(c) HHS-certified laboratories shall develop, implement, and maintain a written manual of standard operating procedures for each assay performed for licensees and other entities for drug and specimen validity testing. 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 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) HHS-certified laboratories shall develop, implement, and maintain written procedures for instrument setup and normal operation, including the following:

(1) A schedule for checking critical operating characteristics for all instruments;

(2) Tolerance limits for acceptable function checks; and

(3) Instructions for major troubleshooting and repair.

(e) HHS-certified laboratories shall develop, implement, and maintain written procedures for remedial actions to be taken when errors are detected or systems are out of acceptable limits.

The laboratory shall maintain documentation that its personnel follow these procedures and take all necessary corrective actions. In addition, the laboratory shall have systems in place to verify all stages of testing and reporting and to document the verification.

§ 26.159 Assuring specimen security, chain of custody, and preservation.

(a) The HHS-certified laboratories performing services for licensees and other entities under this part shall be secure at all times. Each laboratory 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 the laboratory processes or areas where records are stored. Access to these secured areas must be limited to specially authorized individuals whose authorization is documented. All authorized visitors, and maintenance and service personnel, shall be escorted at all times in the laboratory, except personnel who are authorized to conduct inspections and audits on behalf of licensees, other entities, the NRC, or the HHS Secretary, and emergency personnel (including but not limited to firefighters and medical rescue teams).

(b) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and shall compare information on specimen bottles within each package to the information on the accompanying custody-and-control forms.

(1) Any direct evidence of tampering or discrepancies in the information on the specimen bottles and the custody-and-control forms attached to the shipment must be reported to the licensee or other entity within 24 hours of the discovery and must be noted on the custody-and-control forms for each specimen contained in the package. When notified, the licensee or other entity shall ensure that an investigation is initiated to determine whether tampering has occurred.

(i) If the investigation determines that tampering has occurred, the licensee or other entity shall ensure that corrective actions are taken.

(ii) If the licensee or other entity has reason to question the integrity and identity of the specimens, the specimens may not be tested and the licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, if the licensee testing facility has retained the specimen in Bottle B, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

(2) The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen:

(i) The custody-and-control form does not contain information to identify the specimen collector and the collection site cannot provide conclusive evidence of the collector's identity;

(ii) The identification numbers on the specimen bottle seal(s) do not match the identification numbers on the custody-and-control form;

(iii) A specimen bottle seal is broken or shows evidence of tampering and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist;

(iv) The specimen appears to have leaked out of its sealed bottle and there is less than 15 mL remaining, and an intact specimen, as specified in paragraph (b)(1)(ii) of this section, does not exist; or

(v) As required under § 26.165(f)(2).

(c) The HHS-certified laboratory shall retain specimen bottles within the laboratory's accession area until all analyses have been completed. Laboratory personnel shall use aliquots and laboratory internal custody-and-control forms when conducting initial and confirmatory tests. The original specimen and the original custody-and-control form must remain in secure storage.

(d) The laboratory's internal custody-and-control form must allow for identification of the donor, and documentation of the testing process and transfers of custody of the specimen.

(e) Each time a specimen is handled or transferred within the laboratory, laboratory personnel shall document the date and purpose on the custody-and-control form and every individual in the chain shall be identified. Authorized technicians are responsible for each urine specimen or aliquot in their possession and shall sign and complete custody-and-control forms for those specimens or aliquots as they are received.

(f) If a specimen is to be transferred to a second HHS-certified laboratory, laboratory personnel shall ensure that a copy of the custody-and-control form is packaged with the aliquot of a single specimen or Bottle B of a split specimen, as appropriate. Sealed and labeled specimen bottles and aliquots, with their associated custody-and-control forms, being transferred from one laboratory to another must be placed in a second, tamper-evident shipping container designed to minimize the possibility of damage to the specimen during shipment (e.g., specimen boxes, padded mailers, or bulk insulated shipping containers with that capability) so that the contents of the shipping containers are inaccessible without breaking a tamper-evident seal.

(g) Couriers, express carriers, and postal service personnel do not have direct access to the custody-and-control forms or the specimen bottles. Therefore, such personnel are not required to document chain of custody on the custody-and-control forms during transit. Custody accountability of the shipping containers during shipment must be maintained by a tracking system provided by the courier, express carrier, or postal service.

(h) Specimens that do not receive an initial test within 7 days of arrival at the laboratory must be placed in secure refrigeration units for short-term storage. Temperatures may not exceed 6 °C (42.8 °F). The laboratory shall ensure proper storage conditions in the event of a prolonged power failure.

(i) Long-term frozen storage at a temperature of −20 °C (−68 °F) or less ensures that positive, adulterated, substituted, and invalid urine specimens and Bottle B of a split specimen will be available for any necessary retests. Unless otherwise authorized in writing by the licensee or other entity, laboratories shall retain and place in properly secured long-term frozen storage all specimens reported as positive, adulterated, substituted, or invalid. At a minimum, such specimens must be stored for 1 year. Within this 1-year period, a licensee, other entity, or the NRC may ask the laboratory to retain the specimen for an additional period of time. If no retention request is received, the laboratory may discard the specimen after the end of 1 year. However, the laboratory shall retain any specimens under review or legal challenge until they are no longer needed.

(j) The laboratory shall discard a valid specimen that tests negative on initial or confirmatory drug tests or

may pool such specimens for use in the laboratory's internal quality control program after certifying that the specimens are negative and valid. The laboratory may not retain any information linking donors to specimens that are pooled for use in the internal quality control program.

§ 26.161 Cutoff levels for validity testing.

(a) *Validity test results.* Each validity test result for a specimen that the HHS-certified laboratory reports to the MRO as adulterated, substituted, dilute, or invalid must be based on performing an initial validity test on one aliquot and a confirmatory validity test on a second aliquot. Licensees and other entities shall ensure that the HHS-certified laboratory is capable of conducting, and conducts, confirmatory testing for at least one oxidizing adulterant and any other adulterants specified by the licensee's or other entity's testing program. If initial validity test results indicate that the specimen is valid under the criteria in paragraphs (c) through (f) of this section, the HHS-certified laboratory need not perform confirmatory validity testing of the specimen.

(b) *Initial validity testing.* The HHS-certified laboratory shall perform initial validity testing of each specimen as follows:

(1) Determine the creatinine concentration;

(2) Determine the specific gravity of every specimen for which the creatinine concentration is less than 20 mg/dL;

(3) Determine the pH;

(4) Perform one or more initial validity tests for oxidizing adulterants; and

(5) Perform additional validity tests, the choice of which depends on the observed indicators or characteristics below, when the following conditions are observed:

(i) Abnormal physical characteristics;

(ii) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (e.g., non-recovery of internal standards, unusual response); or

(iii) Possible unidentified interfering substance or adulterant.

(c) *Results indicating an adulterated specimen.* The laboratory shall report a specimen as adulterated when the specimen yields any one or more of the following validity testing results:

(1) The pH is less than 3, or equal to or greater than 11, using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(2) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(3) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the LOD of the confirmatory test on the second aliquot;

(4) The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents or a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) or a halogen colorimetric test (halogen concentration equal to or greater than the LOD) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOD of the confirmatory test on the second aliquot;

(5) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the specimen