

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

RULEMAKING ACTION:

Notice of proposed PERMANENT rulemaking.

PROPOSED RULES:

Subchapter 5. Drug Screen Testing Facilities

Section 310:638-5-2. Personnel [AMENDED]

SUMMARY:

An amendment is provided to update the minimum personnel qualifications of the Director of Drug Screen Testing Facilities. This action will expand eligibility requirements for this role to allow for varied education, experience, and professional certifications.

AUTHORITY:

Commissioner of Health, Title 63 O.S. Section 1-104.

COMMENT PERIOD:

February 3, 2020 through March 7, 2020. Interested persons may informally discuss the proposed rules with the contact person identified below; or may, through March 7, 2020, submit written comment to the contact person identified below, or may, at the hearing, ask to present written or oral views.

PUBLIC HEARING:

Pursuant to 75 O.S. Section 303(A), the public hearing for the proposed rulemaking in this chapter shall be on March 6, 2020, at the Oklahoma State Department of Health, 1000 Northeast Tenth Street, Oklahoma City, OK 73117-1207, in room 1102 from 9AM to noon. The alternate date and time in the event of an office closure due to inclement weather is March 10, 2020, in room 1102, from 9AM to noon. Those wishing to present oral comments should be present at that time to register to speak. The hearing will close at the conclusion of those registering to speak. Interested persons may attend for the purpose of submitting data, views or concerns, orally or in writing, about the rule proposal described and summarized in this Notice.

REQUESTS FOR COMMENTS FROM BUSINESS ENTITIES:

Business entities affected by these proposed rules are requested to provide the agency with information, in dollar amounts if possible, on the increase in the level of direct costs such as fees, and indirect costs such as reporting, recordkeeping, equipment, construction, labor, professional services, revenue loss, or other costs expected to be incurred by a particular entity due to compliance with the proposed rule. Business entities may submit this information in writing through March 7, 2020, to the contact person identified below.

COPIES OF PROPOSED RULES:

The proposed rules may be obtained for review from the contact person identified below or via the agency website at www.ok.gov/health.

RULE IMPACT STATEMENT:

Pursuant to 75 O.S., Section 303(D), a rule impact statement is available through the contact person identified below or via the agency website at www.ok.gov/health.

CONTACT PERSONS:

Kim Bailey, General Counsel, Oklahoma State Department of Health, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207; phone (405) 271-6017, e-mail KimB@health.ok.gov or Audrey C. Talley, Rule Liaison, Oklahoma State Department of Health, 1000 N. E. 10th Street, Oklahoma City, OK 73117-1207, phone (405) 271-9444 ext.56535, e-mail AudreyT@health.ok.gov.

INITIAL RULE IMPACT STATEMENT

(This document may be revised based on comment received during the public comment period.)

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

1. **DESCRIPTION:**
An amendment is provided at Section 310:638-5-2 to update the minimum personnel qualifications of the Director of Drug Screen Testing Facilities. This action will expand eligibility requirements for this role to allow for varied education, experience, and professional certifications.
2. **DESCRIPTION OF PERSONS AFFECTED AND COST IMPACT RESPONSE**
Business owners may be affected by this change.
3. **DESCRIPTION OF PERSONS BENEFITING, VALUE OF BENEFIT AND EXPECTED HEALTH OUTCOMES:**
Employers and residents of Oklahoma may experience increased access to workplace drug and alcohol testing facilities due to expanded eligibility requirements of the Director, which is a required role in these licensed facilities.
4. **ECONOMIC IMPACT, COST OF COMPLIANCE AND FEE CHANGES:**
No economic impact is expected. The cost of compliance remains the same. No fee changes are included in this amendment.
5. **COST AND BENEFITS OF IMPLEMENTATION AND ENFORCEMENT TO THE AGENCY:**
No cost impact is expected for the agency as this will not require any additional efforts by the agency.
6. **IMPACT ON POLITICAL SUBDIVISIONS:**
No impact is expected on political subdivisions from either proposed change.
7. **ADVERSE EFFECT ON SMALL BUSINESS:**
Small business may experience a positive effect if the expanded requirements for this position allow for lower personnel/business expense.
8. **EFFORTS TO MINIMIZE COSTS OF RULE:**
No less costly means are currently identified from either proposed change.
9. **EFFECT ON PUBLIC HEALTH AND SAFETY:**
No effect on public health is expected as a result of this rule change
10. **DETRIMENTAL EFFECTS ON PUBLIC HEALTH AND SAFETY WITHOUT ADOPTION:**
No detrimental effects on public health and safety would be experienced without adoption of this rule.
11. **PREPARATION AND MODIFICATION DATES:**
This rule impact statement was prepared on Thursday, December 12, 2019.

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

SUBCHAPTER 5. DRUG SCREEN TESTING FACILITIES

310:638-5-2. Personnel [AMENDED]

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.~~

(A) A bachelor's degree from an accredited institution in the chemical, biological, or physical sciences, or a medical laboratory science, and two (2) or more years of full-time drug testing experience; or

(B) A bachelor's degree from an accredited institution; and four (4) or more years of full-time drug testing experience; or

(C) An associate's degree from an accredited institution in the chemical, biological, or physical sciences or a medical laboratory science, and three (3) 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.