

Subpart F—Licensee Testing Facilities

§ 26.121 Purpose.

This subpart contains requirements for facilities that are operated by licensees and other entities who are subject to this part to perform initial tests of urine specimens for validity, drugs, and drug metabolites.

§ 26.123 Testing facility capabilities.

Each licensee testing facility shall have the capability, at the same premises, to perform either validity screening tests or initial validity tests or both, and initial drug tests for each drug and drug metabolite for which testing is conducted.

§ 26.125 Licensee testing facility personnel.

(a) Each licensee testing facility shall have one or more individuals who are responsible for day-to-day operations and supervision of the testing technicians. The designated individual(s) shall have at least a bachelor's degree in the chemical or biological sciences, medical technology, or equivalent. He or she shall also have training and experience in the theory and practice of the procedures used in the licensee testing facility, and a thorough understanding of quality control practices and procedures, the review, interpretation, and reporting of test results, and proper remedial actions to be taken in response to detection of abnormal test or quality control results.

(b) Other technicians or non-technical staff shall have the necessary training and skills for their assigned tasks. Technicians who perform urine specimen testing shall have documented proficiency in operating the testing instruments and devices used at the licensee testing facility.

(c) Licensee testing facility personnel files must include each individual's resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports, if any; results of tests that establish employee competency for the position he or she holds, including, but not limited to,

certification that personnel are proficient in conducting testing in accordance with manufacturer's most recent instructions for the instruments and devices used and tests for color blindness; and appropriate data to support determinations of honesty and integrity required by this part.

§ 26.127 Procedures.

(a) Licensee testing facilities shall develop, implement, and maintain clear and well-documented procedures for accession, shipment, and testing of urine specimens.

(b) Written chain-of-custody procedures must describe the methods to be used to maintain control and accountability of specimens from receipt through completion of testing and reporting of results, during storage and shipping to the HHS-certified laboratory, and continuing until final disposition of the specimens.

(c) Licensee testing facilities shall develop, implement, and maintain written standard operating procedures for each assay performed for drug and specimen validity testing. If a licensee testing facility performs validity screening tests, the licensee testing facility shall develop, implement, and maintain written standard operating procedures for each test. The procedures must include, but are not limited to, detailed descriptions of—

- (1) The principles of each test;
- (2) Preparation of reagents, standards, and controls;
- (3) Calibration procedures;
- (4) Derivation of results;
- (5) Linearity of the methods;
- (6) Sensitivity of the methods;
- (7) Cutoff values;
- (8) Mechanisms for reporting results;
- (9) Controls;
- (10) Criteria for unacceptable specimens and results;
- (11) Reagents and expiration dates; and
- (12) References.

(d) Licensee testing facilities shall develop, implement, and maintain written procedures for instrument and test setup and normal operation, including the following:

- (1) A schedule for checking critical operating characteristics for all instruments and validity screening tests;