

**TITLE 310. OKLAHOMA STATE DEPARTMENT OF HEALTH  
CHAPTER 638. DRUG AND ALCOHOL TESTING**

"Unofficial Version"

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[**Authority:** Oklahoma State Board of Health; Standards for Workplace Drug and Alcohol Testing Act, 40 O.S. Sections 551 et seq.]

[**Source:** Codified 7-27-1995]

**SUBCHAPTER 1. GENERAL PROVISIONS**

## Section

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**310:638-1-1. Purpose**

The rules in this chapter implement the Standards for Workplace Drug and Alcohol Testing Act (40 O.S. Sections 551 et seq., hereinafter, the Act).

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

**310:638-1-2. Definitions**

The following words or terms, when used in this Chapter, shall have the following meaning, unless the context clearly indicates otherwise:

**"Alcohol concentration"** means the amount of alcohol present in urine or blood expressed in terms of percent of the weight of alcohol per volume of urine or blood (w/v), or the amount of alcohol present in breath expressed in terms of grams of alcohol per two hundred ten (210) liters of breath, or the amount of alcohol present in saliva expressed in grams of alcohol per one hundred (100) milliliters of saliva.

**"Alcohol testing facility"** means any building, place, or facility in which operations, procedures, or examinations of

materials derived from the human body are performed for the purpose of alcohol testing and if, as a result of such testing, mandatory or discretionary consequences may be rendered to the individual.

**"Approved drug screening procedure"** means a procedure approved by the Commissioner of Health to initially screen urine, hair or saliva for the presence or absence of a drug or drugs.

**"Blind performance test specimen"** means a specimen submitted to a testing facility which is blank i.e., certified to contain no drug, or spiked with one or more drugs for which the testing facility is testing;

**"Department"** means the Oklahoma State Department of Health.

**"Drug screen testing facility"** means any building, place, or facility in which operations or procedures for the biological, serological, immunological, chemical, immunohematological, or other examinations of materials derived from the human body are performed for the purpose of drug testing and if, as a result of such testing, mandatory or discretionary consequences may be rendered to the individual.

**"Proficiency testing program"** means performance of testing on specimens containing those drugs and metabolites which each testing facility shall be prepared to assay in concentration ranges that allow detection of the analyte by commonly used immunoassay screening techniques. The proficiency testing program for drug testing facilities shall be approved for use by the Commissioner of Health.

**"Saliva"** means mucosal transudate or a combination of oral fluids consisting of a mixture of gingival crevicular fluid and common saliva.

**"Screening device test"** means non-evidential breath testing apparatus such as tubes filled with materials that turn a certain color when alcohol-laden breath is blown into them or a small, hand-held electronic apparatus that registers the presence or absence of alcohol concentration in breath, or an apparatus which registers a particular alcohol concentration when a swab with saliva from the employee's mouth is inserted into it.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00; Amended at 24 Ok Reg 1183, eff 4-2-2007(emergency); Amended at 25 Ok Reg 2436, eff 7-11-2008]

### **310:638-1-3. Qualifications of testing facilities**

#### **(a) Drug screen testing facilities.**

(1) Drug screen testing facilities not certified for forensic urine drug testing by the United States Department of Health and Human Services or accredited for forensic urine drug testing by the College of American Pathologists shall meet the provisions of this Chapter for the matrices for which they test for drugs of abuse in order to be eligible for licensure as a testing

facility.

(2) Drug screen testing facilities certified for forensic urine drug testing by the United States Department of Health and Human Services, accredited for forensic urine drug testing by the College of American Pathologists, or licensed by a State acceptable to the Department shall be deemed to meet the requirements of OAC 310:638 Subchapter 5 and shall be eligible for licensure as a testing facility.

(b) **Drug confirmation testing facilities.** All facilities performing drug confirmation testing using urine or saliva as the testing matrix shall be certified for forensic urine drug testing by the United States Department of Health and Human Services or accredited for forensic urine drug testing by the College of American Pathologists in order to be eligible for licensure as a testing facility. Facilities performing confirmation testing using hair as the testing matrix, shall have passed an inspection performed by the Department or be licensed by another State acceptable to the Department.

(c) **Notification requirements.** All testing facilities licensed by the Department based on certification by the United States Department of Health and Human Services, accreditation by the College of American Pathologists, or licensed by another State accepted by the Department shall notify the Department in writing within ten (10) days of the loss of such certification, accreditation, or licensure.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00; Amended at 24 Ok Reg 1183, eff 4-2-2007(emergency); Amended at 25 Ok Reg 2436, eff 7-11-2008]

#### **310:638-1-4. Body specimens appropriate for testing**

##### (a) **Drugs.**

(1) **Initial tests.** Urine, saliva or hair shall be used for the initial test for all drugs.

(2) **Confirmation tests.** Urine, saliva or hair shall be used for the confirmation test for all drugs.

##### (b) **Alcohol.**

(1) **Initial tests.** Breath or saliva shall be used for the initial test for alcohol. Blood may be used for initial testing as described in OAC 310:638-7-4(b)(4).

(2) **Confirmation tests.** Breath or blood shall be used for the confirmation test for alcohol.

(3) **Rehabilitation/post-rehabilitation tests.** For alcohol testing which meets the criteria at 310:638-7-8(a), urine may be used as the specimen for initial and/or confirmation testing.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99

(emergency); Amended at 17 Ok Reg 2045, eff 6-12-00; Amended at 24 Ok Reg 1183, eff 4-2-2007(emergency); Amended at 25 Ok Reg 2436, eff 7-11-2008]

**310:638-1-5. Drugs approved for testing in urine or saliva**

(a) A licensed testing facility may test for any drug or class of drugs or their metabolites included in Schedule I, II, or III of the Controlled Substances Act (21 U.S.C. § 801, et seq.) provided testing for such substances has been approved by the Commissioner of Health.

(b) The following drugs or their metabolites have been approved for testing by the Commissioner of Health:

- (1) marijuana;
- (2) opiates:
  - (A) codeine;
  - (B) heroin;
  - (C) morphine;
- (3) semi-synthetic and synthetic narcotics:
  - (A) hydrocodone;
  - (B) hydromorphone;
  - (C) meperidine;
  - (D) methadone;
  - (E) oxycodone;
  - (F) propoxyphene;
- (4) cocaine;
- (5) phencyclidine;
- (6) amphetamines:
  - (A) amphetamines;
  - (B) methamphetamines;
  - (C) methylenedioxyamphetamine;
  - (D) methylenedioxymethamphetamine;
  - (E) phentermine;
- (7) barbiturates:
  - (A) amobarbital;
  - (B) butalbital;
  - (C) pentobarbital;
  - (D) secobarbital
- (8) benzodiazepines:
  - (A) diazepam;
  - (B) chlordiazepoxide;
  - (C) alprazolam;
  - (D) clorazepate; and
- (9) methaqualone.

(c) If the United States Department of Health and Human Services has established an approved protocol and positive threshold for a substance not listed in (b) of this Section, testing for such a substance shall be deemed to be approved by the Commissioner of Health.

(d) Drugs other than those listed shall be tested by scientifically established methods at scientifically established detection levels.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00; Amended at 18 Ok Reg 3592, eff 8-22-2001 (emergency); Amended at 19 Ok Reg 1050, eff 5-13-2002; Amended at 24 Ok Reg 1183, eff 4-2-2007(emergency); Amended at 25 Ok Reg 2436, eff 7-11-2008]

**310:638-1-5.1. Drugs approved for testing in hair**

(a) A licensed testing facility may test for any drug or class of drugs or their metabolites included in Schedule I, II or III of the Controlled Substances Act (21 U.S.C. § 801 et seq.) provided testing for such substances has been approved by the Commissioner of Health.

(b) The following types of drugs or their metabolites have been approved for testing by the Commissioner of Health:

- (1) marijuana;
- (2) opiates:
  - (A) codeine;
  - (B) heroin;
  - (C) morphine;
- (3) cocaine;
- (4) phencyclidine;
- (5) amphetamines:
  - (A) amphetamines;
  - (B) methamphetamine.

(c) If the United States Department of Health and Human Services has established an approved protocol and positive threshold for a substance not listed in (b) of this Section, testing for such a substance shall be deemed to be approved by the Commissioner of Health.

(d) Drugs other than those listed shall be tested by scientifically established methods at scientifically established detection levels.

[**Source:** Added at 17 Ok Reg 381, eff 11-1-99 (emergency); Added at 17 Ok Reg 2045, eff 6-12-00; Amended at 18 Ok Reg 3592, eff 8-22-2001 (emergency); Amended at 19 Ok Reg 1050, eff 5-13-2002]

**310:638-1-6. Cutoff levels for initial drug screening tests in urine**

(a) The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these drugs or their metabolites:

- (1) marijuana metabolites: 50 ng/ml
- (2) cocaine metabolites: 300 ng/ml
- (3) opiates and metabolites: 2000 ng/ml; opiates and metabolites include the following:
  - (A) codeine;
  - (B) heroin;
  - (C) morphine;

- (4) semi-synthetic and synthetic narcotics: 300 ng/ml
- (A) hydrocodone;
  - (B) hydromorphone;
  - (C) meperidine (immunoassay unavailable, initial test level of 1000 ng/ml shall be used for meperidine)
  - (D) methadone;
  - (E) oxycodone;
  - (F) propoxyphene;
- (5) phencyclidine: 25 ng/ml
- (6) amphetamines: 1,000 ng/ml; amphetamines include the following:
- (A) amphetamines;
  - (B) methamphetamines;
  - (C) methylenedioxyamphetamine (immunoassay unavailable);
  - (D) methylenedioxymethamphetamine (immunoassay unavailable);
  - (E) phentermine;
- (7) barbiturates: 300 ng/ml; barbiturates include the following:
- (A) amobarbital;
  - (B) butalbital;
  - (C) pentobarbital;
  - (D) secobarbital;
- (8) benzodiazepines: 300 ng/ml; benzodiazepines include the following:
- (A) diazepam;
  - (B) chlordiazepoxide;
  - (C) alprazolam;
  - (D) clorazepate; and
- (9) methaqualone: 300 ng/ml.

(b) These test levels are subject to change by the Department as advances in technology or other considerations warrant identification of these substances at other concentrations.

(c) Drugs other than those listed shall be tested by scientifically established methods at scientifically established detection levels.

[Source: Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 16 Ok Reg 2514, eff 6-25-99; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00; Amended at 18 Ok Reg 3592, eff 8-22-2001 (emergency); Amended at 19 Ok Reg 1050, eff 5-13-2002]

#### **310:638-1-6.1. Hair cutoff levels for initial drug screening tests**

(a) The following initial cutoff levels shall be used when screening hair specimens to determine whether they are negative for these drugs or their metabolites:

- (1) marijuana: 10pg/10 mg of hair
- (2) cocaine: 5 ng/10 mg of hair
- (3) opiates and metabolites: 5 ng/10 mg of hair; opiates and metabolites include the following:

- (A) codeine;
- (B) heroin;
- (C) morphine;
- (4) phencyclidine: 3 ng/10 mg of hair
- (5) amphetamines: 5 ng/10 mg of hair; amphetamines include the following:
  - (A) amphetamines;
  - (B) methamphetamines.

(b) These test levels are subject to change by the Department as advances in technology or other considerations warrant identification of these substances at other concentrations.

(c) Drugs other than those listed shall be tested by scientifically established methods at scientifically established detection levels.

[**Source:** Added at 17 Ok Reg 381, eff 11-1-99 (emergency); Added at 17 Ok Reg 2045, eff 6-12-00; Amended at 18 Ok Reg 3592, eff 8-22-2001 (emergency); Amended at 19 Ok Reg 1050, eff 5-13-2002]

#### **310:638-1-6.2. Saliva cutoff levels for initial drug screening tests**

The manufacturer of the saliva test system shall establish initial cutoff levels to be used when screening saliva specimens to determine whether they are negative for drugs or their metabolites. Such cutoffs shall be consistently applied for all saliva testing using that test system.

[**Source:** Added at 24 Ok Reg 1183, eff 4-2-2007(emergency); Added at 25 Ok Reg 2436, eff 7-11-2008]

#### **310:638-1-7. Cutoff levels for drug confirmation testing in urine**

(a) All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS), or an equivalent accepted method of equal or greater accuracy as approved by the Commissioner of Health, at the following cutoff levels for these drugs or their metabolites. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the testing facility record as "greater than the highest standard curve value."

- (1) marijuana metabolites: 15 ng/ml (Delta-9-tetrahydrocannabinol-9-carboxylic acid)
- (2) cocaine metabolites: 150 ng/ml (Benzoylecgonine)
- (3) opiates and metabolites: 2000 ng/ml; opiates and metabolites include the following:
  - (A) codeine;
  - (B) morphine;
  - (C) heroin (10 ng/ml for tests for 6-Acetylmorphine when the morphine concentration exceeds 2000 ng/mL);
- (4) semi-synthetic and synthetic narcotics: 300 ng/ml
  - (A) hydrocodone;



- (B) hydromorphone;
  - (C) meperidine; (confirmatory test level of 500 ng/ml shall be used for meperidine)
  - (D) methadone;
  - (E) oxycodone;
  - (F) propoxyphene;
  - (5) phencyclidine: 25 ng/ml
  - (6) amphetamines: 500 ng/ml; amphetamines include the following:
    - (A) amphetamines;
    - (B) methamphetamines; (Specimen must also contain amphetamine at a concentration of greater than 200 ng/mL)
    - (C) methylenedioxyamphetamine;
    - (D) methylenedioxymethamphetamine;
    - (E) phentermine.
  - (7) barbiturates: 300 ng/ml; barbiturates include the following:
    - (A) amobarbital;
    - (B) butalbital;
    - (C) pentobarbital;
    - (D) secobarbital;
  - (8) benzodiazepines: 300 ng/ml; benzodiazepines include the following:
    - (A) diazepam;
    - (B) chlordiazepoxide;
    - (C) alprazolam;
    - (D) clorazepate; and
  - (9) methaqualone: 300 ng/ml.
- (b) These test levels are subject to change by the Department as advances in technology or other considerations warrant identification of these substances at other concentration.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 16 Ok Reg 2514, eff 6-25-99; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00; Amended at 18 Ok Reg 3592, eff 8-22-2001 (emergency); Amended at 19 Ok Reg 1050, eff 5-13-2002]

**310:638-1-7.1. Hair cutoff levels for drug confirmation testing and procedures**

(a) All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry/mass spectrometry (LC/MS/MS), mass spectrometry/mass spectrometry (MS/MS), or an equivalent accepted method of equal or greater accuracy as approved by the Commissioner of Health, at the following cutoff levels for these drugs or their metabolites. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the testing facility record as "greater than the highest standard curve value."

- (1) marijuana metabolites: 1 pg/10 mg of hair (Delta-9-tetrahydrocannabinol-9-carboxylic acid);
  - (2) cocaine: must be at or above 5 ng/10 mg of hair and/or metabolites as follows:
    - (A) benzoylecgonine at 1 ng/10 mg of hair;
    - (B) cocaethylene at 1 ng/10 mg of hair;
  - (3) opiate and metabolites: 5 ng/10 mg of hair; opiate and metabolites include the following:
    - (A) codeine;
    - (B) 6-monoacetylmorphine (heroin metabolite);
    - (C) morphine;
  - (4) phencyclidine: 3 ng/10 mg of hair;
  - (5) amphetamines: 5 ng/10 mg of hair; amphetamines include the following:
    - (A) amphetamines.
    - (B) methamphetamines.
- (b) These test levels are subject to change by the Department as advances in technology or other considerations warrant identification of these substances at other concentrations.
- (c) All hair specimens undergoing confirmation shall be decontaminated using an approved wash procedure which has been published in the peer reviewed literature which at least, has an initial fifteen (15) minute organic solvent wash followed by multiple (at least three) thirty (30) minute aqueous washes and one final one hour aqueous wash.
- (d) After hair is washed, the drug entrapped in the hair shall be released either by digestion (chemical or enzymatic) or by multiple solvent extractions. The resulting digest or pooled solvent extracts shall then be confirmed by approved methods.
- (e) All confirmation analysis methods must eliminate the melanin fraction of the hair before analysis. If a non-digestion method is used, the laboratory must present published data in the peer reviewed literature from a large population study which indicates that their method of extraction does not possess a statistically significant hair color bias.
- (f) Additional hair samples may be collected to reconfirm the initial report. The recollected sample shall be retested as specified, however, the confirmation analysis shall be performed even if the screening test is negative. A second positive report shall be made if the drug concentration in the digest by confirmation methods exceeds the limit of quantitation of the testing laboratory's method. A second test shall be offered to anyone disputing a positive hair test result.
- (g) To assist the Review Officer in the interpretation of results, officers may order sectioning of a hair sample (e.g. segmenting hair into 0.5 inches sections, which is about one months growth, each analyzed separately). The sectioning may occur on the original and any subsequent sample submitted for testing.

[**Source:** Added at 17 Ok Reg 381, eff 11-1-99 (emergency); Added at 17 Ok Reg 2045, eff 6-12-00; Amended at 18 Ok Reg 3592, eff 8-22-2001 (emergency); Amended at 19 Ok Reg 1050, eff 5-13-2002]

**310:638-1-7.2 Cutoff levels for drug confirmation testing in saliva**

(a) All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS), or an equivalent accepted method of equal or greater accuracy as approved by the Commissioner of Health. The manufacturer of the saliva test system shall establish confirmation cutoff levels to be used when confirming saliva specimens that screen positive. Such cutoffs shall be consistently applied for all saliva testing using that test system. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the testing facility record as "greater than the highest standard curve value."

(b) All confirmation testing on saliva shall be performed on the same specimen that was identified as positive on the initial screen.

[**Source:** Added at 24 Ok Reg 1183, eff 4-2-2007(emergency); Added at 25 Ok Reg 2436, eff 7-11-2008]

**310:638-1-8. Urine specimen collection procedures**

(a) **Designation of collection site.** Each urine drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a licensed drug testing facility.

(b) **Security.** Procedures shall provide for the designated collection site to be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for testing shall be secured during drug testing.

(c) **Chain of custody.** Chain of custody standardized forms shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling specimens.

(d) **Access to authorized personnel only.** No unauthorized personnel shall be permitted in any part of the designated collection site when urine specimens are collected or stored.

(e) **Privacy.** Procedures for collecting urine specimens shall allow individual privacy. No employer or representative, agent or designee of the employer shall directly observe an applicant or employee in the process of producing a urine sample, provided collection occurs in a manner reasonably calculated to prevent substitutions or interference with the collection or testing of

reliable samples.

(f) **Integrity and identity of specimen.** Precautions shall be taken to ensure that a urine specimen is not adulterated or diluted during the collection procedure and that information on the urine specimen bottle and on the chain of custody form can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified:

(1) To deter the dilution of specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water i.e., no shower or sink, in the enclosure where urination occurs.

(2) When an individual arrives at the collection site, the collection site person shall request the individual to present photo identification. If the individual does not have proper photo identification, the collection site person shall contact the supervisor of the individual, the coordinator of the drug testing program, or any other employer official who can positively identify the individual. If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The individual may retain his or her wallet.

(5) The individual shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which may be used to adulterate the specimen.

(7) The individual may provide the specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy.

(8) The collection site person shall note any unusual behavior or appearance on the chain of custody form.

(9) In the exceptional event that a drug testing program designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., an accident investigation), a public rest room may be used according to the following procedures: A collection site person of the same gender as the individual shall accompany the individual into the public rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The

collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual shall be instructed to flush the toilet and to participate with the collection site person in completing the chain of custody procedures.

(10) Upon receiving the specimen from the individual, the collection site person shall determine that it contains at least forty-five (45) ml of urine under the split sample method of collection or thirty (30) ml of urine under the single sample method of collection.

(A) If drug testing is to be conducted in a testing facility which performs both the initial screening test and the confirmatory test at the same location, urine may be collected under either the single sample method of collection, or the split sample method of collection.

(B) If drug testing is to be conducted in a testing facility which performs only the initial screening test, the split sample method of collection shall be used.

(i) **Split sample collection method.**

(I) The donor shall urinate into a container or a specimen bottle capable of holding at least sixty (60) ml.

(II) If a collection container is used, the collection site person, in the presence of the donor, pours the urine into two specimen bottles. Thirty (30) ml shall be poured into one bottle, to be used as the primary specimen. At least fifteen (15) ml shall be poured into the other bottle, to be used as the split specimen.

(III) If a single specimen bottle is used as a collection container, the collection site person shall pour thirty (30) ml of urine from the specimen bottle into a second specimen bottle to be used as the primary specimen and retain the remainder, i.e., at least fifteen (15) ml, in the collection bottle to be used as the split specimen.

(IV) Both bottles shall be shipped in a single shipping container to the testing facility.

(ii) **Single sample collection method.**

(I) The collection site person may choose to direct the donor to urinate either directly into a specimen bottle or into a separate collection container.

(II) If a separate collection container is used, the collection site person shall pour at least thirty (30) ml of the urine from the collection container into the specimen bottle in the presence of the donor.

(C) In either collection methodology, upon receiving the specimen from the donor, the collection site person shall determine if it has at least thirty (30) ml of urine for the primary or single specimen bottle, and where the split specimen collection method is used, an additional fifteen

(15) ml of urine for the split specimen bottle. If the individual is unable to provide such a quantity of urine, the collection site person shall instruct the individual to drink not more than twenty-four (24) ounces of fluids and, after a period of up to two (2) hours, again attempt to provide a complete sample using a fresh collection container. The original insufficient specimen shall be discarded. If the donor is still unable to provide an adequate specimen, the insufficient specimen shall be discarded, testing discontinued, and an official of the drug testing program so notified.

(11) After the specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used shall accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement is critical and in no case shall exceed four (4) minutes.

(13) If the temperature of a specimen is outside the range of 32 - 37°C/90 - 100°F, that is a reason to believe that the individual did alter or substitute the specimen, and another specimen shall be collected under direct observation of a same gender collection site person and both specimens shall be forwarded to the testing facility for testing. An individual may volunteer to have an oral temperature taken to provide evidence to counter the reason to believe the individual did alter or substitute the specimen caused by the specimen's temperature falling outside the prescribed range.

(14) Immediately after the specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants such as unusual odor or sudsing. Any unusual findings shall be noted on the chain of custody form.

(15) All specimens suspected of being adulterated shall be forwarded to the testing facility for testing.

(16) Whenever there is reason to believe that a particular individual did alter or substitute the specimen provided, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person.

(17) Both the individual being tested and the collection site person shall keep the specimen in view at all times prior to its being sealed and labeled. If the specimen is transferred to a second bottle, the collection site person shall request the individual to observe the transfer of the specimen and the placement of the tamper-proof seal over the bottle cap and down the sides of the bottle.

(18) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (f)(19) - (f)(22) of this section.

(19) The collection site person shall place securely on the bottle an identification label which contains the date, the

individual's specimen number, and any other identifying information provided or required by the drug testing program.

(20) The individual shall initial the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from the individual.

(21) The collection site person shall indicate on the chain of custody form all information identifying the specimen. The collection site person shall sign the chain of custody form next to the identifying information.

(22) The individual shall be asked to read and sign a statement certifying that the specimen identified as having been collected from the individual is in fact that specimen the individual provided.

(23) A higher level supervisor shall review and concur in advance with any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person based on a reason to believe that the individual did alter or substitute the specimen provided.

(24) The collection site person shall complete the chain of custody form.

(g) **Collection control.** To the maximum extent possible, collection site personnel shall keep the individual's specimen bottle within sight both before and after the individual has urinated. After the specimen is collected, it shall be properly sealed and labeled. An approved chain of custody form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen.

The date and purpose shall be documented on an approved chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(h) **Transportation to the testing facility.** Collection site personnel shall arrange to transport the collected specimens to the drug testing facility. The specimens shall be placed in containers designed to minimize the possibility of damage during transport, for example, specimen boxes or padded mailers; and those containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the container, the collection site supervisor shall sign and enter the date specimens were sealed in the container for transfer. The collection site personnel shall ensure that the chain of custody documentation is sealed separately from the specimen and placed inside the container sealed for transfer to the drug testing facility.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00]

**310:638-1-8.1. Hair specimen collection procedures**

(a) **Designation of collection site.** Each hair drug testing program shall have one (1) or more designated collection sites

which have all necessary personnel, material, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of hair specimens to a licensed drug testing facility.

(b) **Security.** While security is important with any collection, in the case of hair, only the temporary storage area in the designated collection site needs to be secure.

(c) **Chain of custody.** Chain of custody standardized forms shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of hair specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling specimens.

(d) **Access to authorized personnel only.** The hair collection site shall be off limits to unauthorized personnel during the actual collection of specimens.

(e) **Privacy.** Procedures for collecting hair shall be performed on one individual at a time to prevent substitutions or interference with the collection of reliable samples.

(f) **Integrity and identity of specimen.** Precautions shall be taken to ensure that the root end of a hair specimen is indicated for the testing facility who performs the testing. The maximum length of hair that shall be tested is 3.9 cm distal from the skin. This length may be changed if a review officer requests the testing of proximal segments to assist their evaluation of testing data. The collection of pubic hair is not permitted. The information on the hair specimen container and on the chain of custody form shall identify the individual from whom the specimen was collected. The following minimum precautions shall be taken when collecting a hair specimen to ensure specimens are obtained and correctly identified.

(1) When an individual arrives at the collection site, the collection site person shall request the individual to present photo identification. If the individual does not have proper photo identification, the collection site person shall contact the supervisor of the individual, the coordinator of the drug testing program, or any other employer official who can positively identify the individual. If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(2) If the individual fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(3) The collection site person shall note any unusual behavior or appearance on the chain of custody form.

(4) Hair shall be cut as close to the scalp as possible. Upon taking the specimen from the individual, the collection site person shall determine that it contains approximately 1/2 inch of hair when fanned out on a ruler (e.g. about 40 mg of hair).

(5) Both the individual being tested and the collection site person shall keep the specimen in view at all times prior to the specimen container being sealed with a tamper resistant seal and



labeled with the individual's specimen number and other required information.

(6) The collection site person shall label the container which contains the hair with the date, the individual's specimen number, and any other identifying information provided or required by the drug testing program.

(7) The individual shall initial the container for the purpose of certifying that it is the specimen collected from the individual.

(8) The collection site person shall indicate on the chain of custody form all information identifying the specimen. The collection site person shall sign the chain of custody form next to the identifying information or the chain of custody on the specimen container.

(9) The individual shall be asked to read and sign a statement certifying that the specimen identified as having been collected from the individual is in fact the specimen the individual provided.

(10) The collection site person shall complete the chain of custody form.

(g) **Collection control.** To the maximum extent possible, collection site personnel shall keep the individual's specimen container within sight both before and after collection. After the specimen is collected, it shall be properly sealed and labeled. An approved chain of custody form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on an approved chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(h) **Transportation to the testing facility.** Collection site personnel shall arrange to transport the collected specimens to the drug testing facility. The specimens shall be placed in containers which shall be securely sealed to eliminate the possibility of undetected tampering. The collection site personnel shall ensure that the chain of custody documentation is sealed separately from the specimen and placed inside the container sealed for transfer to the drug testing facility.

[**Source:** Added at 17 Ok Reg 381, eff 11-1-99 (emergency); Added at 17 Ok Reg 2045, eff 6-12-00]

### **310:638-1-8.2. Saliva specimen collection procedures**

(a) **Designation of collection site.** Each saliva drug testing program shall have one (1) or more designated collection sites which have all necessary personnel, material, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of saliva specimens to a licensed drug testing facility.

(b) **Security.** While security is important with any collection, in the case of saliva, only the temporary storage area in the

designated collection site needs to be secure.

(c) **Chain of custody.** Chain of custody standardized forms shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of saliva specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling specimens.

(d) **Access to authorized personnel only.** The saliva collection site shall be off limits to unauthorized personnel during the actual collection of specimens.

(e) **Privacy.** Procedures for collecting saliva shall be performed on one individual at a time to prevent substitutions or interference with the collection of reliable samples.

(f) **Integrity and identity of specimen.** Saliva shall be collected in a device approved by the Federal Food and Drug Administration and according to the instructions provided by the manufacturer of the saliva collection device. The information on the saliva specimen container and on the chain of custody form shall identify the individual from whom the specimen was collected. The following minimum precautions shall be taken when collecting a saliva specimen to ensure specimens are obtained and correctly identified.

(1) When an individual arrives at the collection site, the collection site person shall request the individual to present photo identification. If the individual does not have proper photo identification, the collection site person shall contact the supervisor of the individual, the coordinator of the drug testing program, or any other employer official who can positively identify the individual. If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(2) If the individual fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(3) The collection site person shall note any unusual behavior or appearance on the chain of custody form.

(4) Both the individual being tested and the collection site person shall keep the specimen in view at all times prior to the specimen container being sealed with a tamper resistant seal and labeled with the individual's specimen number and other required information.

(6) The collection site person shall label the container which contains the saliva with the date, the individual's specimen number, and any other identifying information provided or required by the drug testing program.

(7) The individual shall initial the container for the purpose of certifying that it is the specimen collected from the individual.

(8) The collection site person shall indicate on the chain of custody form all information identifying the specimen. The collection site person shall sign the chain of custody form next to the identifying information or the chain of custody on the

specimen container.

(9) The individual shall be asked to read and sign a statement certifying that the specimen identified as having been collected from the individual is in fact the specimen the individual provided.

(10) The collection site person shall complete the chain of custody form.

(g) **Collection control.** To the maximum extent possible, collection site personnel shall keep the individual's specimen container within sight both before and after collection. After the specimen is collected, it shall be properly sealed and labeled. An approved chain of custody form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on an approved chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(h) **Transportation to the testing facility.** Collection site personnel shall arrange to transport the collected specimens to the drug testing facility. The specimens shall be placed in containers which shall be securely sealed to eliminate the possibility of undetected tampering. The collection site personnel shall ensure that the chain of custody documentation is sealed separately from the specimen and placed inside the container sealed for transfer to the drug testing facility.

[**Source:** Added at 24 Ok Reg 1183, eff 4-2-2007(emergency); Added at 25 Ok Reg 2436, eff 7-11-2008]

### **310:638-1-9. Training and qualifications of review officers**

(a) The Review Officer is a person responsible for receiving testing facility results generated by an employer's drug and alcohol testing program and who has knowledge of substance abuse disorders and has appropriate training to interpret and evaluate an individual's positive test result together with the individual's medical history and any other relevant biomedical information.

(b) The Review Officer shall possess the following minimum qualifications:

(1) Be licensed to practice medicine and surgery or osteopathic medicine or hold an earned doctoral degree from an accredited institution in clinical chemistry, forensic toxicology, or a similar biomedical science; and

(2) Have completed at least twelve (12) hours of training appropriate for Review Officers provided by the Medical Review Officer Certification Council, American Association of Medical Review Officers, or another organization approved by the Commissioner of Health.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

**310:638-1-10. Training and qualifications of collection site personnel**

(a) Collection procedures and training shall clearly emphasize that the collection site person is responsible for maintaining the integrity of the specimen collection and transfer process, carefully ensuring the modesty and privacy of the donor.

(b) A collection site person shall have successfully completed documented training to carry out this function or shall be a licensed medical professional or technician who acknowledges in writing he or she has been provided instructions for collection as described at OAC 310:638-1-8, 310:638-1-8.1, or 310:638-1-8.2.

(1) A non-medical collection site person shall receive appropriate training in collection procedures as described at OAC 310:638-1-8, 310:638-1-8.1, or 310:638-1-8.2 and shall demonstrate proficiency in the application of these collection procedures prior to serving as a collection site person. A medical professional, technologist, or technician licensed or otherwise approved to practice in the jurisdiction in which the collection takes place is not required to receive such training if that person acknowledges in writing the receipt of instructions for collection as described at OAC 310:638-1-8, 310:638-1-8.1, or 310:638-1-8.2.

(2) Collection site persons shall be provided with detailed, clear instructions on the collection of specimens in compliance with OAC 310:638-1-8, 310:638-1-8.1, or 310:638-1-8.2. Employer representatives and donors subject to testing shall also be provided standard written instructions setting forth their responsibilities.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00; Amended at 24 Ok Reg 1183, eff 4-2-2007(emergency); Amended at 25 Ok Reg 2436, eff 7-11-2008]

**SUBCHAPTER 3. ADMINISTRATION**

- 310:638-3-1. Testing facilities eligible for licensure
- 310:638-3-2. Licensure fee
- 310:638-3-3. Procedures for licensure
- 310:638-3-5. Transfer of ownership of a testing facility
- 310:638-3-6. Enforcement
- 310:638-3-7. Inspections

**310:638-3-1. Testing facilities eligible for licensure**

(a) **Intrastate licensure.** Testing facilities located within the State of Oklahoma shall be licensed by the Department in accordance with this Chapter in order to provide laboratory services to an employer to test for the presence or absence of drugs or alcohol.

(b) **Interstate licensure.** Testing facilities located outside the State of Oklahoma which are certified for forensic urine drug testing by the United States Department of Health and Human Services, accredited for forensic urine drug testing by the College of American Pathologists or licensed by a State acceptable to the Department are eligible for licensure in accordance with this Chapter to provide laboratory services to an employer to test for the presence or absence of drugs or alcohol.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00]

**310:638-3-2. Licensure fee**

The fee for licensure of each testing facility shall be one hundred fifty dollars (\$150.00) annually. Licenses shall be renewed annually provided the provisions of this Chapter are met.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

**310:638-3-3. Procedures for licensure**

(a) Application for licensure shall be made on a form prescribed by the Commissioner of Health by the director of the applicant testing facility.

(1) A separate application shall be completed for each testing facility location, except that a testing facility which is not at a fixed location, that is, a testing facility that moves from testing site to testing site, shall complete a single application using the address of its designated primary site.

(2) Each van or other mobile unit providing laboratory services to an employer to test for the presence or absence of

drugs or alcohol shall complete a separate application using the address of the designated primary site or home base.

(b) The license fee shall be paid at the time of application for each application completed and filed. The license fee is non-refundable.

(c) Prior to licensure, in addition to the completed application and licensure fee, each drug screen testing facility shall provide:

(1) Proof of enrollment and satisfactory performance in an approved proficiency testing program in accordance with OAC 310:638-5-10;

(2) The names and qualifications of all technical staff in accordance with OAC 310:638-5-2;

(3) The name and address of the testing facility(s) utilized for confirmation testing.

(d) Prior to licensure, in addition to the completed application and licensure fee, each testing facility seeking licensure based on certification by the United States Department of Health and Human Services, accreditation by the College of American Pathologists or licensed by a State acceptable to the Department, shall submit proof of current certification, accreditation, or licensure and shall be deemed to meet licensure requirements.

(e) Upon satisfying the requirements for licensure, the testing facility shall be issued the appropriate class of license for initial screening for drugs and/or alcohol or confirmatory testing for drugs and/or alcohol or both.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00]

### **310:638-3-5. Transfer of ownership of a testing facility**

(a) The license for a testing facility is not transferable or assignable.

(b) If an entity is considering acquisition of a licensed testing facility, an application for licensure with the one hundred fifty dollar (\$150.00) fee shall be filed with the Department prior to the effective date of the change.

(c) No license shall be transferred from one location to another unless the Department is notified. If a testing facility is considering relocation, the testing facility shall notify the Department thirty (30) days prior to the intended relocation. The Department shall provide written notification to the testing facility amending the annual license to reflect the new location.

(d) Upon the effective date of a change of ownership or upon cessation of operation of a testing facility, the current license shall be returned to the Department. The testing facility shall advise the Department in writing at the time of cessation of operation where testing facility records shall be archived and how such records shall be accessed.

[Source: Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

### **310:638-3-6. Enforcement**

(a) **Revocation, suspension, or nonrenewal of license.** The license of a testing facility may be revoked, suspended, or nonrenewed upon the filing of an individual proceeding in accordance with Chapter 2 of this Title.

(b) **Factors to consider.** The following factors shall be considered in determining whether revocation, suspension, or nonrenewal is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug or alcohol tests;

(2) Unsuccessful performance in proficiency testing or testing facility inspections;

(3) Failure to conduct confirmatory testing of a positive drug or alcohol test obtained on the initial screening test;

(4) Conviction of any criminal offense committed as an incident to operation of the testing facility;

(5) Loss of certified, licensed or accredited status by the certifying, licensing or accrediting body, or failure to notify the Department of loss of certification, licensure or accreditation as required by this Chapter;

(6) Failure to detect the presence or absence of a drug or drugs in blind performance test specimens if an employer chooses to submit such specimens;

(7) Failure to comply with any provision of the Act or this Chapter;

(8) Any other cause which materially affects the ability of the testing facility to ensure full reliability and accuracy of drug or alcohol tests and the accurate reporting of results.

(c) **Period and terms.** The period and terms of revocation, suspension, or nonrenewal shall be determined by the Commissioner of Health and shall depend on the facts and circumstances of the revocation, suspension, or nonrenewal and the need to ensure accurate and reliable drug and alcohol testing of the employees.

(d) **Following revocation, suspension, or nonrenewal of license.** Upon revocation, suspension, or nonrenewal of the intrastate license a testing facility located in Oklahoma shall cease all drug and alcohol testing. Upon revocation, suspension, or nonrenewal of the interstate license a testing facility located outside the State of Oklahoma shall cease all drug and alcohol testing for Oklahoma employers. Revocation, suspension, or nonrenewal of the license may be appealed in accordance with the Oklahoma Administrative Procedures Act (75 O.S. Sections 309 et seq.)

(e) **Reinstatement of testing facility license.** Following the termination or expiration of any suspension, revocation, or nonrenewal, a testing facility may apply for reinstatement. Upon submission of evidence satisfactory to the Commissioner of Health that the testing facility is in compliance with this Chapter and

any conditions imposed as part of the suspension, revocation, or nonrenewal, the Commissioner of Health may reinstate the testing facility. If the license issued to a testing facility has been suspended, revoked, or nonrenewed because of unsuccessful performance in proficiency testing, the reinstatement shall only occur after the testing facility has demonstrated satisfactory performance on three consecutive proficiency testing events.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00]

### **310:638-3-7. Inspections**

(a) Completed applications received by the Department for initial licensure, licensure renewal, or for licensure reinstatement shall constitute consent for an on-site inspection during normal operating hours by representatives of the Department.

(b) Testing facilities as well as collection sites associated with a testing facility are subject to inspection during normal operating hours any time an on-site inspection is deemed necessary by the Commissioner of Health to protect the health and welfare of the public.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 24 Ok Reg 1183, eff 4-2-2007(emergency); Amended at 25 Ok Reg 2436, eff 7-11-2008]



**SUBCHAPTER 5. DRUG SCREEN TESTING FACILITIES**

## Section

- 310:638-5-1. Eligibility
- 310:638-5-2. Personnel
- 310:638-5-3. Security and chain of custody
- 310:638-5-4. Methods of analysis and specimen storage
- 310:638-5-5. Internal review and certification of test results
- 310:638-5-6. Records and procedure manual
- 310:638-5-7. Instruments and equipment
- 310:638-5-8. Standards and controls
- 310:638-5-9. Quality assurance and quality control
- 310:638-5-10. Proficiency testing

**310:638-5-1. Eligibility**

Drug screen testing facilities shall comply with applicable Federal, State, and local laws.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

**310:638-5-2. Personnel**

The drug screen testing facility shall contract with, or employ, the following personnel to perform, supervise, and report drug screen tests:

(1) **Director.** The drug screen testing facility shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the drug screen testing facility. The director shall possess the following minimum qualifications:

(A) A bachelor's degree from an accredited institution in the chemical, biological, or physical sciences or medical technology; and

(B) Subsequent to graduation have had two (2) or more years of full-time drug testing experience.

(2) **Director responsibilities.** The director shall be engaged in, and be responsible for, the management of the drug screen testing facility even where another individual has overall responsibility for an entire multispecialty testing facility.

(A) The director shall be responsible for ensuring that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the drug screen testing facility. The director shall ensure the continued competency of drug screen testing facility personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(B) The director shall be responsible for the drug screen testing facility having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be

reviewed, signed, and dated by the director whenever procedures are first placed into use, or changed, or when a new individual assumes responsibility for direction of the drug screen testing facility. Copies of all procedures and dates on which they are in effect shall be maintained.

(C) The director shall be responsible:

(i) for maintaining a quality assurance program to ensure the proper performance and reporting of all test results;

(ii) for maintaining acceptable analytical performance for all controls and standards;

(iii) for maintaining quality control testing; and

(iv) for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(D) The director shall be responsible for assuring all necessary action is taken to maintain satisfactory operation and performance of the drug screen testing facility in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. The director shall ensure that sample results are not reported until all corrective actions have been taken and he or she can ensure that the test results provided are accurate and reliable.

(3) **General supervisor.** A qualified general supervisor shall be on the premises during all hours in which tests are performed. The general supervisor shall be responsible for day-to-day operations and supervision of analysts. The general supervisor shall possess the following minimum qualifications:

(A) A high school diploma or equivalent and documented training by the manufacturer, or other qualified person, in the operation and maintenance of the test system utilized, to include the instrumentation, test reagents, calibration and quality control materials, and any other equipment or supplies required in the performance of the drug screen testing procedure; and

(B) Have training and experience in the theory and practice of the procedures used in the drug screen testing facility, resulting in a thorough understanding of:

(i) quality control practices and procedures;

(ii) the review, interpretation, and reporting of test results;

(iii) maintenance of chain of custody; and

(iv) proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(4) **Test validation.** The drug screen testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the drug screen testing facility's test reports. A drug screen testing facility may designate more than one person to perform this function. This individual(s) shall be any employee who is qualified as director or general supervisor.

(5) **Other personnel.** Other technical or nontechnical staff shall have the necessary training and skills for the tasks assigned, and shall perform only those procedures that require a degree of skill commensurate with their training, education, and technical ability.

(6) **Training.** The drug screen testing facility shall make available continuing education programs to meet the needs of facility personnel.

(7) **Personnel records.** Personnel records shall include at least the following:

- (A) verification of education;
- (B) initial skills orientation program;
- (C) resume of training and experience;
- (D) documentation of continuing education;
- (E) certification or license, if any;
- (F) references;
- (G) job descriptions;
- (H) records of performance evaluation and advancement;
- (I) incident reports; and
- (J) results of tests which establish employee competency.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 24 Ok Reg 1183, eff 4-2-2007(emergency); Amended at 25 Ok Reg 2436, eff 7-11-2008]

### **310:638-5-3. Security and chain of custody**

(a) Drug screen testing facilities shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to testing facility processes or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of federal or state agencies, all authorized visitors and maintenance and service personnel shall be escorted at all times. Documentation of individuals accessing these areas, dates, time of entry, and purpose of entry shall be maintained.

(b) Drug screen testing facilities shall use internal chain of custody procedures to maintain control and accountability of specimens from receipt through completion of screening, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Authorized drug screen testing facility personnel shall be responsible for each specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

(c) When specimens are received, drug screen testing facility personnel shall inspect each package for evidence of possible

tampering and compare information on specimen bottles and containers within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and containers and the agency's chain of custody forms shall be immediately reported to the employer and shall be noted on the drug screen testing facility's chain of custody form which shall accompany the specimens while they are in the drug screen testing facility's possession.

(d) Specimen bottles shall normally be retained within the drug screen testing facility's accession area until all analyses have been completed. Aliquots and the drug screen testing facility's chain of custody forms shall be used by drug screen testing facility personnel for conducting initial screening tests.

(e) Urine specimens shall be tested for adulteration.

(f) Testing facilities shall perform integrity checks on saliva specimens as required by facility policy.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00; Amended at 24 Ok Reg 1183, eff 4-2-2007(emergency); Amended at 25 Ok Reg 2436, eff 7-11-2008]

#### **310:638-5-4. Methods of analysis and specimen storage**

##### **(a) Methods of analysis.**

(1) Licensed drug screen testing facilities shall have the capability of performing initial screening for the following classes of drugs or their metabolites: marijuana and cocaine, using an immunoassay which meets the requirements of the United States Food and Drug Administration for commercial distribution or another approved screening procedure or if prepared in-house by the testing facility, documented evidence shall exist indicating that the antibody meets acceptable performance criteria.

(2) Initial screening shall be completed within forty-eight (48) hours following receipt of the specimen by the testing facility. If the initial screening cannot be completed within forty-eight (48) hours, the specimen shall not be accepted or shall be sent to another testing facility for screening.

(3) If the drug screen testing facility is not certified for forensic urine drug testing by the United States Department of Health and Human Services or accredited for forensic urine drug testing by the College of American Pathologists all specimens that do not test negative shall be forwarded to an appropriate testing facility for confirmation.

(4) All confirmatory urine or saliva drug testing shall be performed by a testing facility that is certified for forensic urine drug testing by the United States Department of Health and Human Services or accredited for forensic urine drug testing by the College of American Pathologists.

(5) No positive urine or saliva drug screen shall be reported to the Review Officer until the positive initial screen has been confirmed as required. If the employer operates a drug screen testing facility, the employer shall not base any employment decision on a positive urine drug screen until the positive initial test has been confirmed and reviewed.

(6) No positive hair drug screen shall be reported to the Review Officer until the positive initial screen has been decontaminated and confirmed by the same laboratory.

(b) **Specimen storage.**

(1) Urine specimens that do not receive an initial test within twenty-four (24) hours of arrival at the drug screen testing facility shall be placed in secure refrigeration units where the temperatures do not exceed 6°C. Urine testing facilities shall have emergency power equipment or other appropriate storage shall be available in case of a prolonged power failure.

(2) The drug screen testing facility shall log in the split specimen, with the split specimen bottle seal remaining intact. The drug screen testing facility shall store this sample securely as in 310:638-5-4(b)(1).

(3) If the result of the primary specimen is negative, the drug screen testing facility may discard the split specimen. If the result of the test of the primary specimen is positive, the drug screen testing facility shall forward the split specimen, using appropriate chain of custody procedures, to a qualified testing facility for confirmation testing. The drug screen testing facility shall ensure the confirmatory testing facility retains the split specimen in properly secured frozen storage (-20°C or less) for a minimum of one (1) year.

(4) Because some analytes deteriorate or are lost during freezing and/or storage, quantitation for a retest is not subject to a specific cutoff requirement but must provide data sufficient to confirm the presence of the drug or metabolite.

(5) Saliva specimens shall be stored and transported as required by the manufacturer of the collection device.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00; Amended at 24 Ok Reg 1183, eff 4-2-2007(emergency); Amended at 25 Ok Reg 2436, eff 7-11-2008]

**310:638-5-5. Internal review and certification of test results**

(a) The drug screen testing facility shall report positive test results to the employer's Review Officer within an average of five (5) working days after receipt of the specimen by the drug screen testing facility. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual. The report shall identify the drugs/metabolites tested for, whether positive or negative, and

the cutoff for each, the specimen number assigned by the employer, and the drug screen testing facility specimen identification number.

(b) The drug screen testing facility shall report as negative all specimens which are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported as positive for a specific drug.

(c) The Review Officer may request from the drug screen testing facility and the drug screen testing facility shall provide quantitation of test results. The Review Officer shall not disclose quantitation of test results to the employer but shall report only whether the test was positive or negative.

(d) The drug screen testing facility may transmit results to the Review Officer by electronic means, i.e., teleprinters, facsimile, or computer, in a manner designed to ensure confidentiality of the information. Results shall not be provided verbally by telephone.

The drug screen testing facility shall ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(e) The drug screen testing facility shall send to the Review Officer the positive drug test results, which shall be signed by the individual responsible for the day-to-day management of the drug screen testing facility or the individual responsible for attesting to the validity of the test reports.

(f) All results reported to the employer shall be by the same source.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

### **310:638-5-6. Records and procedure manual**

(a) **Records.** The drug screen testing facility shall maintain and make available for at least two (2) years documentation of all aspects of the testing process.

(1) The required documentation shall include:

(A) personnel files on all individuals authorized to have access to specimens;

(B) chain of custody documents;

(C) quality assurance/quality control records;

(D) procedure manuals;

(E) all test data, including calibration curves and any calculations used in determining test results;

(F) reports;

(G) performance records on proficiency testing;

(H) performance on certification inspections; and

(I) hard copies of computer-generated data or another read-only computerized data storage system that produces exact duplicates of the reported result.

(2) The drug screen testing facility shall maintain documents for any specimen under legal challenge for an indefinite period.

(b) **Procedure manual.** Each drug screen testing facility shall

have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00]

### **310:638-5-7. Instruments and equipment**

(a) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and diluters shall be checked for accuracy and reproducibility before being placed in service and periodically thereafter.

(b) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks and instructions for major trouble shooting and repair. Records shall be available on preventive maintenance.

(c) There shall be written procedures for the actions to be taken when systems are out of acceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

### **310:638-5-8. Standards and controls**

(a) Drug screen testing facility standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates:

- (1) when received;
- (2) when prepared or opened;
- (3) when placed in service; and
- (4) expiration date.

(b) Purchase, storage, and use of all drug standards shall conform to all Federal, State, and local laws.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added

at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

**310:638-5-9. Quality assurance and quality control**

(a) **Quality assurance.** Drug screen testing facilities shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) **Quality control.**

(1) Each analytical run of specimens to be screened shall include:

(A) Urine, hair, or saliva specimens certified to contain no drug;

(B) Urine, hair, or saliva positive controls with the drug or metabolite at or near the threshold (cutoff).

(2) Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall be documented.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00; Amended at 24 Ok Reg 1183, eff 4-2-2007(emergency); Amended at 25 Ok Reg 2436, eff 7-11-2008]

**310:638-5-10. Proficiency testing**

(a) **Enrollment and performance.**

(1) Each drug screening and/or confirmation testing facility shall enroll and demonstrate satisfactory performance in a Department approved proficiency testing program established by an independent group which contains those drugs and metabolites for which urine, hair, or saliva is routinely screened.

(2) The drug testing facility shall satisfactorily perform in one proficiency testing event prior to initial licensure and demonstrate continued satisfactory performance to maintain licensure.

(3) The drug testing facility shall authorize the proficiency testing service to send results to the Oklahoma State Department of Health for review. The drug testing facility shall maintain records which shall document the handling, processing and examination of all proficiency testing samples for a minimum of two (2) years from the date of testing.

(4) The drug testing facility shall ensure that proficiency testing samples are analyzed at least three (3) times each year using the same techniques as those employed for screening unknown specimens.



(5) The proficiency testing samples shall be included with the routine sample run and tested with the same frequency as unknown samples by the individuals responsible for testing unknown specimens.

(6) The drug testing facility shall not engage in discussions or communications concerning proficiency testing results with other drug testing facilities nor shall they send proficiency testing samples or portions of the samples to another drug testing facility for analysis.

(b) **Satisfactory performance.**

(1) The drug testing facility shall maintain an overall testing event score of at least eighty (80) percent for proficiency testing performance to be considered satisfactory.

(2) Failure to participate in a proficiency testing event shall result in a score of zero (0) percent for the testing event.

(c) **Unsuccessful performance.** Failure to achieve satisfactory performance in two (2) consecutive testing events, or two (2) out of three (3) consecutive testing events, shall be determined to be unsuccessful performance.

[**Source:** Added at 11 Ok Reg 4339, eff 7-14-94 (emergency); Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 17 Ok Reg 381, eff 11-1-99 (emergency); Amended at 17 Ok Reg 2045, eff 6-12-00; Amended at 24 Ok Reg 1183, eff 4-2-2007(emergency); Amended at 25 Ok Reg 2436, eff 7-11-2008]

**SUBCHAPTER 7. ALCOHOL TESTING FACILITIES**

## Section

- 310:638-7-1. Qualifications of alcohol testing facilities
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- 310:638-7-3. Testing locations for alcohol screening device and evidential breath testing (EBT) devices
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- 310:638-7-11. Maintenance of records

**310:638-7-1. Qualifications of alcohol testing facilities**

(a) Testing facilities conducting alcohol screening tests shall meet the requirements of this subchapter to be eligible for licensure as an alcohol testing facility.

(b) Testing facilities conducting blood alcohol or urine alcohol confirmation testing shall be certified for forensic urine drug testing by the United States Department of Health and Human Services or accredited for forensic urine drug testing by the College of American Pathologists and meet the provisions of this subchapter to be eligible for licensure as an alcohol testing facility.

[**Source:** Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

**310:638-7-2. Notification requirements**

All alcohol testing facilities licensed by the Department based on certification by the United States Department of Health and Human Services or accreditation by the College of American Pathologists shall notify the Department in writing within ten (10) days of the loss of such certification or accreditation.

[**Source:** Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

**310:638-7-3. Testing locations for alcohol screening device and evidential breath testing (EBT) devices**

(a) Each testing facility shall conduct alcohol testing in a location that affords visual and aural privacy to the individual being tested, sufficient to prevent unauthorized persons from seeing or hearing test results. All necessary equipment, personnel, and materials for alcohol testing shall be provided at the location where testing is conducted.

(b) A testing facility may use a mobile collection facility, e.g., a van equipped for alcohol testing, that meets the requirements of OAC 310:638-7-3(a).

(c) In unusual circumstances, e.g., when it is essential to conduct a test outdoors at the scene of an accident, a test may be conducted at a location that does not fully meet the requirements of OAC 310:638-7-3(a). In such a case the testing facility or testing personnel shall provide visual and aural privacy to the employee to the greatest extent practicable.

(d) The testing personnel shall supervise alcohol device testing of only one (1) employee at a time. The testing personnel shall not leave the alcohol testing location while the testing procedure for a given employee is in progress.

[**Source:** Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

#### **310:638-7-4. Initial alcohol screening tests**

(a) **Cutoff level for initial alcohol screening tests.** An alcohol concentration of 0.02 or greater shall be considered a positive initial test for alcohol and shall be confirmed as required. A positive result obtained utilizing an alcohol screening device which meets the requirements at OAC 310:638-7-4(b) shall be considered a positive initial test for alcohol and shall be confirmed as required.

(b) **Alcohol screening device and initial blood tests.**

(1) All alcohol screening devices with the exception of evidential breath testing devices (EBT) shall comply with the requirements specified in the National Highway Traffic Safety Administration's Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids (59 FR 7372).

(2) Evidential breath testing devices shall comply with the National Highway Traffic Safety Administration's Model Specifications for Evidential Breath Testing Devices (58 FR 48705) and be included on the Conforming Products List (59 FR 18839).

(3) All alcohol screening device and initial blood testing shall follow the manufacturer's instructions for test system operation and test performance.

(4) Enzyme blood tests for alcohol initial testing shall be used only under limited circumstances when an alcohol screening device, EBT, or appropriately trained breath alcohol technician (BAT) is not readily available to conduct alcohol testing by another method. Blood alcohol testing is not intended to be an equal alternative method to saliva or breath testing which an employer may choose as a matter of preference.

(c) **Procedures for alcohol screening device tests.**

(1) When the employee enters the alcohol testing location, the testing personnel shall require the individual to provide positive identification, e.g., through use of a photo I.D. card or identification by an employer representative.

(2) Alcohol testing facilities shall use internal chain of

custody procedures to maintain control and accountability of specimens from receipt through completion of screening, reporting of results, during storage (if applicable), and continuing until final disposition of specimens. Each chain of custody/test report form shall include a unique sequential test identification number.

(3) There shall be a log book that is used to identify every test conducted unless an EBT is used. The log book shall include the unique sequential test identification number and the date of the test. The log book or the chain of custody form shall include the test identification number, date and time of the test, name of the testing personnel, location of the test, and test result. If the test is conducted using a disposable alcohol screening device, the log book or chain of custody form shall also contain the manufacturer's lot number and expiration date for each device used. Log books, chain of custody forms, and test results shall be maintained in a confidential manner secured from unauthorized review.

(4) The testing personnel shall explain the testing procedure to the employee, and the test shall then be conducted according to the manufacturer's instructions and the results recorded on the chain of custody/test report form.

(5) The testing personnel and employee shall sign a statement certifying the performance and results of the alcohol screening test.

(6) In any case in which the result of the screening test is an alcohol concentration of less than 0.02, no further testing is authorized. The testing personnel shall transmit the result of less than 0.02 to the employer in a confidential manner, and the employer shall receive and store the information so as to ensure that confidentiality is maintained.

(7) If the result of the screening test is an alcohol concentration of 0.02 or greater, a confirmation test shall be performed as described at OAC 310:638-7-6 or OAC 310:638-7-7.

**(d) Procedures for enzyme initial alcohol blood tests.**

(1) Blood used for initial alcohol tests shall be collected as specified at OAC 310:638-7-7(a), however, at least three (3), five (5) milliliter samples of blood shall be collected. One (1) sample shall be used for the test performance and two (2) samples shall remain unopened and securely stored under refrigeration at two (2) to eight (8) degrees centigrade for possible confirmation testing. Collection control and transportation of specimens to the testing facility shall comply with OAC 310:638-7-7(b) & (c).

(2) The enzyme initial alcohol test shall be performed as specified by the test manufacturer's instructions and the results shall be recorded on the chain of custody/test report form. If the result of this analysis is an alcohol concentration of less than 0.02, the alcohol testing facility shall transmit the test result to the employer as negative. If the alcohol concentration is 0.02 or greater, a blood alcohol confirmation test shall be performed as described at OAC 310:638-7-7.

[Source: Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added

at 12 Ok Reg 3069, eff 7-27-95]

**310:638-7-5. Cutoff level and alcohol confirmation tests**

All positive initial alcohol screening tests shall be confirmed using breath analyzed by an EBT or blood analyzed by gas chromatography (GC). A test performed on blood and analyzed by gas chromatography shall be considered a confirmed alcohol test. An alcohol concentration of 0.02 or greater shall be considered a positive confirmation test for alcohol.

[**Source:** Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

**310:638-7-6. Breath alcohol confirmation tests**

(a) **The breath alcohol technician.**

(1) The breath alcohol technician (BAT) shall be trained to proficiency in the operation of the EBT(s) the BAT is using and in the alcohol testing procedures of this chapter.

(2) Proficiency shall be demonstrated by successful completion of a course of instruction which, at a minimum, provides the following:

(A) Training in the principles of EBT methodology, operation and calibration checks;

(B) The fundamentals of breath analysis for alcohol content; and

(C) Procedures required in this chapter for obtaining a breath sample, and interpreting and recording EBT results.

(3) Only courses of instruction for operation of EBTs that are equivalent to the United States Department of Transportation model course, as determined by the National Highway Traffic Safety Administration (NHTSA), shall be used to train BATs to proficiency.

(4) The course of instruction shall provide documentation that the BAT has demonstrated competence in the operation of the specific EBT(s) the BAT shall use.

(5) Any BAT who shall perform an external calibration check of an EBT shall be trained to proficiency in conducting the check on the particular model of EBT, to include practical experience and demonstrated competence in preparing the breath alcohol simulator or alcohol standard, and in maintenance and calibration of the EBT.

(6) The BAT shall receive additional training, as needed, to ensure proficiency, concerning new or additional devices or changes in technology that the BAT will use.

(7) The alcohol testing facility or its agent shall establish documentation of the training and proficiency test of each BAT it uses to test employees and maintain the documentation as required at OAC 310:638-7-11(a)(3).

(8) A BAT, who is a qualified supervisor of an employee, may conduct the alcohol confirmation test for that employee only if another BAT is unavailable to perform the test in a timely

manner.

(9) Law enforcement officers who have been certified by state or local governments to conduct breath alcohol testing are deemed to be qualified as BATs. The officer shall have been certified by a state or local government to use the EBT that is to be used for the test.

(b) **Devices for breath alcohol confirmation tests.** For confirmation tests, alcohol testing facilities shall use EBTs that meet the following requirements:

(1) EBTs shall have the capability of providing, independently or by direct link to a separate printer, a printed result of each breath test;

(2) EBTs shall be capable of assigning a unique and sequential number to each completed test, with the number capable of being read by the BAT and the employee before each test and being printed out along with the test result.

(3) EBTs shall be capable of printing out the manufacturer's name for the device, the device's serial number, and the time of the test.

(4) EBTs shall be able to distinguish alcohol from acetone at the 0.02 alcohol concentration level.

(5) EBTs shall be capable of testing an air blank prior to each collection of breath; and

(6) EBTs shall be capable of performing an external calibration check.

(c) **Quality assurance plans for EBTs.**

(1) In order to be used in confirmation alcohol testing an EBT shall have a quality assurance plan (QAP) developed by the manufacturer.

(2) The QAP shall designate the method or methods to be used to perform external calibration checks of the device, using only calibration devices on the NHTSA "Conforming Products List of Calibrating Units for Breath Alcohol Tests."

(3) The QAP shall specify the minimum intervals for performing external calibration checks of the device. Intervals shall be specified for different frequencies of use, environmental conditions, e.g., temperature, altitude, humidity, and contexts of operation, e.g., stationary or mobile use.

(4) The QAP shall specify the tolerances on an external calibration check within which the EBT is regarded to be in proper calibration.

(5) The QAP shall specify inspection, maintenance, and calibration requirements and intervals for the device.

(6) The alcohol testing facility shall comply with the quality assurance plan for each EBT it uses for alcohol screening or confirmation testing.

(7) The alcohol testing facility shall ensure that external calibration checks of each EBT are performed as provided in the QAP.

(8) The alcohol testing facility shall take an EBT out of service if any external calibration check results in a reading outside the tolerances for the EBT specified in the QAP. The EBT shall not be used for alcohol testing until it has been

serviced and had an external calibration check resulting in a reading within the tolerances for the EBT.

(9) The alcohol testing facility shall ensure that inspection, maintenance, and calibration of each EBT are performed by the manufacturer or a manufacturer's representative as required. The alcohol testing facility shall also ensure that each BAT or other individual who performs an external calibration check of an EBT has demonstrated proficiency in conducting such a check of the model of EBT in question.

(10) The alcohol testing facility shall maintain records of the external calibration checks of EBTs as required at OAC 310:638-7-11(c).

(11) When the alcohol testing facility is not using the EBT at an alcohol testing site, the employer shall store the EBT in a secure space.

(d) **Chain of custody.** Alcohol testing facilities shall use internal chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage (if applicable), and continuing until final disposition of specimens. Each chain of custody/test report form shall include a unique test identification number.

(e) **Procedures for confirmation tests.**

(1) If the BAT conducting the confirmation test is not the person who conducted the screening test, the BAT shall follow the procedures at OAC 310:638-7-4(c)(1).

(2) The BAT shall instruct the employee not to eat, drink, put any object or substance in the mouth, and, to the extent possible, not belch during a waiting period before the confirmation test. This time period begins with the completion of the screening test, and shall not be less than fifteen (15) minutes. The confirmation test shall be conducted within twenty (20) minutes of the completion of the screening test. The BAT shall explain to the employee the reason for this requirement, i.e., to prevent any accumulation of mouth alcohol leading to an artificially high reading, and that it is for the employee's benefit. The BAT shall also explain that the test shall be conducted at the end of the waiting period, even if the employee has disregarded the instruction. If the BAT becomes aware that the employee has not complied with this instruction, the BAT shall so note in the "Remarks" section of the chain of custody/test report form.

(3) Before the confirmation test is administered for each employee, the BAT shall ensure that the EBT registers 0.00 on an air blank. If the reading is greater than 0.00, the BAT shall conduct one more air blank. If the reading is greater than 0.00, testing shall not proceed using that instrument. However, testing may proceed on another instrument.

(4) Before the confirmation test is administered for each employee, the BAT shall ensure that he or she and the employee read the sequential number displayed on the EBT and confirm that the number matches the number on the chain of custody/test report form.

(5) Any EBT taken out of service because of failure to perform an air blank accurately shall not be used for testing until a check of external calibration is conducted and the EBT is found to be within tolerance limits.

(6) An individually sealed mouthpiece shall be opened in view of the employee and BAT and attached to the EBT in accordance with the manufacturer's instructions.

(7) The BAT shall instruct the employee to blow forcefully into the mouthpiece for at least six (6) seconds or until the EBT indicates that an adequate amount of breath has been obtained.

(8) In the event that the screening and confirmation test results are not identical, the confirmation test result shall be deemed to be the final result.

(9) If the EBT provides a printed result, but does not print the results directly onto the chain of custody/test report form, the BAT shall show the employee the result displayed on the EBT. The BAT shall then affix the test result printout to the chain of custody/test report form in the designated space, using a method that shall provide clear evidence of removal, e.g., tamper-evident tape. The printout shall include the test result and the sequential number.

(10) If the EBT prints the test results directly onto the chain of custody/test report form, the BAT shall show the employee the result displayed on the EBT. The printout shall include the test result and the sequential number.

(11) The testing personnel and employee shall sign a statement included on the chain of custody/test report form certifying the performance and results of the alcohol confirmation test.

(12) If a test result printed by the EBT does not match the displayed result, the BAT shall note the disparity in the "Remarks" section. Both the employee and the BAT shall initial or sign the notation. The test shall be invalid and the employer and employee shall be so advised.

(13) The BAT shall transmit all results to the employer in a confidential manner.

(14) An employer shall designate at least one (1) employer representative for the purpose of receiving and handling alcohol testing results in a confidential manner. All communications by BATs to the employer concerning the alcohol testing results of employees shall be to a designated employer representative. The employer shall store the information so as to ensure confidentiality is maintained.

(15) Such transmission shall be in writing, in person, or by electronic means, but the BAT shall ensure immediate transmission to the employer of results that require the employer to prevent the employee from performing a safety-sensitive function.

**(f) Refusal to test and uncompleted tests.**

(1) Refusal by an employee to sign the certification statement, to provide breath, to provide an adequate amount of breath, or otherwise not cooperate with the testing process in a way that prevents the completion of the test, shall be noted by



the BAT in the "Remarks" section of the chain of custody/test report form. The testing process shall be terminated and the BAT shall immediately notify the employer.

(2) If a confirmation test cannot be completed, or if an event occurs that invalidates the test, the BAT shall, if practicable, begin a new confirmation test, as applicable, using a new chain of custody/test report form with a new sequential test number.

(g) **Inability to provide an adequate amount of breath.**

(1) The following procedures shall be completed in any case in which an employee is unable, or alleges an inability, to provide an amount of breath sufficient to permit a valid breath test because of a medical condition.

(2) The BAT shall again instruct the employee to attempt to provide an adequate amount of breath. If the employee refuses to make the attempt, the BAT shall immediately inform the employer.

(3) If the employee attempts and fails to provide an adequate amount of breath, the BAT shall so note in the "Remarks" section of the chain of custody/test report form and immediately inform the employer.

(4) If the employee attempts and fails to provide an adequate amount of breath, the employer shall proceed as follows:

(A) The employer shall direct the employee to obtain, as soon as practical after the attempted provision of breath, an evaluation from a licensed physician who is acceptable to the employer concerning the employee's medical ability to provide an adequate amount of breath.

(B) If the physician determines that a medical condition has, or with a high degree of probability, could have, precluded the employee from providing an adequate amount of breath, the employee's failure to provide an adequate amount of breath shall not be deemed a refusal to take a test. The physician shall provide to the employer a written statement of the basis for this conclusion.

(C) If the physician is unable to make the determination set forth at OAC 310:638-7-6(g)(2)(i), the employee's failure to provide an adequate amount of breath shall be regarded as a refusal to take a test. The physician shall provide a written statement of the basis for this conclusion to the employer.

(h) **Invalid tests.** A breath alcohol test shall be invalid under the following circumstances:

(1) The next external calibration check of an EBT produces a result that differs by more than the tolerance stated in the QAP from the known value of the test standard. In this event, every test result of 0.02 or above obtained on the device since the last valid external calibration check shall be invalid;

(2) The BAT does not observe the minimum fifteen (15) minute waiting period prior to the confirmation test, as provided at OAC 310:638-7-6(e)(2);

(3) The BAT does not perform an air blank of the EBT before a confirmation test, or an air blank does not result in a reading of 0.00 prior to or after the administration of the test, as

provided at OAC 310:638-7-6(e)(3);

(4) The BAT does not sign the chain of custody/test report form as required;

(5) The BAT fails to note on the "Remarks" section of the chain of custody/test report form that the employee failed or refused to sign the form following the recording or printing on, or attachment to, the form of the test result;

(6) An EBT fails to print a confirmation test result; or

(7) The sequential test number of alcohol concentration displayed on the EBT is not the same as the sequential test number of alcohol concentration on the printed result.

[**Source:** Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

### **310:638-7-7. Blood alcohol confirmation tests**

(a) **Collection procedures for blood alcohol tests.** Personnel who collect blood for alcohol tests shall be licensed, certified, or otherwise authorized to withdraw blood in accordance with Federal, State, and local laws.

(1) Blood shall be withdrawn in accordance with accepted medical practices using at least the following items:

(A) A suitable clean, sterile, dry tube with inert closure, containing the appropriate anticoagulant(s) and preservative(s) for alcohol analysis by gas chromatography;

(B) A chain of custody form;

(C) A label for the tube;

(D) A sterile, non-alcoholic swab; and

(E) An appropriate, disposable blood extraction device.

(2) Blood shall be withdrawn by venipuncture, after appropriate preparation of the puncture site, and with necessary precautions to maintain asepsis and avoid contamination of specimens. Puncture site preparation and skin cleansing shall be performed without the use of alcohol or other volatile organic disinfectants.

(3) At least two (2), five (5) milliliter samples of blood shall be collected directly in or immediately deposited into suitable tubes as described at OAC 310:638-7-7(a). The collection personnel shall immediately label the tube as required by chain of custody procedures and transport to the testing facility as specified at OAC 310:638-7-7(c).

(4) Collection personnel shall use blood alcohol collection materials in accordance with the supplier's instructions, and as required to meet the specimen requirements of the testing facility. Collection personnel shall not use collection materials after their expiration date. Collection personnel shall not re-use a blood extraction device.

(b) **Collection control.** Chain of custody standardized forms shall be properly executed by authorized collection site personnel upon collection of specimens. Handling and transportation of blood specimens from one (1) authorized individual or place to another shall always be accomplished through chain of custody

procedures. Every effort shall be made to minimize the number of persons handling specimens.

(c) **Transportation to the testing facility.** Collection site personnel shall arrange to transport the collected specimens to the alcohol testing facility. The specimens shall be placed in containers designed to minimize the possibility of damage during transport, e.g., specimen boxes or padded mailers; and those containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the tube, the collection site supervisor shall sign and enter the date specimens were sealed in the container for transfer. The collection site personnel shall ensure that the chain of custody documentation is placed in each container sealed for transfer to the alcohol testing facility.

(d) **Methods of analysis and result reporting.** The alcohol testing facility shall analyze an unopened sample for its alcohol concentration using gas chromatography. If the result of this analysis is an alcohol concentration of less than 0.02, the alcohol testing facility shall transmit the test result to the employer as negative. If the alcohol concentration is 0.02 or greater, the alcohol testing facility shall transmit the quantitative result to the Review Officer. One (1) sample shall remain unopened and refrigerated at two (2) to eight (8) degrees centigrade for at least one (1) year for further confirmation or the challenge of results by the employee. The alcohol testing facility shall transmit the results of alcohol confirmation tests to the employer in a confidential manner, and the employer shall receive and store the information so as to ensure that confidentiality is maintained.

[**Source:** Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95; Amended at 16 Ok Reg 2514, eff 6-25-99]

### **310:638-7-8. Rehabilitation/post-rehabilitation urine alcohol testing**

(a) **Criteria for urine alcohol testing.** Urine shall be considered an appropriate specimen for alcohol testing only when monitoring an employee's compliance with program requirements during the course of a substance abuse rehabilitation program and for a defined time period after completion of such a substance abuse rehabilitation program. The period of time an employee shall be subject to urine alcohol testing after completion of a substance abuse rehabilitation program shall be specified by the employer's written policy or as part of a written agreement between employer and employee. Urine shall not be considered an appropriate specimen for alcohol testing under any other conditions.

(b) **Cutoff levels for urine alcohol testing.** A urine alcohol concentration of 0.02 or greater shall be considered a positive initial test for alcohol. A urine alcohol concentration of 0.02 or greater shall be considered a positive confirmation test for

alcohol.

(c) **Urine specimen collection procedures.** Urine for rehabilitation/post-rehabilitation alcohol testing shall be collected as required for urine drug testing as described at OAC 310:638-1-8 by collection site personnel who meet the qualifications and training requirements at OAC 310:638-1-10.

(d) **Urine alcohol tests.**

(1) All initial urine alcohol screening tests shall be performed using gas chromatography or an enzyme assay which meets the requirements of the United States Food and Drug Administration for commercial distribution or another approved screening procedure. A test performed on urine and analyzed by gas chromatography shall be considered a confirmed urine alcohol test.

(2) All specimens identified as positive on the initial test shall be confirmed using gas chromatography, or an equivalent accepted method of equal or greater accuracy approved by the Commissioner of Health. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the testing facility record as "greater than the highest standard curve value."

(3) If the urine alcohol testing facility is not certified for forensic urine drug testing by the United States Department of Health and Human Services or accredited for forensic urine drug testing by the College of American Pathologists the urine alcohol testing facility shall meet the requirements at OAC 310:638-5-1 through OAC 310:638-5-9 for drug screen testing facilities with the exception of OAC 310:638-5-4(a)(1) for initial urine alcohol testing.

[**Source:** Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

**310:638-7-9. Internal review and certification of results**

(a) The testing facility shall report positive test results to the employer's Review Officer within an average of five (5) working days after receipt of the specimen by the testing facility. Before any test result is reported, including the results of initial tests, confirmatory tests, or quality control data, it shall be reviewed and the test certified as an accurate report by the responsible individual. The report shall quantify the concentration of alcohol (ethanol), whether positive or negative, the cutoff, the specimen number assigned by the employer, and the testing facility specimen identification number.

(b) The testing facility shall report as negative all specimens which are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported as positive.

(c) The Review Officer shall not disclose quantitation of test results to the employer but shall report only whether the test was positive or negative.

(d) The testing facility may transmit results to the Review Officer by electronic means, i.e., teleprinters, facsimile, or computer, in a manner designed to ensure confidentiality of the information. Results shall not be provided verbally by telephone. The testing facility shall ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(e) The testing facility shall send to the Review Officer positive alcohol test results, which shall be signed by the individual responsible for the day-to-day management of the testing facility or the individual responsible for attesting to the validity of the test reports.

(f) All results reported to the employer shall be by the same source.

[**Source:** Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

### **310:638-7-10. Proficiency testing**

#### **(a) Enrollment and performance.**

(1) The testing facility performing blood and/or urine alcohol testing shall enroll in and demonstrate satisfactory performance in an approved proficiency testing program for the blood and/or urine alcohol testing method(s) it performs.

(2) The testing facility performing blood and/or urine alcohol testing shall satisfactorily perform at least one (1) proficiency testing event prior to initial licensure and demonstrate continued satisfactory performance to maintain licensure.

(3) The testing facility performing blood and/or urine alcohol testing shall authorize the proficiency testing service to send results to the Oklahoma State Department of Health for review. The testing facility shall maintain records which shall document the handling, processing and examination of all proficiency testing samples for at least two (2) years from the date of testing.

(4) The testing facility performing blood and/or urine alcohol testing shall ensure that proficiency testing samples are analyzed at least three (3) times each year using the same techniques as those employed for screening unknown specimens.

(5) The proficiency testing samples shall be included with the routine sample run and tested with the same frequency as unknown samples by the individuals responsible for testing unknown specimens.

(6) The testing facility performing blood and/or urine alcohol testing shall not engage in discussions or communications concerning proficiency testing results with other testing facilities nor shall they send proficiency testing samples or portions of the samples to another testing facility for analysis.

#### **(b) Satisfactory performance.**

(1) The testing facility performing blood and/or urine alcohol

testing shall maintain an overall testing event score of at least eighty (80) percent for proficiency testing performance to be considered satisfactory.

(2) Failure to participate in a proficiency testing event shall result in a score of zero (0) percent for the testing event.

(c) **Unsuccessful performance.** Failure to achieve satisfactory performance in two (2) consecutive testing events, or two (2) of three (3) consecutive testing events, shall be determined to be unsuccessful performance.

[**Source:** Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]

### **310:638-7-11. Maintenance of records**

(a) **EBTs and BATs.** Each alcohol testing facility or its agent shall maintain the following records for at least two (2) years:

(1) Records of the inspection and maintenance of each EBT used in employee testing;

(2) Documentation of the alcohol testing facility's compliance with the QAP for each EBT it uses for alcohol testing;

(3) Records of the training and proficiency testing of each BAT used in employee testing;

(4) Records of tests performed. Records shall include copies of chain of custody forms and test results. These records shall be maintained in a confidential manner secured from unauthorized review.

(b) **Other screening and confirmatory testing.** Each alcohol testing facility or its agent shall maintain the following records for at least two (2) years:

(1) Records of the inspection and maintenance of each device/instrument used in employee testing;

(2) Records of proficiency testing results;

(3) Records of tests performed, including log books, copies of chain of custody forms, and test reports. These records shall be maintained in a confidential manner secured from unauthorized review.

(c) **Calibration records.** Each alcohol testing facility or its agent shall maintain for at least five (5) years records pertaining to the calibration of each device/instrument used in alcohol testing, including records of the results of external EBT calibration checks.

[**Source:** Added at 12 Ok Reg 517, eff 12-12-94 (emergency); Added at 12 Ok Reg 3069, eff 7-27-95]