

40:15-1-1. Purpose

The rules in this Chapter concern approval and regulation by the Board of forensic alcohol laboratories, forensic drug laboratories, and other facilities involved in tests for alcohol and other intoxicating substances under the provisions of 47 O.S., Sections 751-761 and 3 O.S., Section 303 and 63 O.S., Section 4210A. They include qualifications and requirements for initial issuance and renewal of permits for such entities.

[Source: Amended at 14 Ok Reg 1525, eff 7-1-97]

40:15-1-2. Forensic alcohol analysis laboratories

(a) **Initial approval.** Any laboratory in which analysis for alcohol of specimens of blood, hereafter termed "forensic alcohol analysis," is performed under the provisions of Title 47 or Title 3 or Title 63, Oklahoma Statutes, shall possess at least the following qualifications and shall meet the following requirements. Any laboratory complying with such qualifications and requirements shall be deemed by this Board to be a Forensic Alcohol Laboratory approved by the Board of Tests for Alcohol and Drug Influence, and shall be entitled to issuance of a Forensic Alcohol Laboratory Permit. Such laboratory shall continue to satisfy such qualifications and requirements as a condition of the continued validity of such Permit.

(1) **Qualifications.** Qualifications for forensic alcohol analysis laboratories (initial permits) are as follows:

(A) Location within the State of Oklahoma.

(B) Possession of all current and valid Federal, State, and local licenses and permits required to engage in the activities and operations carried out by or in the laboratory, and compliance with all current Federal, State, and local requirements for such activities and operations.

(C) The laboratory shall be at least one (1) of the following:

(i) A clinical laboratory located within and operated and controlled by an institution which is currently licensed by the Oklahoma State Department of Health as a general hospital, and which is currently accredited as a general hospital by the Joint Commission on Accreditation of Healthcare Organizations. Such clinical laboratory shall be directed by a qualified doctoral-level director.

(ii) A clinical laboratory which is currently Federally licensed and/or approved under the implementing Federal regulations applicable to laboratories pursuant to the Federal Clinical Laboratory Improvement Amendments of 1988 (P.L. No. 100-578) for the performance of clinical chemistry and/or toxicology procedures, Title 42, Part 405 et al., Code of Federal Regulations, adopted in this Section by reference. Such clinical laboratory shall be directed by a qualified doctoral-level director.

(iii) A central or branch forensic laboratory operated and controlled by the Oklahoma State Bureau of Investigation.

(iv) A forensic laboratory operated and controlled by a county or municipal law enforcement agency.

(v) The Toxicology/Forensic Science Laboratories of The University of Oklahoma Health Sciences Center.

(D) The laboratory shall regularly employ or have on its permanent staff at least one (1) person holding a currently valid Forensic Alcohol Analysis Permit issued by the Board of Tests for Alcohol and Drug Influence.

(E) The laboratory shall have space, facilities, equipment, and apparatus adequate and appropriate for the performance of forensic alcohol analysis.

(2) **Requirements.** Requirements for forensic alcohol analysis laboratories (initial permits) are as follows:

- (A) Submission of a properly completed application form for Initial Approval, obtainable from the Board, together with all supporting documentation specified therein.
- (B) Maintenance of an adequate and appropriate quality assurance program and activities in forensic alcohol analysis, meeting nationally-recognized standards.
- (C) Regular and satisfactory participation and performance in any program of proficiency testing in forensic alcohol analysis conducted by or on behalf of the Board of Tests for Alcohol and Drug Influence, or required by the Board.
- (D) Regular and satisfactory participation and performance in any program of proficiency testing in clinical chemistry or toxicology in which the laboratory is voluntarily enrolled or required to be enrolled as a condition of Federal or state licensure or approval.

(b) **Renewal of approval.** Laboratories which have been approved by the Board of Tests for Alcohol and Drug Influence for performance of forensic alcohol analysis and which hold a current valid Forensic Alcohol Laboratory Permit shall be eligible for renewal of such Permit upon satisfying the following qualifications and requirements. Such laboratory shall continue to satisfy such qualifications and requirements as a condition of the continued validity of such Permit.

(1) **Qualifications.** Qualifications for forensic alcohol analysis laboratories (renewal permits) are as follows:

(A) Possession of all qualifications stipulated in this Rule for Initial Approval as a Forensic Alcohol Laboratory.

(B) Possession of a valid Forensic Alcohol Laboratory Permit issued by authority of the Board of Tests for Alcohol and Drug Influence within the preceding twelve (12) months upon compliance with the Qualifications and Requirements then in force for, Initial Approval or for Renewal of Approval as a Forensic Alcohol Laboratory.

(2) **Requirements.** Requirements for forensic alcohol laboratories (renewal permits) are as follows:

(A) Submission of a properly completed application form for Renewal of Approval, obtainable from this Board, together with all supporting documentation specified therein.

(B) Continued satisfactory participation and performance in the quality assurance and proficiency testing programs and activities stipulated in this Section as requirements for Initial Approval.

(c) **General conditions of approval.** The following general and continued conditions of Approval apply to every Forensic Alcohol Laboratory.

(1) Every such Laboratory may be inspected periodically, during its normal working hours, by the State Director of Tests for Alcohol and Drug Influence or by the State Director's duly authorized representative(s). Such inspection may include examination of the Laboratory's pertinent files and records, as well as its facilities.

(2) Every such Laboratory shall maintain a current file of all methods and procedures employed in such Laboratory for forensic alcohol analysis.

(3) Every such Laboratory shall maintain and retain at least the following records for a period of at least three (3) years from the date of origin of such records:

(A) An up-to-date record of persons in its employ or on its staff who are or were engaged in the performance of forensic alcohol analysis. Such records shall include, at least, the inclusive employment dates, qualifications of each such person, and any continuing education or training pertinent to forensic alcohol analysis received by each such person within or outside of the Laboratory.

(B) Records of specimens received by and subjected to forensic alcohol analysis within the Laboratory under the provisions of Title 47 or Title 3 or Title 63, Oklahoma Statutes, including all pertinent dates and times, identification of such specimens, results obtained and reported, and the identity of the person(s) who performed each such analysis.

(C) Records of the internal and external quality assurance programs and proficiency testing activities and results, in or pertinent to forensic alcohol analysis, in which the Laboratory participates or has participated.

(4) Every such Laboratory shall be operated and shall perform its forensic alcohol activities in substantial compliance with applicable nationally-recognized standards of good laboratory practice.

(5) In every such Laboratory, forensic alcohol analysis shall be performed only by methods and procedures approved by the Board of Tests for Alcohol and Drug Influence, and only by persons holding valid Forensic Alcohol Analysis Permits.

(d) **Period of validity.** Forensic Alcohol Laboratory Approval and Forensic Alcohol Laboratory Permits shall be valid for one (1) year from the date of Approval or the date of Permit issuance, respectively, and shall be subject to earlier suspension, termination, or revocation at the discretion of the Board.

[Source: Amended at 14 Ok Reg 1525, eff 7-1-97; Amended at 27 Ok Reg 2659, eff 8-26-10]

40:15-1-3. Forensic drug analysis laboratories

(a) **Initial approval.** Any laboratory in which analysis for drugs and other intoxicating substances (as defined in 47 O.S., Section 751) of specimens of blood, hereafter termed "forensic drug analysis," is performed under the provisions of Title 47 or Title 3 or Title 63, Oklahoma Statutes, shall possess at least the following qualifications and shall meet the following requirements. Any laboratory complying with such qualifications and requirements shall be deemed by this Board to be a Forensic Drug Laboratory approved by the Board of Tests for Alcohol and Drug Influence, and shall be entitled to issuance of a Forensic Drug Laboratory Permit. Such Laboratory shall continue to satisfy such qualifications and requirements as a condition of the continued validity of such Permit.

(1) **Qualifications.** Qualifications for forensic drug analysis laboratories (initial permits) are as follows:

(A) Location within the State of Oklahoma.

(B) Possession of all current and valid Federal, State, and local licenses and permits required to engage in the activities and operations carried out by or in the laboratory, and compliance with all current Federal, State, and local requirements for such activities and operations.

(C) The laboratory shall be at least one (1) of the following:

(i) A clinical laboratory located within and operated and controlled by an institution which is currently licensed by the Oklahoma State Department of Health as a general hospital, and which is currently accredited as a general hospital by the Joint Commission on Accreditation of Healthcare Organizations. Such clinical laboratory shall be directed by a qualified doctoral-level director.

(ii) A clinical laboratory which is currently Federally licensed and/or approved under the implementing Federal regulations applicable to laboratories pursuant to the Federal Clinical Laboratory Improvement Amendments of 1988 (P.L. No. 100-578), for the performance of clinical chemistry and/or toxicology procedures, Title 42, Part 405 et al., Code of Federal Regulations, adopted in this Section by reference. Such clinical laboratory shall be directed by a qualified doctoral-level director.

(iii) A central or branch forensic laboratory operated and controlled by the Oklahoma State Bureau of Investigation.

(iv) A forensic laboratory operated and controlled by a county or municipal law enforcement agency.

(v) The Toxicology/Forensic Science Laboratories of The University of Oklahoma Health Sciences Center.

(D) The laboratory shall regularly employ or have on its permanent staff as least one (1) person holding a currently valid Forensic Drug Analysis Permit issued by the Board of Tests for Alcohol and Drug Influence.

(E) The laboratory shall have space, facilities, equipment, and apparatus adequate and appropriate for the performance of forensic drug analysis.

(2) **Requirements.** Requirements for forensic drug analysis laboratories (initial permits) are as follows:

(A) Submission of a properly completed application form for Initial Approval, obtainable from the Board, together with all supporting documentation specified therein.

(B) Maintenance of an adequate and appropriate quality assurance program and activities in forensic drug analysis, meeting nationally-recognized standards.

(C) Regular and satisfactory participation and performance in any program of proficiency testing in forensic drug analysis conducted by or on behalf of the Board of Tests for Alcohol and Drug Influence, or required by the Board.

(D) Regular and satisfactory participation and performance in any program of proficiency testing in clinical chemistry or toxicology in which the laboratory is voluntarily enrolled or required to be enrolled as a condition of Federal or state licensure or approval.

(b) **Renewal of approval.** Laboratories which have been approved by the Board of Tests for Alcohol and Drug Influence for performance of forensic drug analysis and which hold a current valid Forensic Drug Laboratory Permit shall be eligible for renewal of such Permit upon satisfying the following qualifications and requirements as a condition of the continued validity of such Permit.

(1) **Qualifications.** Qualifications for forensic drug laboratories (renewal permits) are as follows:

(A) Possession of all qualifications stipulated in this Rule for Initial Approval as a Forensic Drug Laboratory.

(B) Possession of a valid Forensic Drug Laboratory Permit issued by authority of the Board of Tests for Alcohol and Drug Influence within the preceding twelve (12) months upon compliance with the Qualifications and Requirements then in force for Initial Approval or for Renewal of Approval as a Forensic Drug Laboratory.

(2) **Requirements.** Requirements for forensic drug analysis laboratories (renewal permits) are as follows:

(A) Submission of a properly completed application form for Renewal of Approval, obtainable from the Board, together with all supporting documentation specified therein.

(B) Continued satisfactory participation and performance in the quality assurance and proficiency testing programs and activities stipulated in this Section as requirements for Initial Approval.

(c) **General conditions of approval.** The following general and continued conditions of Approval apply to every Forensic Drug Laboratory.

(1) Every such Laboratory may be inspected periodically, during its normal hours, by the State Director of Tests for Alcohol and Drug Influence or by the State Director's duly authorized representative(s). Such inspection may include examination of the Laboratory's pertinent files and records, as well as its facilities.

(2) Every such Laboratory shall maintain a current file of all methods and procedures employed in such Laboratory for forensic drug analysis.

(3) Every such Laboratory shall maintain and retain at least the following records for a period of at least three (3) years from the date of origin of such records:

(A) An up-to-date record of persons in its employ or on its staff who are or were engaged in the performance of forensic drug analysis. Such records shall include, at least, the inclusive employment

dates, qualifications of each such person, and any continuing education or training pertinent to forensic drug analysis received by each such person within or outside of the Laboratory.

(B) Records of specimens received by and subjected to forensic drug analysis within the Laboratory under the provisions of Title 47 or Title 3 or Title 63, Oklahoma Statutes, including all pertinent dates and times, identification of such specimens, results obtained and reported, and the identity of the person(s) who performed each analysis.

(C) Records of the internal and external quality assurance programs and proficiency testing activities and results, in or pertinent to forensic drug analysis,

(4) Every such Laboratory shall be operated and shall perform its forensic drug activities in substantial compliance with applicable nationally-recognized standards of good laboratory practice.

(5) In every such Laboratory, forensic drug analysis shall be performed only by methods and procedures approved by the Board of Tests for Alcohol and Drug Influence, and only by persons holding valid Forensic Drug Analysis Permits.

(d) **Period of validity.** Forensic Drug Laboratory Approval and Forensic Drug Laboratory Permits shall be valid for one (1) year from the date of Approval or the date of Permit issuance, respectively, and shall be subject to earlier suspension, termination, or revocation at the discretion of the Board.

[Source: Amended at 14 Ok Reg 1525, eff 7-1-97; Amended at 27 Ok Reg 2659, eff 8-26-10]