

CHAPTER 59A-24 DRUG-FREE WORKPLACE STANDARDS

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59A-24.003 Definitions.

In addition to the definitions set forth in Section 112.0455(5), F.S., as used in this rule chapter the following terms shall mean:

- (1) "Agency" means the Agency for Health Care Administration.
- (2) "Aliquot" means a portion of a specimen used for testing.
- (3) "Approved Proficiency Testing Provider" means a private non-profit proficiency testing organization that meets the following requirements:
 - (a) Supplies a shipment of no less than 10 drug of abuse proficiency testing samples for screening and confirmation testing at least 3 times per year. Samples shall consist of a combination of negative specimens and a selection of positive specimens containing the drugs or metabolites of the substances listed in Section 112.0455(5)(a), F.S.
 - (b) Evaluates proficiency testing sample results using statistical methods based on results obtained from participant peer group comparisons.
 - (c) Provides no communication with the participant laboratory regarding the drug content of the samples prior to the issuance of the proficiency testing report.
 - (d) Provides explanatory information to assist the participant laboratory in the interpretation of the proficiency testing results.
- (4) "Collection Site" means a place owned, operated, or contracted by a laboratory licensed under this rule chapter, or a site prepared by a collector authorized under Section 112.0455, F.S., and Chapter 59A-24, F.A.C., where individuals present themselves for the purpose of providing a specimen or specimens to be analyzed for the presence of drugs.
- (5) "Collection Site Person" or "Collector" means a person who instructs and assists donors at a collection site and who collects or receives and makes an initial observation of the specimen provided by those donors. The laboratory is responsible to ensure that the collector(s) is trained to carry out his or her responsibilities under this rule chapter.
- (6) "Donor" means a job applicant or employee who present themselves to a collection site for the purpose of submitting to a drug test.
- (7) "Federal Workplace Drug Testing Programs" means the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs as contained in Volume 59, Number 110, of the Federal Register published June 9, 1994, and the criteria found in the National Laboratory Certification Program Guidance Document for Laboratories and Inspectors as published by the Substance Abuse and Mental Health Services Administration Center for Substance Abuse Prevention, August 29, 1994, each incorporated by reference herein.
- (8) "Forensic Toxicology Laboratory" or "Laboratory" means a place where examinations are performed on specimens taken from the human body to provide information regarding the presence or absence of drugs or their metabolites for the purpose of promoting a drug free workplace under the provisions of Section 112.0455, F.S.
- (9) "Medical Review Officer" or "MRO" means a licensed physician qualified under paragraphs 59A-24.008(1)(a)-(e), F.A.C., who evaluates a donor's test result, together with his or her medical history or any other biomedical information, and makes the final determination of the donor's test results.
- (10) "Prescription or Nonprescription Medication" means a drug or medication obtained pursuant to a prescription as defined by s. 893.02(17), F.S., or a medication that is authorized pursuant to federal or state law for general distribution and use without a prescription in the treatment of human diseases, ailments, or injuries.
- (11) "Reason to Believe" means a belief by the collection site person that a particular individual intends to alter or has altered or substituted a specimen. Reason to believe includes, for example:
 - (a) A urine specimen temperature falling outside the specified range of 90-100 degrees fahrenheit.
 - (b) Unusual urine color or signs of contaminants in the urine.
 - (c) A finding of contaminants on the individual.
 - (d) Unusual behavior or appearance by the individual.
- (12) "Peer reviewed literature" includes literature approved for publication.
- (13) "Run" or "batch" means an interval in which tests are performed within which the accuracy and precision of a testing system is expected to be stable. This interval shall not exceed 24 hours; nor shall it exceed the stability limits indicated by the instrument manufacturer.

(14) "Split sample" means a specimen that is divided into two separate containers, for the purpose of using one container for immediate testing and the other being tested at the donor's request if the first sample tested results in a confirmed positive test.

Specific Authority 112.0455(13)(a) FS. Law Implemented 112.0455 FS. History--New 3-15-90, Amended 6-28-91, Formerly 10E-18.003, Amended 5-1-96, 3-11-98.

59A-24.004 Drugs to be Tested/Body Specimens.

(1) Notwithstanding the definition of drug in Section 112.0455(5)(a), F.S., the only hallucinogen to be tested for is phencyclidine (PCP), the only synthetic narcotics to be tested for are methadone and propoxyphene, and there will be no designer drugs tested for until standard testing procedures are developed for such drugs.

(2) Body Specimens.

(a) Urine. Urine will be used for the initial test for all drugs except alcohol and for the confirmation for all drugs except alcohol.

(b) Blood. Blood will be used as the initial and confirmation specimen for alcohol.

Specific Authority 112.0455(13)(a) FS. Law Implemented 112.0455 FS. History--New 3-15-90, Amended 6-28-91, Formerly 10E-18.004, Amended 5-1-96.

59A-24.005 Collection Site and Specimen Collection Procedures.

(1) Designation of Collection Sites. For urine and blood specimen collection, each laboratory, that has a contract or agreement for testing services with an employer, shall provide collection sites under contract and training for collectors, or shall provide a trained collector to collect specimens for the employer at any time designated by the employer in his contract or agreement with the laboratory. The collector shall be responsible to the laboratory for implementing collection procedures and chain of custody procedures as designated in Chapter 59A-24, F.A.C. The laboratory shall provide to the collection site, or collector, specimen collection kits which, as applicable, shall contain chain of custody forms, as incorporated in subsection 59A-24.005(2), F.A.C., mailing boxes or containers, specimen identification labels, laboratory address labels, urine specimen bottles, external temperature strips, tamper-proof plastic sealable bags and forensic tamper-proof tape to seal the specimen container(s). Kits for alcohol testing must have a 7ml blood vial that contains an anticoagulant and a preservative of sodium fluoride. Employers who do not use hair testing for their drug-free workplace program shall not be required to maintain collection facilities and personnel as described in Section 112.0455(13)(b)3.a., F.S. Employers that choose to use hair as a specimen for testing shall meet the requirements found in Section 112.0455(13)(b)3.a., F.S.

(2) Chain of Custody Form and Procedures. Chain of custody refers to the methodology of documenting the tracking of specified materials or substances for the purpose of maintaining control and accountability from initial collection to final disposition of all such materials or substances and providing for accountability at each stage in handling, testing, storing and reporting of the test results. The agency chain of custody forms, AHCA Form 3170-5006 July 95; Drug Testing Chain of Custody for urine and AHCA Form 3170-5008, Sept. 97; Drug Testing Chain of Custody – Hair, incorporated by reference herein, shall be utilized for this purpose. These forms will be available from each laboratory licensed under these rules. Each laboratory shall be responsible for obtaining these forms from a vendor of their choosing. The agency shall provide one camera-ready copy of this form to each laboratory upon request.

(a) A chain of custody form shall be completed for each donor tested.

(b) Each laboratory licensed under these rules shall provide legally defensible chain-of-custody forms to be used for each donor. Laboratories licensed prior to the effective date of these rules are permitted to use Drug Testing Chain of Custody, HRS Form 1806, Revised 5/91 (currently AHCA Form 3170-5006 Nov. 94), which is incorporated by reference herein, until 12 months after this rule chapter is effective. Laboratories licensed after the effective date of these rules shall use Drug Testing Chain of Custody form AHCA Form 3170-5006 July 95, for urine and AHCA Form 3170-5008 Sept. 97 for hair.

(c) All chain of custody forms shall provide a unique identifier which shall not be used to identify any other Florida Drug Free Workplace specimen. The employer is permitted to assign an employee identification number for use with each donor tested.

(d) The design of the chain of custody forms shall meet the following requirements:

1. Prominently indicate the name and address of the laboratory performing the drug test(s).

2. A section to be completed by the collector or employer representative that solicits the following information:

a. Employer name and address;

b. Medical review officer name and address;

c. Employee identification number;

d. Reason for the test(s); and

e. Test(s) to be performed.

3. A section which indicates the temperature of urine specimens taken within 4 minutes of collection. This shall not be required for chain-of-custody forms for hair specimens.

4. A section to be completed by the collector that indicates the following:

a. The collection facility name, address and telephone number;

b. A designation that a split sample was or was not collected;

- c. A remarks section;
 - d. A statement for the collector to sign incorporating the following language: I certify that the specimen identified on this form is the specimen presented to me or collected by me from the donor providing certification on Copy 4 of this form, that it bears the same identification number as set forth above, and that it has been collected, labeled and sealed in accordance with the Florida Drug-Free Workplace as found in Section 112.0455, F.S., and Chapter 59A-24, F.A.C.; and
 - e. A place for the collector to print his name, a place for the collector's signature and the date and time.
 - 5. A section to be initiated by the collector and completed as necessary thereafter that documents the transfer of the specimen for the purpose of maintaining control and accountability for the specimen. At a minimum, this section shall indicate:
 - a. Date of transfer;
 - b. Signature and name of the person releasing the specimen;
 - c. Signature and name of the person receiving the specimen; and
 - d. Purpose of the transfer.
 - 6. A section to be completed by the laboratory which indicates the following:
 - a. An indication as to whether the specimen was received with intact specimen seals;
 - b. The test results;
 - c. Contains the following statement for the certifying scientist to sign: I certify that the specimen identified by the laboratory accession number on this form is the same specimen that bears the specimen identification number set forth above, that the specimen has been examined upon receipt, handled and analyzed in accordance with the Florida Drug-Free Workplace Program requirements as found in Section 112.0455, F.S., and Chapter 59A-24, F.A.C., and that the results set forth are for that specimen; and
 - d. A place for the certifying scientist to print his name, the signature of the certifying scientist and the date.
 - 7. A section to be completed by the Medical Review Officer including the following:
 - a. The statement: I have reviewed the laboratory test(s) for the specimen identified by this form in accordance with the Florida Drug-Free Workplace Program as found in Section 112.0455, F.S., and Chapter 59A-24, F.A.C.;
 - b. A space for determination of test results as one of the following:
 - I. Negative;
 - II. Positive;
 - III. Test not performed; and
 - IV. Test canceled.
 - c. A place for remarks;
 - d. The signature of the Medical Review Officer; and
 - e. The name of the Medical Review Officer and the date.
 - 8. The chain of custody form shall be comprised of the following copies for distribution:
 - a. Original laboratory copy (Copy 1) which shall be routed to the laboratory with the specimen; the laboratory will retain upon the completion of testing.
 - b. Second Original Laboratory copy (Copy 2) which shall be routed to the laboratory with the specimen; as a means of reporting the test result, the laboratory will forward the copy to the Medical Review Officer.
 - c. Split specimen copy (Copy 3) which must accompany the split portion to the laboratory. Split sample testing is optional.
 - d. Medical Review Officer copy (Copy 4) which shall be routed directly to the MRO by the collection site personnel; this form copy is not to be sent to the laboratory.
 - e. Donor copy (Copy 5) which shall be given to the donor by the collector. Do not send to the laboratory.
 - f. Collector copy (Copy 6) which shall be retained by the collector. Do not send to the laboratory.
 - g. Employer copy (Copy 7) which shall be forwarded to the employer.
- (e) AHCA Form 3170-5006 July 95 and AHCA Form 3170-5008 Sept. 97 are permitted to be modified to indicate specialized specimen identification numbering systems, laboratory identification information and logos, and specimen labels provided that:
1. The content of each section of the form is not altered.
 2. The instructions are not altered.
 3. The sequence, number and color of the copies are not altered.
 4. The drugs listed in the reverse of Copy 5 are not altered.
- (f) The form shall contain no information which can be traceable to the donor except the unique identifier, the employee identification number, if used, and the laboratory's specimen identification number.
- (g) The form shall also contain the following list of over-the-counter and prescription drugs which could alter or affect a test result. Due to the large number of obscure brand names and constant marketing of new products, this list, as follows, is not intended to be all-inclusive.

Alcohol

All liquid medications containing ethyl alcohol (ethanol). Please read the label for alcohol content. As an example, Vick's Nyquil is 25% (50 proof) ethyl alcohol, Comtrex is 20% (40 proof), Contact Severe

Amphetamines	Cold Formula Night Strength is 25% (50 proof) and Listerine is 26.9% (54 proof). Obetrol, Biphetamine, Desoxyn, Dexedrine, Didrex, Ionamine, Fastin.
Cannabinoids	Marinol (Dronabinol, THC).
Cocaine	Cocaine HCl topical solution (Roxanne).
Phencyclidine	Not legal by prescription.
Methaqualone	Not legal by prescription.
Opiates	Paregoric, Parepectolin, Donnagel PG, Morphine, Tylenol with Codeine, Empirin with Codeine, APAP with Codeine, Aspirin with Codeine, Robitussin AC, Guiatuss AC, Novahistine DH, Novahistine Expectorant, Dilaudid (Hydromorphone), M-S Contin and Roxanol (morphine sulfate), Percodan, Vicodin, Tussi-organidin, etc.
Barbiturates	Phenobarbital, Tuinal, Amytal, Nembutal, Seconal, Lotusate, Fiorinal, Fioricet, Esgic, Butisol, Mebaral, Butabarbital, Butalbital, Phrenilin, Triad, etc.
Benzodiazepines	Ativan, Azene, Clonopin, Dalmane, Diazepam, Librium, Xanax, Serax, Tranxene, Valium, Verstran, Halcion, Paxipam, Restoril, Centrax.
Methadone	Dolophine, Metadose.
Propoxyphene	Darvocet, Darvon N, Dolene, etc.

(h) Handling and transportation of a specimen from one authorized individual or place to another shall always be accomplished through the chain of custody form and procedures. The chain of custody form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen at the laboratory. The purpose of the transfer of possession, the name and signature of the person releasing and receiving the specimen, and the date shall be documented on the form each time a specimen is handled or transferred and every individual in the chain shall be identified. Since the specimen and the chain of custody form are sealed in tamper-proof sealable plastic bags that would indicate any tampering during transit to the laboratory, and since couriers, express carriers and postal service personnel do not have access to the chain of custody forms, there is no requirement that such personnel document chain of custody for the shipping container during transit. Nor is there a requirement that there be a chain of custody entry when a specimen which is sealed in such a shipping container is placed in or taken out of secure storage at the collection site prior to pickup by such personnel. A test shall not be canceled because couriers, express carriers, postal service personnel or other persons involved solely with the transportation of a specimen to a laboratory have not documented their participation in the chain of custody or because the chain of custody does not contain entries related to placing the specimen in or removing it from secure temporary storage at the collection site.

(i) Once the specimen has arrived at the laboratory, an internal chain of custody form shall be used by the laboratory until the laboratory has finalized the test results.

(j) Every effort shall be made to minimize the number of persons handling the specimens.

(3) Security Procedures and Specimen Collection. Collection site security and specimen collection security are the responsibility of the collector through contract with the licensed laboratory. Security procedures shall provide for the designated collection site to be secure including the providing of privacy for the donor and the integrity of the specimen.

(a) Access to Authorized Personnel Only. No unauthorized personnel shall be permitted in any part of the designated collection site when specimens are collected or stored.

(b) Privacy. Procedures for collecting urine specimens shall allow individual privacy unless there is reason to believe that a particular individual intends to alter or has altered or substituted the specimen to be provided.

(c) Integrity and Identity of Specimen. The collection site person shall take precautions to ensure that a specimen not be adulterated or diluted during the collection procedure and that information on the collection bottle and on the chain of custody form can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified.

1. To prevent specimen contamination at the collection site:

a. For urine specimens, toilet bluing agents shall be placed in toilet tanks so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water in the enclosure or partitioned area where urination occurs. All other sources of water shall be controlled by the collector.

2. When a donor arrives at the collection site, the collection site person shall request the donor to present a photo identification. If the donor does not have the proper photo identification, the collection site person shall contact the employer who can positively identify the donor. If the donor's identity cannot be established, the collection site person shall not proceed with the collection. The collection site person shall document the reason for not collecting the specimen and provide the donor with a copy of this documentation.

3. Before collecting a specimen, the collection site person shall check to see that the donor has a chain of custody form or has a letter from the employer authorizing the drug test. If a letter is used, the letter shall contain the following information:

- a. The name of the individual to be tested;
- b. The name of the employer and the employer's address, phone number, and fax number;
- c. The name, address and phone number of the laboratory with which the employer has contracted or established an agreement for testing services;
- d. The name, address, phone number, and secured fax number of the employer's Medical Review Officer;
- e. The reason for the test (i.e., either job applicant, reasonable suspicion, routine fitness, or follow-up to treatment);
- f. The drugs for which the laboratory will test; and
- g. The signature of the employer's representative authorizing the testing.

4. If a collection time is assigned by the employer or collection site, and the donor fails to arrive at the collection site at the assigned time, the collection site person shall notify the employer of the missed appointment.

5. The collection site person shall ask the individual to remove any unnecessary outer garments, such as a coat or jacket, and to empty all clothing pockets. The collection site person shall ensure that all personal belongings, such as a purse or briefcase, remain with the outer garments. The individual may retain his or her wallet, provided that the collection site person shall check it for possible contaminants.

6. The individual shall be instructed to wash and dry his or her hands prior to urination. After washing hands, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or any other materials which could be used to adulterate the specimen.

7. The individual may provide his or her urine specimen in a stall or otherwise partitioned enclosure that allows for individual privacy. The collection site person shall remain in the restroom or area, but outside the stall or partitioned enclosure.

8. Upon receiving the specimen from the individual, the collection site person shall determine that:

a. Urine specimens contain at least 30 milliliters (mL) of urine. The approximate volume of the specimen shall be documented by the collector at the time of collection. If there is less than 30 mL of urine in the container, another urine specimen shall be collected in a separate container. Collected specimens which contain less than 30 mL of urine shall not be submitted to the laboratory for testing. Such specimens shall be discarded in the presence of the donor and such procedure shall be annotated by the collector on the chain of custody form. The collector is permitted to give the donor water to drink for the purpose of providing another urine specimen not to exceed an 8 ounce glass of water every 30 minutes for up to 2 hours. If the donor still fails to provide 30 mL of urine, the collection site person shall reschedule another collection within 24 hours and notify the employer as soon as possible of such rescheduling.

b. Blood alcohol specimens shall be collected using aseptic venipuncture technique. The venipuncture site for blood alcohol shall be cleansed with a non-alcoholic antiseptic substance prior to collection. Blood specimens shall contain 7 mL of blood which shall be collected in one tube containing an anticoagulant and a preservative of sodium fluoride. Immediately after collection, the collection site person shall rock the tube gently to mix the anticoagulant and preservative substance with the blood.

c. A quantity of hair shall be collected as described in Section 112.0455(13)(b)3.f.(IV), F.S.

9. After a urine specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

10. No longer than 4 minutes following collection, the collection site person shall measure and record the temperature of the urine specimen, as indicated, on the chain of custody form. The temperature measuring device must be placed on the outside of the container to prevent contamination. If the temperature measurement exceeds 4 minutes, the specimen shall be rendered invalid and shall be rejected. A second specimen shall be collected and a new chain of custody form generated.

11. If the temperature of a urine specimen is outside the range of 90-100 degrees fahrenheit, there is reason to believe that the donor may have altered or substituted the specimen and another urine specimen shall be collected under direct observation by an observer of the same gender as the donor, as specified in subparagraph 59A-24.005(3)(c)13., F.A.C. The reason for the observed collection and the identity of the direct observer shall be documented on the chain of custody form.

12. Immediately after a urine specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted on the chain of custody form.

13. Whenever a collection site person has reason to believe that a particular individual may alter or has altered or substituted a urine specimen, a higher level supervisor at the collection site or at the laboratory shall review the decision and concur in advance with the collection of a second specimen under the direct observation of an observer of the same gender as the donor. Once approved by a higher level supervisor, the collector shall require the individual to provide another specimen under direct observation. If the same gendered observer is not the collector, the observer shall be identified on the chain of custody form. The observer, if different from the collector, shall not handle the specimen and the specimen shall be handed to the collector by the donor in the observer's presence. The observer shall keep the specimen in sight at all times prior to it being sealed. A new chain of

custody form shall be executed to accompany any specimen collected under direct observation. Information regarding a specimen collected under direct observation shall be included on both the new chain of custody form and on the original form in the remarks section. In addition, the new chain of custody specimen identification number shall be annotated on the original form. Both specimens shall be sent to the laboratory to be analyzed.

14. The individual being tested, the collection site person, and the observer if used for direct observation, shall keep the specimen in view at all times prior to its being sealed and labeled.

15. The collection site person shall place securely on the bottle an identification label containing the donor's specimen number, which matches the specimen number on the chain of custody form, and the date.

16. The employee (donor) and the collector shall initial the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from the donor.

17. The collector shall enter on the chain of custody form all required information.

18. The individual shall be asked to sign a statement on the chain of custody form certifying that the specimen identified as having been collected from him or her is in fact that specimen he or she provided. It shall be noted and signed on the chain of custody form by the collection site person, with a witness' signature, if the individual refuses to sign this statement.

19. The collection station is permitted to store unrefrigerated urine specimens up to 72 hours after collection, provided they are sealed for shipment as described in subparagraph 59A-24.005(3)(c)21., F.A.C., and kept in locked, secure temporary storage. Hair specimens shall be stored at all times in unrefrigerated locked, secured storage.

20. While any part of the above chain of custody procedures is being performed, it is essential that the specimen and the chain of custody form be under the control of the collection site person. If the collection site person leaves his or her work station momentarily, the specimen and the chain of custody form shall be taken with him or her or shall be secured in a locked room, drawer, file cabinet, etc. After the collection site person returns to the work station, the chain of custody process will continue. If the collection site person is leaving for an extended period of time, the specimen shall be packaged for shipment before he or she leaves the site.

21. The collection site person shall arrange to send the collected specimens by express shipment, courier, or U.S. Mail to the drug testing laboratory which is designated by the employer. The specimens shall be placed in containers designed to minimize the possibility of damage during shipment. Prior to shipping or storage, the collection site person shall ensure that:

a. The specimen container is sealed with forensic tamper-proof tape;

b. The forensic tamper-proof tape contains the initials of the donor, the date the specimen was sealed in the specimen container; and

c. The completed chain of custody form and specimen container is enclosed and sealed in a tamper-proof sealable plastic bag before packaging for shipment to the drug testing laboratory.

22. This rule chapter does not prohibit the use of split samples provided that such samples are collected in accordance with the provisions of the Mandatory Guidelines for Federal Workplace Drug Testing Programs as defined in subsection 59A-24.003(7), F.A.C.

Specific Authority 112.0455(13)(a) FS. Law Implemented 112.0455 FS. History--New 3-15-90, Amended 6-28-91, Formerly 10E-18.005, Amended 5-1-96, 3-11-98, 3-29-00.

59A-24.006 Drug Testing Laboratories.

Laboratories shall be licensed by the agency in accordance with this rule chapter in order to collect or analyze specimens for an employer's drug testing program and shall also comply with the provisions of Chapter 483, Part I, F.S.

(1) Laboratory Personnel.

(a) Qualifications of Director. The laboratory shall have a qualified director to assume professional, technical, educational, and administrative responsibilities for the laboratory's drug testing. The director shall meet one of the following requirements:

1. Is duly licensed as a physician in the state in which he or she practices medicine; and is licensed under Chapter 458 or 459, F.S., if the laboratory is located in the State of Florida; and has had at least four years of experience in forensic analytical toxicology; or

2. Holds a doctoral degree from an accredited institution with Chemistry, Toxicology or Pharmacology as a major subject of study; and has had at least four years of experience in forensic analytical toxicology; and shall be licensed as a director under Chapter 483, Part IV, F.S., in the specialty of clinical chemistry, if the laboratory is located in the State of Florida.

(b) Responsibilities of Director. The director shall be responsible for the following:

1. The director shall be engaged in and responsible for the day-to-day management of the drug testing laboratory.

2. The director shall be engaged in and responsible for ensuring that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

3. The director shall ensure that the laboratory has a procedure manual which is complete, up-to-date, available to the personnel performing tests. All such procedures must, at a minimum, meet the requirements stipulated in this rule chapter. The director shall ensure that the procedures are followed by personnel performing tests. The procedure manual shall be reviewed,

signed, and dated by this director whenever procedures are first placed into use, or changed, or when a new director assumes responsibility of the drug testing laboratory. Copies of all procedures and the dates that they are in effect shall be maintained as required in paragraph 59A-7.029(3)(e), F.A.C.

4. The director shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; for maintaining acceptable analytical performance for all controls and standards; for maintaining quality control testing; and for assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

5. The director shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory. The director shall ensure that sample results are not reported until all corrective actions have been taken and that he or she can assure that the tests results provided are accurate and reliable.

(c) Certifying Scientists. The laboratory shall have a qualified individual who serves as certifying scientist. This individual reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function.

1. The certifying scientist(s) shall have a minimum of 2 years experience in forensic analytical toxicology and be qualified as a director or licensed as a supervisor under the provisions of Chapter 483, Part IV, F.S., in the specialty of clinical chemistry if the laboratory is located in the State of Florida.

2. The laboratory director is permitted to designate technical personnel to certify results that are negative on the initial screening test. These individuals shall be technologists licensed in the specialty of clinical chemistry in accordance with the provisions of Chapter 483, Part IV, F.S., if the laboratory is located in the State of Florida.

(d) Laboratory Operation and Supervision.

1. The laboratory's drug testing facility shall have an individual(s) responsible for day-to-day operation of the laboratory and the supervision of the technical analysts. This individual(s) shall be licensed as a laboratory supervisor in the specialty of clinical chemistry or qualified as a director in accordance with Chapter 483, Part IV, F.S., in the specialty of clinical chemistry if the laboratory is located in the State of Florida; and

2. Have a minimum of 2 years experience in forensic analytical toxicology.

(e) Technical and Non-Technical Personnel.

1. Technical personnel shall have the training and skills to conduct forensic toxicology testing and shall be licensed in accordance with Chapter 483, Part IV, F.S., if the laboratory is located in the State of Florida. Documentation of such training and skills shall be maintained by the laboratory and available upon request by the agency.

2. Non-technical personnel, including all persons collecting specimens under these rules shall have the necessary training and skills for the tasks assigned but shall not perform drug testing.

(f) Collection Site Person or Persons Collecting Specimens. A specimen for a drug test shall be taken or collected by:

1. A physician, a physician's assistant, a registered professional nurse, a licensed practical nurse, a nurse practitioner, or a certified paramedic who is present at the scene of an accident for the purpose of rendering emergency medical service or treatment.

2. A qualified person employed by a licensed laboratory who has the necessary training and skills for the assigned tasks.

(2) Training. The laboratory's drug testing program shall make available continuing education programs to meet the needs of laboratory personnel.

(3) Files. Laboratory personnel files shall include: resume of training and experience; certification or license, if any; references; job descriptions; records of performance evaluations and advancement; incident reports; and results of tests which establish employee competency for the position he or she holds, such as a test for color blindness, if appropriate.

(4) Specimen Security and Analysis Procedures.

(a) Specimen Security and Internal Chain of Custody.

1. Drug testing laboratories shall be secure at all times. They 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 to areas where records or specimens are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. For the purposes of subparagraph 59A-24.006(4)(a)1., F.A.C., authorized individuals means those persons designated by the laboratory to have access to the drug testing laboratory. All authorized visitors, including maintenance and service personnel, shall be escorted by laboratory personnel at all times. Documentation of individuals accessing these areas, dates, time of entry and egress, and purpose of entry must be maintained for no less than 2 years.

2. Laboratories shall use internal chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on the internal chain of custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized personnel shall be responsible for each specimen or aliquot in their possession and shall sign and complete internal chain of custody forms for those specimens or aliquots as they are received. Aliquots and internal chain of custody forms shall be used by laboratory personnel for conducting both initial and confirmation tests.

(b) Receiving Specimens. When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible damage or tampering and compare information listed on specimen containers within each package to the information on the accompanying chain of custody forms. The laboratory shall establish written standards for the rejection or

acceptance of specimens. In addition, any evidence of tampering, mismatched or omitted specimen identification numbers, spillage, damage or other discrepancies in the information on specimen containers and the chain of custody form shall render a specimen invalid and shall be rejected by the laboratory for testing. The laboratory shall immediately report any rejection to the employer and shall note such rejection on the chain of custody form.

(c) Short-Term Refrigerated Storage. Urine or blood specimens that do not receive an initial test within 72 hours of arrival at the laboratory shall be placed in locked, secure refrigerated units. Temperatures of these units shall not exceed 6 degrees Celsius. Emergency power equipment shall be available and used in case of power failure.

(d) Specimen Testing Requirements. A laboratory must be capable of testing for all drugs listed in Section 112.0455(5)(a), F.S., and be capable of conducting testing to ensure that a specimen has not been diluted or adulterated. The laboratory shall test and report drug test results no more than 3 working days after the receipt of the specimen in the laboratory.

(e) Initial Test. The initial screen for all drugs shall be an immunoassay except that the initial test for alcohol shall be an enzyme oxidation methodology.

1. Levels on initially screened urine specimens which are equal to or exceed the following shall be considered to be presumptively positive and submitted for confirmation testing:

Amphetamines	1,000 ng/mL
Cannabinoids (11-nor-Delta-9-tetrahydrocannabinol-9-carboxylic acid)	50 ng/mL
Cocaine (benzoylecgonine)	300 ng/mL
Phencyclidine	25 ng/mL
Methaqualone	300 ng/mL
Opiates	2,000 ng/mL
Barbiturates	300 ng/mL
Benzodiazepines	300 ng/mL
Methadone	300 ng/mL
Propoxyphene	300 ng/mL

The only specimen for alcohol testing shall be blood and the initially screened specimen shall be considered presumptively positive and submitted for confirmation testing if the level is equal to or exceeds 0.04 g/dL.

2. Levels which exceed the following for hair specimens shall be considered presumptively positive on initial screening and submitted for confirmation testing:

Marijuana	10 pg/10 mg of hair
Cocaine	5 ng/10 mg of hair
Opiate/synthetic narcotics and metabolites	5 ng/10 mg of hair
Phencyclidine	3 ng/10 mg of hair
Amphetamines	5 ng/10 mg of hair

3. Laboratories are permitted to use multiple screening tests for the same drug or drug class to eliminate any possible presumptive positives due to structural analogs, provided that such tests meet the requirements of this rule chapter.

(f) Confirmation Test. All specimens identified as presumptively positive on the initial test shall be confirmed using mass spectrometry/mass spectrometry (MS/MS) or gas chromatography/mass spectrometry (GC/MS), except that alcohol will be confirmed using gas chromatography. All confirmations shall be done by quantitative analysis.

1. Levels on confirmation testing for urine specimens which are equal to or exceed the following shall be reported as positive:

Amphetamines (amphetamine, methamphetamine) ¹	500 ng/mL
Cannabinoids (11-nor-Delta-9-tetrahydrocannabinol-9-carboxylic acid)	15 ng/mL
Cocaine (benzoylecgonine)	150 ng/mL
Phencyclidine	25 ng/mL
Methaqualone	150 ng/mL
Opiates	
Codeine	2000 ng/mL
Morphine	2000 ng/mL
6-Acetylmorphine ²	10 ng/mL
Barbiturates	150 ng/mL
Benzodiazepines	150 ng/mL
Methadone	150 ng/mL
Propoxyphene	150 ng/mL

¹A laboratory shall not report a specimen positive for methamphetamine only. The specimen must contain amphetamine at a concentration equal to or greater than 200 ng/mL, by the confirmation test. If this criterion is not met, the specimen shall be reported as negative for methamphetamine.

²Tests for 6-Acetylmorphine when the morphine concentration exceeds 2000 ng/mL.

The alcohol level on confirmation testing for blood which is equal to or exceeds 0.04 g/dL shall be reported as positive.

2. Levels for hair specimens on confirmation testing which are equal to or exceed the following shall be reported as positive:

Marijuana Metabolites	1 pg/10 mg of hair
Cocaine	5 ng/10 mg of hair
Opiate/synthetic narcotics and metabolites	5 ng/10 mg of hair
Phencyclidine	3 ng/10 mg of hair
Amphetamines	5 ng/10 mg of hair

(g) Reporting Results.

1. The laboratory shall report all test results to the MRO indicated on the chain of custody form. Before any test result is reported by the laboratory, the results of initial tests, confirmation tests, and quality control data of such tests shall be reviewed by the certifying scientist and the test certified as an accurate report. The report, at a minimum, shall identify the drugs or metabolites tested for, the results of the drug test either positive or negative, the specimen number assigned on the chain of custody form, the name and address of the laboratory performing the testing, and the drug testing laboratory's specimen accession number.

2. The following criteria shall be used when reporting drug testing results.

a. Specimens that test negative as specified in subparagraphs 59A-24.006(4)(e)1. and 2., F.A.C., on the initial test shall be reported as negative. If an employer wishes to retest a negative specimen under the provisions of Section 112.0455(9)(a), F.S., such testing is authorized to be conducted only once and must be requested no more than 7 working days from the time the original negative test result was reported to the employer by the MRO. Hair specimens may be re-collected only once to perform repeat confirmation testing under the provisions of Section 112.0455(9)(a), F.S.

b. Specimens that test positive as specified in subparagraph 59A-24.006(4)(e)1., F.A.C., on initial immunoassay tests, but test negative as specified in paragraph 59A-24.006(4)(f), F.A.C., on confirmation shall be reported as negative.

c. The laboratory is permitted to report drug test results for specimens that do not meet the adulteration/dilution criteria of the laboratory. Reports on specimens that do not meet the laboratory's adulteration/dilution requirements shall not indicate the actual results of the adulteration/dilution tests, but the report shall indicate the adulteration/dilution test results in non-quantitative terms.

d. The laboratory report shall indicate solely that the test(s) resulted in a positive drug test result or resulted in a negative drug test result.

3. The MRO may request from the laboratory, and the laboratory shall provide, detailed quantification of initial and confirmation test results.

4. The laboratory may transmit results to the MRO by various electronic means (for example, teleprinter, facsimile, or computer) in a manner designed to ensure confidentiality of the information. The laboratory and MRO must ensure the security of the data transmission and restrict access to any data transmission, storage, and retrieval system to only those individuals authorized under these rules to obtain such information.

5. The laboratory shall send the MRO a copy of the original chain of custody form (copy 2) signed by the certifying scientist responsible for attesting to the validity of the test report.

6. The laboratory shall make available copies of all analytical results of donor testing upon request by the MRO or the agency.

7. Unless otherwise specified in this rule chapter, all records pertaining to a given specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(h) Storage of Specimens. Drug testing laboratories shall retain and place all confirmed positive urine specimens in locked, secured long-term frozen storage (-15 degrees Celsius or less) and confirmed positive blood specimens in locked, secured long-term refrigerated storage (2-8 degrees Celsius) for a minimum of 210 days. Within this 210 day period an employer, employee, job applicant, or MRO is permitted to request in writing that the laboratory retain the specimen for an additional period of time. If no such request is received, the laboratory is permitted to discard the specimen after 210 days of storage. When notified in writing, the laboratory shall be required to maintain any specimens under legal challenge until such challenge is resolved. To maintain applicable storage temperatures for stored specimens, emergency power equipment shall be available and used in the case of power failure. After the required retention time has passed, laboratories are permitted to either discard the specimens or pool all or part of these specimens for use in the laboratory's internal quality control program.

1. When an employee or job applicant undertakes an administrative or legal challenge to the test result, it shall be the employee's or job applicant's responsibility to notify the employer and laboratory in writing of such challenge and such notice shall include reference to the chain of custody specimen identification number. After such notification, the sample shall be retained by the laboratory until the case or administrative appeal is settled.

2. During a 180 day period after written notification of a positive test result, the employee or job applicant who has provided the specimen shall be permitted by the employer to have a portion of the specimen retested, at the employee or job applicant's expense. The laboratory which performed the original test for the employer shall be responsible for transferring a portion of the specimen to be retested at a second laboratory licensed under these rules, selected by the employee or job applicant, and shall be responsible for the integrity of the specimen and for the chain of custody during such transfer.

3. Urine specimens that test negative shall be stored in locked, secured refrigerated (2-8 degrees Celsius) or frozen storage (-15 degrees Celsius or less). Blood specimens that test negative shall be stored in locked, secured, refrigerated storage (2-8 degrees Celsius). These specimens shall be retained for no less than 7 working days after the test result has been reported to the employer by the MRO. After the required retention time has passed, laboratories are permitted to either discard the specimens or pool all or part of these specimens for use in the laboratory's internal quality control program.

4. The laboratory is permitted to discard or pool specimens that test negative immediately after the negative test result is transmitted to the MRO, provided that the laboratory has written authorization from the employer that specimens which test negative are not to be retained for retesting under Section 112.0455(9)(a), F.S.

5. Under no circumstances shall a laboratory be required to retain a specimen, which has been reported as negative, for a period longer than 14 working days after receipt of that specimen in the laboratory unless a confirmation test has been requested by the employer under the provisions of Section 112.0455(9)(a), F.S.

(i) Retesting Specimens. As some analytes deteriorate or are lost during freezing, refrigeration, or storage, quantification for a retest is not subject to a specific cutoff requirement but must provide data sufficient to detect the presence of the drug or metabolite.

(5) Subcontracting. Drug testing laboratories shall not subcontract, except for collection sites, and shall perform all analysis with their own personnel and equipment. The laboratory must be capable of performing testing for the classes of drugs defined in Section 112.0455(5)(a), F.S., using the specimens indicated in Section 112.0455(5)(k), F.S., and initial and confirmation methods specified in paragraphs 59A-24.006(4)(e) and (f), F.A.C.

(6) Contracted Collection Sites. Collection sites or collectors shall contract with laboratories licensed under this rule chapter to collect specimens for analysis. Such contracts shall be in writing and include the utilization of all the necessary facilities, personnel, materials, equipment, or other supplies, as needed, to collect specimens as required in Rule 59A-24.005, F.A.C. For the purposes of Section 112.0455(8)(e), F.S., persons collecting specimens under contract with a forensic drug testing laboratory shall be deemed to be employees of the licensed laboratory. In addition, the collectors shall be trained by, and shall be accountable to, the licensed laboratory. However, after an accident, if an employee is taken to a facility for medical treatment and the facility does not have a contract with the laboratory, an individual authorized in paragraph 59A-24.006(1)(f), F.A.C., is permitted to collect a specimen provided that this collector utilize, and complete to the fullest extent possible, a chain of custody form. In addition, the collector shall follow the collection procedures found in Rule 59A-24.005, F.A.C., to the fullest extent possible and shall maintain full control of the specimen until the specimen is sealed and packaged for shipment to the employer's selected laboratory.

(7) Inspections. The agency or the representatives of the federal Department of Health and Human Services Federal Workplace Drug Testing Program shall conduct announced or unannounced inspections of the laboratory at any reasonable time for the purpose of determining compliance with this rule chapter. The right of entry and inspection shall also be extended to any collection sites under contract with the laboratory. Inspections shall document the overall quality of the laboratory setting for the purpose of licensure to conduct drug free workplace testing. Inspection reports shall also contain any requirements of the laboratory to correct deficiencies noted during the inspections.

(a) Prior to laboratory licensure and at least twice a year after licensure, an on-site inspection of the laboratory shall be conducted.

(b) In order to be considered for licensure renewal, laboratories certified by the federal Department of Health and Human Services Federal Workplace Drug Testing Programs shall submit one inspection report of the federal Department of Health and Human Services Federal Workplace Drug Testing Programs in lieu of one of the two required bi-annual inspections. This provision does not apply to laboratories applying for initial licensure. In addition, such laboratories certified by the federal Department of Health and Human Services Federal Workplace Drug Testing Programs shall:

1. Maintain a policy to conduct the testing of all specimens authorized under Section 112.0455, F.S., in the same manner as required for those drugs included under the Mandatory Guidelines for Federal Workplace Drug Testing Programs. This policy must be in writing and contained in the laboratory's policy and procedure manual.

2. Submit to the agency all reports of such inspections, post inspection activities and reports including any corrective action taken by the laboratory within 45 days of the receipt of the initial evaluation report in the laboratory.

3. Request in writing that the inspection report be accepted in lieu of an on-site inspection by the agency.

(8) Documentation. Laboratories shall maintain and make available for at least 2 years all documentation of the testing process. Except that the laboratory shall be required to maintain documents and records for any specimen(s) under legal challenge until such challenge is resolved. The required documentation shall include:

(a) Personnel files on all individuals authorized to have access to specimens;

(b) Chain of custody documents;

(c) Quality assurance records;

(d) Quality control records;

(e) Procedure manuals;

(f) All test data, calibration curves and any calculations used in determining test results;

(g) Donor test reports;

(h) Proficiency testing records;

(i) Computer generated data used for testing and reporting specimen results.

(9) Additional Requirements for Laboratory Licensure.

(a) Procedure Manual. Each laboratory shall have a procedure manual which meets the applicable requirements of paragraphs 59A-7.029(3)(b), (d), and (e), F.A.C.

(b) Standards and Controls. Laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with dates indicating when received, when prepared or opened, when placed in service, and the expiration date.

(c) Instruments and Equipment.

1. Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedures on a quarterly basis. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked quarterly thereafter.

2. There shall be written procedures for instrument setup and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks and instructions for major trouble shooting, repair, and maintenance in accordance with manufacturer's specifications. Manufacturer's specifications for, and records of preventive and regular maintenance shall be maintained for as long as the instrument is in use and for at least 2 years after the instrument is discontinued from use and shall be available upon request by the agency.

(d) Remedial Actions. There shall be written procedures for the actions to be taken when test systems are not operating correctly or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(e) Personnel Available to Testify at Proceedings. A laboratory director shall assure that technical personnel, including the director, be available to testify in an administrative or disciplinary proceeding regarding any employee or a job applicant when that proceeding is based on a test result which was analyzed and reported by the laboratory.

(10) Quality Assurance and Quality Control. Quality assurance and quality control for hair analyses shall be conducted in accordance with Section 112.0455(13)(b)4., F.S.

(a) General. Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmation testing and validation of analytical procedures. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs.

(b) Laboratory Quality Control Requirements for Initial and Confirmation Tests. At a minimum, each analytical run of specimens for an initial or confirmation test shall include the following quality control samples:

1. Negative specimens certified to contain no drug;

2. Urine specimens fortified with known standards; and

3. Positive controls with the drug or metabolite at or near the threshold (cutoff).

4. At least 1 percent of each initial screening run, with a minimum of one sample per run, shall consist of a blind sample(s) of known concentration. Such samples shall appear as ordinary test specimens to the laboratory analysts.

(11) Proficiency Testing. Proficiency testing is a part of the initial evaluation of a laboratory seeking licensure and is required as a continuing assessment of laboratory performance necessary to maintain continued licensure.

(a) General Considerations.

1. The laboratory must successfully participate in proficiency testing surveys, as described in subsection 59A-24.006(11), F.A.C.

2. Proficiency testing specimens are permitted to consist of negative specimens as specified in subparagraph 59A-24.006(4)(e)1., F.A.C., and positive specimens, as specified in paragraph 59A-24.006(4)(f), F.A.C.

3. Proficiency testing specimens are permitted to contain interfering substances.

4. Proficiency testing specimens are permitted to be identified for screening or confirmation testing only.

5. All procedures associated with the laboratory's handling and testing of any proficiency testing specimens shall be carried out in the same manner as the laboratory tests donor samples.

6. The laboratory shall report results of proficiency testing samples using the same criteria applied to routine drug testing specimens.

7. Failure to submit the results of each proficiency testing survey within the time frames indicated in sub-subparagraphs 59A-24.006(11)(c)1.c., and 59A-24.006(11)(c)3.h., F.A.C., is considered unsuccessful participation and will result in a failing score for that proficiency testing survey and administrative action up to and including revocation of licensure, as provided in subsection 59A-24.006(12), F.A.C.

8. Failure to participate in any proficiency testing survey is considered unsuccessful participation and will result in a failing score for that proficiency testing survey and administrative action up to and including revocation of licensure as provided in subsection 59A-24.006(12), F.A.C.

9. The laboratory shall be permitted to request that the agency supply additional proficiency testing samples to be tested to document whether the source of unsuccessful proficiency testing performance has been corrected. The agency shall permit no more than two such additional shipments of proficiency testing samples. The laboratory will be required to pay the cost of such samples.

10. In addition to the proficiency testing requirements, any licensed laboratory shall be subject to blind performance testing by the agency. Blind performance testing means proficiency test samples which are shipped to a laboratory in a manner such that the samples appear to be actual drug testing samples.

(b) Initial Licensure. Laboratories applying for initial licensure shall be required to successfully complete three proficiency testing surveys supplied by the agency before the laboratory is eligible to be considered for licensure.

1. Two of these proficiency testing surveys shall be completed prior to the initial inspection of the laboratory.

2. The third proficiency testing survey shall be provided so that it arrives prior to the initial inspection. These samples will be analyzed in conjunction with the on-site inspection as directed by the agency.

3. Evaluation of initial proficiency testing surveys shall be in accordance with the requirements set forth in subparagraph 59A-24.006(11)(c)3., F.A.C.

4. Any initial applicant whose proficiency testing evaluation does not meet the requirements of subparagraph 59A-24.006(11)(c)3., F.A.C., on any of the three initial proficiency testing surveys shall automatically be disqualified for licensure. To be considered for future licensure, the laboratory must reapply for licensure and must submit the required licensure fee as a new applicant.

(c) Continued Licensure. In order to remain licensed, the laboratory shall participate in four proficiency testing surveys per year. The laboratory must participate in 3 non-agency proficiency testing surveys supplied by an approved proficiency testing organization as defined in subsection 59A-24.003(3), F.A.C., and 1 annual proficiency testing survey supplied by the agency as described below. Failure to meet the applicable grading criteria found in subparagraph 59A-24.006(11)(c)3., F.A.C., shall be considered unsuccessful proficiency testing participation. The agency shall revoke or suspend the laboratory's license or take no further action, taking into consideration the potential for such errors to affect the reporting of reliable drug test results.

1. Non-Agency Supplied Proficiency Testing.

a. Three of the four required proficiency testing surveys shall be obtained at the laboratory's expense from an approved proficiency testing provider, as defined in subsection 59A-24.003(3), F.A.C.

b. Proficiency testing results from the approved non-agency providers shall be graded using the grading criteria required in subparagraph 59A-24.006(11)(c)3., F.A.C.

c. The laboratory shall submit the reports of non-agency supplied proficiency testing results and any corrective action taken with regards to unsuccessful results within 14 working days of their receipt in the laboratory.

2. Agency Supplied Proficiency Testing. The remaining proficiency testing survey shall be supplied by the agency and shall be shipped to the laboratory at any time during the licensure year.

3. In order to obtain initial licensure or to remain licensed, the laboratory must meet the following criteria for successful participation on any proficiency testing shipment:

a. Report no false positive drug identifications.

b. Correctly screen 90 percent of the samples in each proficiency testing survey.

c. Achieve a combined score of 90 percent for screening and confirmation testing.

d. Correctly confirm 90 percent of the drug challenges for proficiency samples that screen as positive.

e. For all proficiency samples screened as positive, quantitate 80 percent of all drug challenges at ± 20 percent of the group mean.

f. Detect and quantitate 50 percent of the total drug challenges for any individual drug or drug classes.

g. Submit the results of agency supplied proficiency testing surveys no more than 10 working days from receipt of the samples by the laboratory.

h. Submit any remedial action taken in regard to proficiency testing errors found in agency supplied proficiency testing samples within five days of such notification by the agency.

4. Consequences of Unsuccessful Proficiency Testing Performance.

a. Failure to achieve successful proficiency testing performance as described in subsection 59A-24.006(11), F.A.C., shall result in administrative action up to and including revocation of licensure as provided in subsection 59A-24.006(12), F.A.C.

b. In the event that a laboratory's license is suspended due to unsatisfactory proficiency testing performance, re-instatement of licensure shall not be considered until the laboratory can demonstrate:

i. Satisfactory performance on no more than 2 agency supplied proficiency surveys;

ii. That the source of unsuccessful proficiency testing performance has been corrected; and

iii. That payment for any additional proficiency testing samples supplied by the agency has been received.

(12) Administrative Enforcement and Hearings.

(a) The agency shall enforce the provisions of Section 112.0455, F.S., and Chapter 59A-24, F.A.C., by administering remedies for statutory and rule violations as provided in Section 112.0455(14), F.S.

(b) Whenever the agency has reason to believe that immediate action is necessary in order to protect the interests of an employer, employee, or job applicant, the agency shall immediately suspend or revoke a laboratory's license to conduct drug testing.

(c) Grounds for Disciplinary Action. The following actions shall result in the agency taking administrative action:

1. Failure to accurately analyze and report donor drug tests;
2. Unsuccessful participation in proficiency testing surveys;
3. A violation of a licensure standard;
4. Participation in a pretrial intervention or other first-offender agreement respecting a charge of, the entering of a plea of nolo contendere or guilty to a charge of, a finding of guilt regardless of adjudication of, or a conviction or any criminal offense under federal law or the law of any state relating to the operation of any laboratory;
5. Making a fraudulent statement on an application for a forensic toxicology license or any other document required by the agency;
6. Permitting unauthorized persons to perform technical procedures or issue reports;
7. Demonstrating incompetence or making consistent errors in the performance and reporting of drug free workplace testing or proficiency testing samples;
8. Performing a test and rendering a report thereon to a person not authorized by law to receive such services;
9. Knowingly having professional connection with or knowingly lending the use of the name of the licensed forensic toxicology laboratory or the license of the director to an unlicensed forensic toxicology laboratory;
10. Violating or aiding and abetting in the violation of any provision of this part or the rules promulgated hereunder;
11. Failing to file any report required by the provisions of this part or the rules promulgated hereunder;
12. Reporting a drug test result when no such test was performed;
13. Knowingly advertising false services or credentials;
14. Failure to correct deficiencies within the time required by the agency;
15. Failing to maintain a secured area for toxicology tests; or
16. Any other cause which affects the ability of the laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results.
17. Failure to submit statistical reports as required in subsection 59A-24.009(3), F.A.C.

(d) Hearings. All administrative hearings shall be in accordance with Chapter 120, F.S., and applicable rules and regulations. Those proceedings brought in the circuit courts of Florida to enjoin or restrain the unlawful operation of a forensic laboratory without a valid license under Section 112.0455, F.S., shall be governed by Section 112.0455, F.S., and the Florida Rules of Civil Procedure.

(13) Re-instatement of Licensure. Upon the submission of evidence to the agency that the laboratory is in compliance with this rule chapter and Section 112.0455, F.S., and any other conditions imposed as part of a suspension, the agency shall reinstate the laboratory's license. A laboratory having its license revoked shall be required to reapply for licensure in accordance with the provisions for initial applicants and pay the applicable licensure fee.

(14) Licensure Fee.

(a) Laboratories seeking licensure must complete licensure application form, AHCA Form 3170-5001 July 95, which is hereby incorporated by reference. This form is available from the agency.

1. Initial and annual licensure renewal fees shall be \$8,000 and shall be made payable to the agency.
2. For late filing of an application for renewal, the provisions of Section 112.0455(17), F.S., shall apply.

(b) Refunds are authorized pursuant to provisions of Section 215.26, F.S., and shall be approved only in the following instances:

1. An overpayment of a fee;
2. A payment where no fee is due; and
3. Any payment made into the State Treasury in error.

(c) Applications for refunds shall be filed with the Comptroller within 3 years from the date of the payment into the State Treasury, or else such right shall be barred. Refund claims shall not otherwise be barred under the laws of this state.

(15) Statistical Information Reporting.

(a) The laboratory shall submit statistical information on drug testing to the agency. No statistical information reported to the agency shall reveal the names of the persons tested, nor shall it reveal the employer's identity. This data shall contain the following information on specimens received for all drug testing conducted under Section 112.0455, F.S.:

1. The total number of specimens received for testing.
2. The total number of specimens that tested positive on the initial screening.
3. The total number of specimens that were confirmed and reported as positive for each drug class tested.
4. The total number of samples that were received but not tested.

(b) Statistical summaries shall be submitted to the agency on a monthly basis no later than 14 working days after the end of a reporting month. Reporting is required even if no Florida Drug Free Workplace testing has been done for that reporting month.

(c) Failure of a laboratory to submit the statistical reports as authorized in Section 112.0455(12)(c), F.S., shall result in administrative action pursuant to paragraph 59A-24.006(12)(a), F.A.C.

Specific Authority 112.0455(12)(c), (13)(a) FS. Law Implemented 112.0455 FS. History--New 3-15-90, Amended 6-28-91, Formerly 10E-18.006, Amended 5-1-96, 12-5-96, 3-11-98, 3-29-00.

59A-24.008 Review of Test Results.

Prior to the transmission of test results to the employer, both positive and negative test results shall be reviewed and verified by a medical review officer (MRO) qualified under subsection 59A-24.008(1), F.A.C. The MRO is permitted to use a language interpreter to assist in communicating the results of drug tests with employees and job applicants. Such language interpreters are subject to the confidentiality provisions of Section 112.0455(11), F.S. After the results have been reviewed and verified by the MRO, the test result is reported to the employer.

(1) Qualifications of Medical Review Officers.

(a) Persons serving as medical review officers shall be medical or osteopathic physicians duly licensed in the state in which he or she practices medicine.

(b) The MRO shall have knowledge of substance abuse disorders, laboratory testing procedures, chain of custody procedures, collection procedures, and have the appropriate medical training to interpret and evaluate an individual's drug test result together with the individual's medical history or any other biomedical information.

(c) Beginning January 1, 1998, medical review officers shall be certified as medical review officers by the American Association of Medical Review Officers, American Society of Addiction Medicine or the American College of Occupational and Environmental Medicine.

(d) The MRO shall be employed by or contracted by the employer and shall not be employed or contracted by a drug testing laboratory performing drug free workplace testing under Section 112.0455, F.S. The drug testing laboratory is permitted to assist the employer in locating qualified medical review officers.

(e) An employer shall not serve as the MRO for his or her own employees and job applicants.

(2) Responsibilities of Medical Review Officer. The MRO shall evaluate the drug test result(s), which is reported out by the laboratory, to verify by checking the chain of custody form that the specimen was collected, transported, and analyzed under proper procedures, as specified in these rules, and to determine if any alternative medical explanations caused a positive test result. This determination could include conducting a medical interview with the individual, review of the individual's medical history, or the review of any other relevant bio-medical factors. The MRO shall review all medical records made available by the tested individual. The MRO shall not consider the results of samples that are not obtained or processed in accordance with these rules.

(a) Negative Results. To verify that a negative test result was properly analyzed and handled according to these rules, the MRO shall:

1. Receive and review the test result(s) from the laboratory;
2. Verify the laboratory report by checking the chain of custody form for required signatures, procedures, and information;
3. Ensure that the donor's specimen identification number on copy 2 of the laboratory test report and on copy 4 of the chain of custody form which was sent to the MRO by the collection site accurately identifies the donor with the negative test result; and
4. Notify the employer in writing of the negative test result no more than 7 working days after the specimen was received by the laboratory, and appropriately file copy 2 and 4 of the chain of custody form under confidential procedures for a period of 2 years.
5. Within 24 hours of notification of the employer of a negative test result, notify the testing laboratory that the negative test result has been submitted to the employer.

(b) Positive Results. To verify that a positive test result was properly analyzed and handled according to these rules, the MRO shall:

1. Receive and review the test result(s) from the laboratory;
2. Verify the laboratory report by checking the chain of custody form for required signatures, procedures, and information;
3. Ensure that the donors specimen identification number on copy 2 of the laboratory test report and on copy 4 of the chain of custody form which was sent to the MRO by the collection site accurately identifies the donor with the positive test result;
4. Notify the employee or job applicant of a confirmed positive test result, within 3 days of receipt of the test result from the laboratory, and inquire as to whether prescriptive or over-the-counter medications could have caused the positive test result;
5. Within 5 days of notification to the donor of the positive test result, provide an opportunity for employee or job applicant to discuss the positive test result and to submit documentation of any prescriptions relevant to the positive test result;
6. Review any medical records provided by the employee or job applicant, or authorized by the employee or job applicant and released by the individual's physician, to determine if the positive test result was caused by a legally prescribed medication. If the donor does not have prescribed medication, the MRO shall inquire about over-the-counter medications which could have caused the positive test result. The donor shall be responsible for providing all necessary documentation, (i.e., a doctor's report, signed prescription, etc.) within the 5 day period after notification of the positive test result;
7. Notify the employer in writing of the verified test result, either negative, positive, or unsatisfactory, no more than 7 working days after the specimen was received by the laboratory, and appropriately file the chain of custody form under confidential procedures for 2 years;
8. If the MRO determines that there is a legitimate medical explanation for the positive test result, based on the medical judgment of the MRO and accepted standards of practice, the MRO shall report a negative test result to the employer.

9. Process any employee or job applicant requests for a retest of the original specimen, within 180 days of notice of the positive test result, at another licensed laboratory selected by the employee or job applicant. The donor requesting the additional test shall be required to pay for the costs of the retest, including handling and shipping expenses. The MRO shall contact the original testing laboratory to initiate the retest.

10. The MRO shall not declare a confirmed positive as verified, until the MRO receives copy 2 of the chain of custody form from the drug testing laboratory and copy 4 from the collection site.

(3) Chain of Custody Procedures. A strict chain of custody procedure, initiated at the time of specimen collection, is mandatory for the validation of any test result. The MRO shall be responsible, before reporting either positive or negative test result(s) to the employer, to review all signatures, procedures, and information as required on the chain of custody form to determine that the specimen was under authorized control both before and during laboratory analysis. If proper chain of custody procedures have not been followed, the MRO shall declare the test result as unsatisfactory, due to an unacceptable chain of custody procedure.

(4) Verification for Opiates. Before a positive test for opiates is verified, the MRO shall determine that there is clinical evidence in addition to the urine test, of illegal use of any opium, opiate, or opium derivative (e.g., morphine/codeine). This requirement does not apply if the GC/MS confirmation test for opiates confirms the presence of 6-monoacetylmorphine.

(5) Reanalysis Authorized. Should any question arise as to the accuracy or validity of a test result which has been collected and analyzed in accordance with these rules, the MRO may order a reanalysis of the original sample at any licensed laboratory licensed under these rules.

(6) Scientifically Unsatisfactory Results. The MRO, based on a review of the chain of custody form, quality control data, multiple samples and other pertinent results, is permitted to determine that the result is scientifically unsatisfactory for further action and may request the donor to provide another sample or request a reanalysis of the original sample before making such decision. The MRO is permitted to request that the reanalysis be performed by the same laboratory or, that an aliquot of the original specimen be sent to another licensed laboratory. The laboratory shall assist in this review process as requested by the MRO and shall make available appropriate personnel to provide consultation as required by the MRO. The MRO shall report all findings based on the unsatisfactory specimen, as required by this rule chapter, but shall not include any personal identifying information in such reports.

(7) Contacting Donors Who Test Positive.

(a) If the MRO is unable to contact a donor who tested positive within 3 working days of receipt of the test results from the laboratory, the MRO shall contact the employer and request that the employer direct the donor to contact the MRO as soon as possible. If the MRO has not been contacted by the donor within 2 working days from the request to the employer, the MRO shall verify the report as positive.

(b) As a safeguard to employees and job applicants, once a MRO verifies a positive test result, the MRO may change the verification of the result if the donor presents information to the MRO which documents that a serious illness, injury, or other circumstance unavoidably prevented the employee from contacting the MRO within the specified time frame and if the donor presents information concerning a legitimate explanation for the positive test result.

(c) If the donor declines to talk with the MRO regarding a positive test result, the MRO shall validate the result as positive and annotate such decline in the remarks section.

(8) Identification of Donor. Prior to providing an employee or job applicant with the opportunity to discuss a test result, the MRO shall confirm the identity of the employee or job applicant. At a minimum, to confirm the identity of the donor, the MRO shall ask the donor to respond with the following information:

(a) If the request is in person, the MRO shall request a picture identification.

(b) If the request is over the telephone, the MRO shall request:

1. An employee identification number or social security number;

2. Date of birth;

3. Employer's name; and

4. Work telephone number.

(9) Information for Donor. Once the donor's identification has been established, and before any additional information is solicited from the donor, the MRO shall:

(a) Inform the donor that the MRO is an agent of the employer whose responsibility is to make a determination on test results and report them to the employer;

(b) Inform the donor that medical information revealed during the MRO's inquiry will be kept confidential; unless the donor is in a safety sensitive or special risk position and the MRO believes that such information is relevant to the safety of the donor or to other employees. Any additional release of information shall be solely pursuant to a written consent form signed voluntarily by the donor, except where such release is compelled by a hearing officer or a court of competent jurisdiction pursuant to an appeal, or where deemed appropriate by a professional or occupational licensing board in a related disciplinary proceeding.

(c) Outline the rights and procedures for a retest of the original specimen by the donor.

(d) If the donor voluntarily admits to the use of the drug in question without a proper prescription, the MRO shall advise the donor that a verified positive test report will be sent to the employer.

(10) Verification Signature. After the MRO reviews the chain of custody forms from the laboratory and the collection site (copy 2 from the laboratory and copy 4 from the collection site) and, in the case of a positive test result, has contacted the donor who tested positive, the MRO shall:

(a) On copy 2 of the chain of custody form, mark the appropriate box if the verified result is positive or negative and if positive, write in for which drug(s). If the test was not performed or the test was canceled, mark the appropriate box. The reason for the cancellation or non-performance of the test shall be explained in the remarks section.

(b) On copy 2 of the chain of custody form, sign and date the verification of the final test result.

(c) Prepare and sign a verification letter to the employer revealing the final verified test result. Copies of the laboratory report form or chain of custody are not suitable for this purpose.

Specific Authority 112.0455(13)(a) FS. Law Implemented 112.0455 FS. History—New 6-28-91, Formerly 10E-18.008, Amended 5-1-96, 3-11-98.