~A~~Affixed with a~~n~~ UNIQUE identification label THAT INCLUDES THE SUBJECT NAME and evidence seal.

6.1.1.9~~2.4~~ The specimens must be placed in secured STORAGE UNTIL SHIPPED. ~~temporary refrigerated storage at less than 8 degrees Centigrade or frozen 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, s~~S~~pecimens SHOULD ~~must~~ 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~~3~~ 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~~42~~ Any remaining blood specimen must be retained and stored by the certified laboratory at OR BELOW ~~less than~~ 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~~23~~ The second blood specimen must be analyzed by a DEPARTMENT certified laboratory WHEN REQUESTED ~~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 UNIQUE identification label THAT INCLUDES THE SUBJECT NAME and evidence seal.

7.1.1.4 The specimens must be placed in secured ~~temporary refrigerated~~ 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 CONTANER.~~at less than 8 degrees Centigrade or frozen until shipped.~~

7.1.1.6 WHENEVER POSSIBLE, Specimens SHOULD ~~must~~ 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~~3~~2 Any remaining urine specimen(s) must be retained by the certified laboratory AT OR BELOW 8 DEGREES CENTIGRADE IN AN APPROPRIATE CONTAINER ~~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~~2~~3 Any remaining urine specimen(s) must be analyzed by a DEPARTMENT certified laboratory WHEN REQUESTED ~~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. Postm ~~M~~ortem Forensic Toxicology – Collection and Testing Requirements

8.1 Postm ~~M~~ortem Specimen Collection

8.1.1 Collection of specimens from deceased persons ~~is~~ conducted ~~as~~ per Section 42-4-1304, C.R.S. WILL BE PERFORMED by a person ~~who's~~ WHOSE training and normal duties include the collection of blood OR OTHER BODILY SUBSTANCES ~~specimens~~ 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~~'S~~ 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.

8.1.42 The laboratory must develop and provide detailed guidelines and instructions for the collection of post-mortem specimens THAT INCLUDES THE DATE AND TIME OF COLLECTION, THE TIME OF THE INCIDENT AND THE TIME OF DEATH.

8.1.53 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.

8.1.64 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 Postm-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 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 receipted by a representative from another certified laboratory FOR ADDITIONAL TESTING. acting on behalf of the defendant.

Part 9. Violations and Remedies 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 offor the laboratory as well as for assuring compliance with these regulations and the accuracy of the results reported by the laboratory.

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. ~~must supervise and maintain documentation that the established protocols of the laboratory are being followed and monitored on an ongoing basis to ensure compliance (the Supervisory Analyst can be delegated this responsibility if 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 ~~Testing Analyst(s)~~ 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 ~~ongoing~~ 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. ~~Corrective actions implemented, and (when applicable).~~

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~~2~~ 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.~~director and all testing analysts participating in the PT challenge must sign the corresponding attestation statements.~~

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~~S~~ 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. ~~The laboratory must perform and document a calibration curve with each analysis (that has a correlation coefficient of 0.99) using at least calibrators throughout the reporting range.~~

9.4.8 IF THE LABORATORY USES HISTORICAL CALIBRATION DATA FOR AN ASSAY, CONTROL MATERIALS MUST BE INCLUDED WITH EACH BATCH OF SPECIMENS TESTEDTO 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 ~~either~~ source, ~~or,~~ lot number, or concentration from the calibration material used with each analytical run. IN INSTANCES WHERE THE SAME SOURCE MUST BE UTILIZED, SEPARATE WEIGHINGS OR SOLUTIONS MUST BE USED TO PREPARE THESE CONTROLS.

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 ~~commercially prepared SOLUTION control that is certified by an ISO/ IEC 17043~~accredited manufacturer when available.~~,~~ FOR QUANTITATIVE PUPOSES, THE CONTROL ~~which~~ 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), ~~limits of quantitation (~~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. ~~from receipt to 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.

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~~7~~ The laboratory must restrict entry into the laboratory only to authorized personnel.

9.5.7~~8~~ The laboratory must have provisions for securing the laboratory during non-working hours.

9.5.8~~9~~ The laboratory must secure short and long-term storage areas when not in use.

9.5.9~~10~~ 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~~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, ~~and~~ 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 must adequately document the available external chain of custody information.~~

9.6.11~~2~~ 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~~3~~ 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 SPECTOMETERY (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 SPECTOMETRY OR WITH TANDEM MASS SPECTOMETRY (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~~9.1~~ Violations

10.1.1~~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.

10.1.2 ~~9.1.2~~ Violation of these rules and regulations may result in denial, suspension or revocation of certification as DESCRIBED IN 10.4. ~~outlined in Part 8 of these rules and regulations.~~

10.1.3 ~~9.1.3~~ Generally, a violation will not be cited if:

10.1.3.1 ~~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.

10.1.3.2 ~~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~~10.2 Complaints

10.2.1~~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.

10.3 ~~9.3~~ Right to appeal the denial, suspension or revocation of certification.

10.3.1 ~~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~~ Section 24-4-105, C.R.S.

~~9.4~~10.4 Denial, Suspension or Revocation of Certification:

10.4.1~~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:

10.4.1.1~~9.4.1.1~~ Falsification of data or other deceptive practices including false statements by omission or commission relevant to the certification process.

10.4.1.29.4.1.2 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.

10.4.1.39.4.1.3 Gross incompetence or negligent practice.

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

10.4.1.59.4.1.5 Inadequate space, equipment, PERSONNEL or methods utilized for testing.

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

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

10.4.1.8 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.

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

10.59.5 Injunction

10.5.19.5.1 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 ± 12v (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~~

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 (±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 NIST-traceable 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 carry-over? How is this verified?
6. Y N NA Does the laboratory measure all appropriate RF values for qualitative identification purposes?
7. Y N NA If the laboratory uses sequential color reactions, are these recorded?
8. Y N NA Does the laboratory maintain records of thin layer chromatographic plates?
9. Y N NA Does the laboratory analyze an appropriate matrix blank with each batch of specimens analyzed?

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 Spectroscopy (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?

8. 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?

9. Y N NA Within each run, does the laboratory compare two transitions and retention times between calibrators, controls and specimens?

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

13. Y N NA Does the laboratory evaluate the performance of the instrument when changes in: source, source conditions, eluent, or column are made prior to reporting test results? How?

COMMENTS SECTION: