

RULES AND REGULATIONS CONCERNING
 TESTING FOR ALCOHOL AND OTHER DRUGS
 This part was effective August 30, 1998, unless otherwise noted below

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Revisions subsequent to August 30, 1998

- * Definitions: “appropriate clinical or public safety facility” and “certification” were revised effective 1/30/1999.
- **1.7 Violations. Entire section was revised effective 1/30/1999.
- ***1.9 Denial, Suspension or Revocation of Certification: 1.9.1 was revised effective 1/30/1999.
- ****1.10 Injunction. Section was revised effective 1/30/1999.

PART 1
TESTING FOR ALCOHOL AND OTHER DRUGS

1.1 Purpose and Scope

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

1.2 Definitions

“Alcohol Percent (%)” - grams of ethanol per 100 milliliters of blood or grams of ethanol per 210 liters of breath.

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

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

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

“Delayed Breath Alcohol Specimens” - the saved ethanol or other analytical components of the EBAT specimen(s).

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

“Evidential Breath Alcohol Test (EBAT)” - is an evidentiary breath alcohol test as described by section 42-4-1301, 11 C.R.S. (1997).

“Evidential Breath Alcohol Test (EBAT) device” - any instrument certified to perform “Evidential” Breath Alcohol Tests.

“Facility” - any location approved by the Department to perform Evidential Breath Alcohol Testing.

“Proficiency Testing” - The evaluation of unknown specimens supplied by a provider which determines target values for those unknown specimens.

1.3 Specimen Collection

1.3.1 Blood

1.3.1.1 Living Persons

1.3.1.1.1 Blood specimen(s) must be:

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

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

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

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

1.3.1.2 Deceased Persons

1.3.1.2.1 Collection of specimens from deceased persons is conducted as per section 42-4.1304, C.R.S. (1997), by a person whose training and normal duties include the collection of blood specimens from deceased persons.

1.3.1.3 Living and Deceased Persons

1.3.1.3.1 After collection, blood specimens must be:

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

1.3.1.3.1.2 inverted to properly mix the blood with the sodium fluoride.

1.3.1.3.1.3 affixed with an identification label and evidence seal.

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

- 1.3.1.3.2 At the Certified Laboratory:
- 1.3.1.3.2.1 one tube of blood must be used for the State's test(s). The State's test(s) must be completed within 15 days of collection.
- 1.3.1.3.2.2 the second tube of blood must be refrigerated by the certified laboratory at less than 8 degrees Centigrade for a period of not less than 12 months from the date of collection.
- 1.3.1.3.3 The second specimen may be released if it is requested and receipted for by defendant's legal counsel or a Certified Laboratory.
- 1.3.1.3.4 The second specimen must be analyzed within 10 days of its receipt by the defendant's legal counsel or Certified Laboratory.
- 1.3.2 Breath - Evidential
- 1.3.2.1 Evidential breath specimens must be analyzed on EBAT devices approved by the Department. Approval or disapproval of EBAT devices will be based on standards of performance established by the Department.
- 1.3.2.2 The Department will certify each EBAT device initially and periodically thereafter.
- 1.3.2.3 The Department will issue a certificate for each certified EBAT device. The certificate will reflect the EBAT device facility name, serial number and the inclusive dates for the certification period. The certificate for mobile facilities will also include the vehicle identification number.
- 1.3.2.4 A breath specimen must only be collected by certified evidential breath test operators using certified EBAT devices pursuant to the procedure in Appendix A.
- 1.3.2.5 Breath specimens consisting of end-expiratory alveolar air are analyzed to determine their ethyl alcohol concentration.
- 1.3.3 Breath - Delayed
- 1.3.3.1 A delayed breath alcohol specimen must be collected with each evidential breath alcohol test pursuant to Appendix A.
- 1.3.3.2 Delayed breath alcohol specimens are considered the personal property of the defendant and retained by the facility for 12 months from the date of collection unless requested and receipted for by the defendant's legal counsel or a Department certified laboratory.
- 1.3.4 Urine
- 1.3.4.1 Living Persons
- 1.3.4.1.1 Urine specimen(s) must be collected in the presence of collection personnel who can authenticate the specimen(s).

1.3.4.2 Deceased Persons

1.3.4.2.1 Collection of specimens from deceased persons is conducted as per section 42-4-1304, 11 C.R.S. (1997) by a person whose training and normal duties include the collection of urine samples from deceased persons.

1.3.4.3 Living and Deceased Persons

1.3.4.3.1 Urine specimen(s) must be:

1.3.4.3.1.1 collected in a sterile container.

1.3.4.3.1.2 affixed with an identification label and evidence seal.

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

1.3.4.3.2 At the Certified Laboratory:

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

1.3.4.3.2.2 Any remaining specimen(s) must be retained by the laboratory in frozen storage for a period of not less than 12 months unless requested and accepted for by defendant or deceased's legal counsel or a Certified Laboratory.

1.3.4.3.2.3 The second specimen must be analyzed within 15 days of its receipt by the defendant's legal counsel or Certified Laboratory.

1.4 Methods of Analysis

1.4.1 Alcohol in Evidential Breath Specimens

1.4.1.1 The Standard Operating Procedure for Evidential Breath Alcohol Tests must be followed as found in Appendix A.

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

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

1.4.1.4 A completed EBAT is one in which the Standard Operating Procedure is followed and a printout obtained.

1.5 Certified Operators of Evidential Breath Alcohol Test Devices

1.5.1 Certification of Operators of Evidential Breath Alcohol Test Devices to Determine Alcohol Concentration of Breath Specimens.

- 1.5.1.1 Certified operators must have a minimum of 8 hours of instruction following a course outline provided by the Department to include a comprehensive practical and written exam. A score of 80% or greater on the written exam is passing. Upon successful completion of the Operator course, a certificate will be issued by the Department indicating the name of the Operator, the Operator Instructor(s), and the initial date of certification.
- 1.5.1.2 To maintain certified status, an Operator must proficiently perform one breath test, following the procedures outlined in Appendix A in the presence of an Operator Instructor at least every 6 months.
- 1.5.1.3 An Operator who does not recertify in the six 6 month period will be decertified by the Operator Instructor(s) and must repeat the eight 8 hours of instruction.
- 1.5.1.4 A facility must keep records showing each certified operator's date of original certification and all dates of re-certification.
- 1.5.2 Certification of Operator Instructors of EBAT Devices
 - 1.5.2.1 Certified Operator Instructors must have a minimum of 16 hours of instruction provided by the Department to include a comprehensive practical and written exam. A score of 80% or greater on the written exam is passing. Upon successful completion of the Operator Instructor course, a certificate will be issued by the Department indicating the name of the Operator Instructor, the course Instructor(s), and the date of certification.
 - 1.5.2.2 A certified Operator Instructor is also a certified Operator. Certified Operator Instructors are qualified to train and certify operators of EBAT devices.
 - 1.5.2.3 To maintain certified status an Operator Instructor must annually participate in presenting a certification class to Operators or pass a written recertification examination provided by the Department.
 - 1.5.2.4 An Operator Instructor who does not recertify annually is decertified and must repeat the 16 hours of instruction provided by the Department.
 - 1.5.2.5 A facility must keep records showing each certified Operator Instructor's date of original certification and all dates of classes instructed or written exams taken.
- 1.6 Laboratory Analysis of Blood, Urine and Delayed Breath Specimens
 - 1.6.1 Laboratories must be certified to provide analysis.
 - 1.6.2 Laboratories will be certified to perform tests for one or more of the following: blood alcohol, delayed breath alcohol, blood drugs, and urine drugs.
 - 1.6.3 Laboratories must meet standards of performance as established by the Department. Standards of performance will include personnel qualifications, standard operating procedure manual, analytical process, proficiency testing, quality control, security, chain of custody, specimen retention, space, records, and results reporting.

1.6.4 Laboratory inspections must be performed prior to initial certification and periodically thereafter by Department staff as established by the Department standards.

1.7 Violations

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

1.7.2 Violation of these rules and regulations may result in denial, suspension or revocation of certification as outlined in part 1.9 of these rules and regulations.

1.7.3 Generally, a violation will not be cited if:

1.7.3.1 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.

1.7.3.2 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.

1.8 Notification of Violation, Hearings and Determinations:

1.8.1 All parties shall comply with the statutory requirements of section 24-4-105, 7 C.R.S. (1997).

1.9 Denial, Suspension or Revocation of Certification:

1.9.1 The Department may deny, suspend or revoke the certificate of an EBAT device located in a facility, the certificate of an operator, the certificate of an operator instructor or the certificate of a laboratory for one or more of the following causes:

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

1.9.1.2 Gross incompetence or negligent practice.

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

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

1.9.1.5 Submission of any test results of another party as those of the party being evaluated.

1.9.1.6 For a laboratory, failure to continuously participate in proficiency testing and obtain a successful score at least once each certificate period.

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

1.10 Injunction

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

APPENDIX A

TITLE: Standard Operating Procedure for Evidential Breath Alcohol Test(s).

1. The subject must remove foreign objects from the nose and mouth to include dentures. The subject must be closely and continuously observed for 20 minutes prior to testing to assure no belching, regurgitation or intake of any foreign material by nose or mouth has occurred. If such occurs, another 20 minutes of close and continuous observation must elapse under the same conditions.
2. Turn power switch on and/or observe the power switch has been activated.
3. Observe the simulator temperature is between 33.8 degrees centigrade and 34.2 degrees centigrade.
4. Activate the Start Test switch.
5. Follow the instructions and sequence of events as they appear on the device display.
6. After the sequence of events has been completed package and seal the Delayed Breath Alcohol specimen.
7. Record the evidential breath alcohol test information on the standard simulator log sheet.

APPENDIX B

TITLE: Requirements for Permanent and Mobile Evidential Breath Alcohol Test Facilities

1. Initial Certification Procedure:
 - a. Facilities must submit in writing to the Department a request for approval of an EBAT facility.
 - b. The Department will supply a copy of Appendix B of these Rules and Regulations to the requesting facility.
 - c. Written verification of compliance with the requirements of Appendix B is required from the facility.
 - d. The Department will perform an initial facility inspection to verify compliance with the requirements of Appendix B. Facility inspections will be performed periodically thereafter by Department staff.
 - e. The EBAT device may not be moved from its initial approved facility without authorization from the Department.
2. Requirements:
 - a. Power
 1. Permanent:
 - (A) AC line voltage of 120 volts, 60 Hz with grounded 3 prong outlets and a 20 ampere or less circuit breaker.
 - (B) The power line to the EBAT device must be a dedicated line. Written verification of compliance with this requirement must be provided to the Department by a certified electrician.
 - (C) A surge protection device approved by the Department must be placed between the EBAT device and the power source.
 2. Mobile:
 - (A) Acceptable power sources are:
 - (1) Square wave power inverter capable of generating an AC line voltage of 140 volts RMS.
 - (2) Power inverter/sine wave converter combinations that generate 120 volts AC from 14 volts DC.
 - (B) Electric motor/generator combinations that use a 12 volt DC motor to run a 120 volt AC 60 Hz generator.
 - (C) The power line to the EBAT device must be a dedicated line. This requirement will be verified by the Department.

(D) Surge protection is required as stated in step a.1.(C) above.

3. Environment

- a. The temperature of the EBAT device facility must be maintained between 70 and 80 degrees Fahrenheit.
- b. The facility must have adequate lighting.
- c. The area around and under the EBAT device must be free of dust and dirt. The immediate area around the evidential breath alcohol testing device must be kept orderly.
- d. The EBAT device and breath alcohol simulator must be placed on the organizer stand. The stand will be placed on a solid and adequate work surface.
- e. The EBAT shall be in a smoke free environment.
- f. The facility must be ventilated.
- g. Automobile emissions are not allowed in Mobile EBAT Facilities. A system blank consisting of a delayed breath specimen must be collected every 2 hours during testing. The specimen must be sent to the Department for testing.
- h. The facility must not be used to store any cleaning compounds or volatile organics to include gasoline and petroleum products.

4. Documents

- a. The following documents relating to EBAT devices must be posted at the facility:
 - (1) Certificate of Approval for EBAT
 - (2) Standard Operating Procedure
 - (3) No Smoking Sign
 - (4) Error Message Sheet
 - (5) Current list of certified operators and operator instructors including dates of recertification
- b. The Standard Simulator Log Sheet must be maintained with the EBAT device.
- c. Records pertaining to EBAT specimens must be retained by the facility for 2 years.