Kansas Administrative Regulations

Department of Health and Environment

Article 33.—Laboratories Performing Other Tests

28-33-12. General provisions.

(a) Definitions.

(1) "Department" means the department of health and environment.

(2) "Division" means the division of Kansas health and environmental laboratory.

(3) "Laboratory director" means the person responsible for the professional, administrative, organizational, and educational duties of a laboratory.

(4) "Laboratory supervisor" means the individual responsible for providing day-to-day supervision of testing personnel, including the proper performance of all laboratory procedures and reporting of test results.

(5) "Testing personnel" means individuals responsible for specimen processing, test performance, and reporting test results.

(6) "Test for controlled substance" means a procedure to evaluate a specimen for compounds identified in schedule I or II of the Kansas controlled substance act, K.S.A. 1996 Supp. 65-4105 and 65-4107.

(7) "Threshold" means a defined drug or metabolite concentration that is established at a level resulting in the following:

(A) a concentration at or above this level defines a positive result; and

(B) a concentration below this level defines a negative result.

(8) "Screening test" means a test designed to eliminate true negative specimens from further consideration. Threshold limits used for screening tests shall conform to the mandatory guidelines for federal workplace drug testing programs established by the substance abuse and mental health services administration of the department of health and human services in the federal register, volume 59, number 110, page 29921, published June 9, 1994.

(9) "Confirmatory test" means a mass spectrometry analytical procedure used to specifically identify the presence of a drug or drug metabolite. Threshold limits used for

confirmatory testing shall conform to the mandatory guidelines for federal workplace drug testing programs established by the substance abuse and mental health services administration of the department of health and human services in the federal register, volume 59, number 110, pages 29921-29922, published June 9, 1994.

(10) "Unsatisfactory performance" means a score for any analyte of less than 80% as determined by the proficiency testing provider.

(11) "Unsuccessful participation" means unsatisfactory performance for the same analyte in two consecutive or two out of three consecutive proficiency testing events.

(12) "CLIA" means the clinical laboratory improvement amendments of 1988, Public Law 100-578, as implemented by 42 CFR part 493, issued February 28, 1992, as amended and in effect on April 24, 1995.

(b) Approval procedure. (1) Except as provided in subsection (k), each laboratory located in Kansas seeking approval of the department to perform tests on biological specimens for controlled substances, as defined in schedule I and II of the Kansas controlled substance act, K.S.A. 1996 Supp. 65-4105 and 65-4107, shall be a laboratory that the division director or director's designee determines meets the requirements for certification under CLIA for the type and complexity of the tests being performed.

(2) (A) Except as set out in paragraph (C), each laboratory seeking approval to test biological specimens for the following drugs or their metabolites shall meet the requirements set out in paragraph (B):

(i) amphetamines;

(ii) cannabinoids or tetrahyrocannabinoids (THC);

(iii) cocaine;

(iv) opiates; and

(v) phencyclidine.

(B) In addition to meeting requirements for certification under CLIA, each laboratory seeking approval under paragraph (A) shall submit the following:

(i) a completed application on standard forms furnished by the division; and

(ii) documents demonstrating successful performance in one testing event using a proficiency testing program approved by the division.

(C) Any laboratory facility testing specimens for emergency diagnosis and treatment may test for drugs listed on schedule I or II of the Kansas controlled substance act, K.S.A. 1996 Supp. 65-4105 and 65-4107, without meeting the requirements of paragraph (B), if test results are used only for diagnosis and treatment.

(c) Upon receipt of a laboratory's application for approval, the laboratory shall be inspected by a representative of the division. The laboratory shall be evaluated to determine compliance using the following criteria.

(1) Screening test methods shall screen for the following five classes of drugs:

(A) amphetamines;

(B) cannabinoid or THC metabolites;

(C) cocaine metabolites;

(D) opiates; and

(E) phencyclidine.

(2) Each test procedure shall be performed in accordance with a written protocol. The protocol shall be approved by the laboratory director. The protocol shall require that a blank control containing no drug and a control fortified with a known analyte concentration greater than the threshold limit for each analyte be included with each batch of specimens tested. At least one fortified control shall be at or near the threshold cutoff. The protocol shall insure that carryover between specimens does not occur.

(3) A laboratory quality assurance program shall be developed and implemented. The program shall contain the following components:

(A) requirements for sample collection that adhere to the criteria of the division director or the director's designee, or a signed statement that the specimen was properly collected according to these criteria, if collection is at a location other than the laboratory performing the test;

(B) identification and chain of custody procedures for specimens;

(C) procedures for assuring the security of the testing area, test records, and test reports;

(D) confirmation procedures for all positive screening tests unless evidenced by documentation that the testing is performed for one of the following:

(i) medical purposes on a hospital inpatient or patient currently undergoing treatment in a hospital emergency room;

(ii) a specimen from an individual currently under treatment for substance abuse; or

(iii) a correctional facility solely for the purpose of internal management of persons as defined in regulations promulgated by the secretary of corrections;

(E) a policy stating that only confirmed positive results shall be reported as positive;

(F) procedures for an internal quality control program that monitors the accuracy and precision of laboratory performance;

(G) procedures for an instrument maintenance program that, at a minimum, conforms to the manufacturer's specifications;

(H) provision for retention of all confirmed positive specimens for at least one year;

(I) policies requiring disposal of all medical wastes in accordance with K.A.R. 28-29-27; and

(J) documentation of adherence to the foregoing policies and procedures.

(4) Equipment required by the test system shall meet the specifications of the test system's manufacturer.

(5) Reagents, controls, and any other required materials for the procedure being performed shall be available and shall be stored according to the manufacturer's specifications.

(d) During the inspection by the division, one or more testing personnel may be required to demonstrate performance of the procedure under consideration.

(e) Except as provided in subsection (k), each approved laboratory located in Kansas shall be inspected by the division biennially. A follow-up inspection of any approved laboratory may be conducted by the division at any time.

(f) Each laboratory performing tests for controlled substances shall have an individual serving as laboratory director who holds one of the following credentials:

(1) current licensure as a physician in the state where the laboratory is located, with additional training in pharmacology, toxicology, clinical pathology or forensic pathology; or

(2) an earned doctoral degree from an accredited institution in a chemical or biological science and at least two years of laboratory experience in chemistry or analytical toxicology.

(g) Each laboratory performing tests for controlled substances shall have an individual or individuals serving as a laboratory supervisor. Each laboratory supervisor shall hold one of the following credentials:

(1) an earned doctoral degree from an accredited institution in a chemical or biological science and at least two years of laboratory experience in chemistry or analytical toxicology; or

(2) an earned baccalaureate degree from an accredited institution in a chemical or biological science or medical technology and at least four years of experience in chemistry or analytical toxicology.

(h) Each laboratory performing tests for controlled substances shall have one or more individuals serving as testing personnel. Each individual serving as testing personnel shall hold one of the following credentials:

(1) an earned baccalaureate degree from an accredited institution in a chemical or biological science or medical technology;

(2) an earned associate degree from an accredited institution in a chemical or biological science or medical technology; or

(3) have achieved a satisfactory grade in the health and human services written clinical laboratory technologist examinations offered between March 7, 1975 and August 28, 1987 by the professional examination service.

(A) The laboratory director shall document that testing personnel performing tests have been adequately trained in each test procedure being performed.

(B) Records of educational credentials and training shall be maintained for each individual qualified under subsections (f), (g), or (h) of this regulation.

(i) One copy of each test requisition, test record, and test report shall be maintained in a readily retrievable manner by the laboratory for a period of two years.

(j) Proficiency program. Each laboratory shall enroll and participate in an approved external proficiency testing program for opiates, cocaine, cannabinoids or THC,

amphetamines, and phencyclidine. A list of approved proficiency testing programs shall be available from the division.

(1) The results of each laboratory's performance in the proficiency testing program shall be sent directly from the approved program provider to the division.

(2) The approval for any laboratory may be revoked by the director of the division or the director's designee when the laboratory meets the criteria for unsuccessful participation in an approved external proficiency testing program.

(3) Each laboratory shall undertake an investigation and institute corrective action for all incorrect responses identified in the proficiency testing program. The laboratory shall maintain documentation of the investigation and corrective action for a period of two years.

(k) (1) Any laboratory that is not located in the state of Kansas may apply for approval. Such a laboratory shall be added to the list of approved laboratories if it meets the following conditions.

(A) The laboratory shall be certified or approved by a federal, state, or independent agency having standards that are determined by the director of the division, or the director's designee, to be generally equivalent or more stringent than the standards set out in subsections (b) through (j) of this regulation.

(B) The laboratory seeking approval shall submit the following documentation for inspection by the department:

(i) a completed application on standard forms furnished by the division;

(ii) a report of the most recently completed onsite inspection by the approving agency addressing subsections (c) through (e);

(iii) proficiency testing results from the most recently completed proficiency challenge;

(iv) documents demonstrating that the laboratory personnel meet the qualifications set forth in subsections (f), (g), and (h); and

(v) any other documentation deemed necessary by the division.

(2) Any laboratory located in Kansas may seek approval under this subsection in lieu of following approval procedures in subsection (b) and meeting the on-site inspection requirements in subsections (c) through (e).

(l) List of approved laboratories. A current list of approved laboratories shall be maintained by the division. Each laboratory shall be approved biennially.

(m) Removal from approved list.

(1) A laboratory shall be removed from the approved list after voluntarily terminating or after notice and an opportunity for a hearing. All orders of revocation shall become final 15 days after service unless an appeal is filed in writing. All appeals shall be conducted according to the Kansas administrative procedure act, K.S.A. 77-501 et seq. and any amendments.

(2) Notification of removal of a laboratory from the approved list shall be made by certified mail.

(Authorized by K.S.A. 1996 Supp. 65-1,107; implementing K.S.A. 1996 Supp. 65-1,107, 65-1,108, and 65-1,108a; effective Oct. 2, 1989; amended May 3, 1996; amended Oct. 10, 1997.)