

NOTE: The Division of Workplace Programs received comments on draft #1 from 28 different individuals, manufacturers, laboratories, or organizations. This second draft document incorporates many of the submitted comments.

All interested parties are invited to comment on this second draft document. Please submit your comments by September 29, 2000. Comments may be emailed to wvog1@samhsa.gov or to clodico@samhsa.gov, mailed to the Division of Workplace Programs, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, or faxed to 301-443-3031.

MANDATORY GUIDELINES

for

FEDERAL WORKPLACE DRUG TESTING PROGRAMS

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Authority:

Subpart A - Applicability

§1.1 Whom do these Guidelines cover?

These guidelines apply to:

- (a) Executive Agencies as defined in 5 U.S.C. 105, excluding the testing of persons in the criminal justice system (e.g., arrestees, detainees, probationers, incarcerated persons, parolees);
- (b) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));
- (c) Any other employing unit or authority of the Federal Government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and
- (d) The Intelligence Community, as defined by Executive Order No. 12333, only to the extent agreed to by the head of the affected Agency.

§1.2 Who is responsible for developing and issuing authoritative interpretations of the Guidelines?

- (a) Executive Order 12564 and Public Law 100-71 require the Department of Health and Human Services (HHS) to establish a Drug-Free Federal Workplace Program.
- (b) Within HHS, the Division of Workplace Programs (DWP) in the Center for Substance Abuse Prevention, Substance Abuse and Mental Health Services Administration (SAMHSA), has been delegated the responsibility of providing:
 - (1) The day-to-day oversight of the Drug-Free Federal Workplace Program; and
 - (2) The development of comprehensive procedural and scientific standards for all aspects of a drug testing program.
- (c) The Division of Workplace Programs provides written interpretations of the provisions in these Guidelines as written or electronic program documents, handbooks, manuals, and Federal Register notices.

§1.3 How is an exemption granted from these Guidelines?

- (a) A Federal agency may not deviate from the provisions of these Guidelines without the written approval of the Secretary of Health and Human Services.
- (b) In requesting approval for a deviation, a Federal agency must petition the Secretary in writing and describe the specific provision or provisions for which a deviation is sought and the rationale for the deviation.

§1.4 How are these Guidelines revised?

- (a) The Secretary of Health and Human Services is responsible for approving and publishing in the **Federal Register** major changes to these Guidelines. Examples of major changes include, but are not limited to, changes in cutoff concentrations, drugs tested, and

scientific methods used.

(b) The Division of Workplace Programs is responsible for making minor changes as a result of improvements in the available science and technology. These minor changes are published as program documents or as **Federal Register** notices.

§1.5 What do the terms used in these Guidelines mean?

The following definitions are adopted:

Aliquot A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.

Adulterated A specimen containing either a substance that is not a normal constituent for that type of specimen or containing an endogenous substance at a concentration that is not a normal physiological concentration.

Batch A set of specimens being tested as a group.

Blind Sample A sample with a known drug concentration or a negative sample used to evaluate the ability of a laboratory to test a specimen for drugs and/or metabolites. The laboratory does not know either the concentration of the drug or that it is a blind sample

Calibrator A solution of known concentration in the appropriate matrix that is used to define expected outcomes of a measurement procedure or to compare the response obtained with the response of a test specimen aliquot/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a calibration curve over a range of interest.

Canceled test The MRO determines that the result reported by the laboratory cannot support reporting either a positive nor a negative test to the employer.

Certifying Scientist (CS) The individual who is responsible for verifying the forensic and scientific supportability of a test result.

Chain of Custody (COC) Procedures to account for the integrity of each specimen or aliquot by tracking its handling and storage from point of specimen collection to final disposition of the specimen and its aliquots.

Chain of Custody Document The form(s) used to document the security of the specimen and all aliquots of the specimens during testing and storage. The form, which may account for an entire test batch, shall include the names and signatures of all individuals who handled the specimens or aliquots and the date and purpose of the access.

Collection Site A place where donors present themselves for the purpose of providing a specimen.

Collector A person who instructs and assists donors at a collection site and receives the specimen provided by the donor.

Confirmatory Drug Test A second analytical procedure performed on a specimen to identify and quantify the presence of a specific drug or metabolite.

Confirmatory Validity Test A second test performed on a specimen to further support a validity test result.

Control A sample used to evaluate whether or not the analytical procedure is operating within predefined tolerance limits.

Cutoff The concentration used to establish and report a specimen as negative or positive.

Dilute Refers to a specimen with less than normal physiological constituents.

Donor The individual from whom a specimen is collected.

Failed to Reconfirm The result reported when a laboratory is unable to corroborate the original result (i.e., positive, adulterated, substituted) reported to the Medical Review Officer.

Federal Custody and Control Form An OMB approved form used to document the collection, transport, security, and test results of the specimen.

Follow-up Test A specimen collected from a donor to ensure that the donor remains drug-free after being reinstated to a testing designated position.

HHS The Department of Health and Human Services or designee of the Secretary of Health and Human Services.

HHS-Certified Instrumented Initial Test Facility (IITF) A location where initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

HHS-Certified Laboratory A location where initial and confirmatory testing is performed under the supervision of an RP and where certifying scientists perform the final review and release of test results.

Initial Drug Test The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

Initial Validity Test The first test used to determine if a specimen is adulterated, diluted, or substituted.

Invalid Result The result reported when a scientifically supportable test result cannot be established for a specimen.

Medical Review Officer (MRO) A licensed physician who is certified to review, verify,

and report test results to the employer.

Negative Result The result reported by a laboratory or test facility when a specimen contains no drug or the concentration of the drug is less than the cutoff concentration for that drug or drug class.

Point of Collection Test Facility A collection site where a point of collection test is conducted.

Positive Result Laboratory result for a specimen that contains a drug or drug metabolite greater than or equal to the cutoff concentration.

Post Accident Test A specimen collected from a donor after the donor is involved in a job-related accident.

Pre-employment Test A specimen collected from a donor who is applying for a testing designated position.

Quality Control Sample A calibrator, control, or blind sample.

Random Test A specimen collected from a donor who is selected at random from a group of individuals who are included in a workplace drug testing program.

Reasonable Suspicion/Cause Test A specimen collected from a donor when there is sufficient evidence to indicate that the donor may have used an illicit substance.

Reconfirmed The result reported when a laboratory is able to corroborate the original result (i.e., positive, adulterated, substituted) reported to the Medical Review Officer.

Rejected for Testing The result reported by a laboratory or test facility when it does not perform any tests on the specimen because of a fatal flaw or an unrecovered correctable error.

Responsible Person (RP) The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory.

Responsible Technician (RT) The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified instrumented initial test facility.

Return to Duty Test A specimen collected from a donor to ensure that the donor is drug free prior to being reinstated in a testing designated position.

Sample A representative portion of a specimen or quality control material used for testing.

Secretary The Secretary of Health and Human Services or the Secretary's designee (e.g., Administrator, SAMHSA; Director, Division of Workplace Programs; a contractor; or other

recognized organization which acts on behalf of the Secretary in implementing these Guidelines).

Specimen Fluid or material derived from the body and which may be subdivided or concomitantly collected (if a split specimen is required).

Split Specimen A specimen collected at the collection site that is fluid or material derived from the body which has been subdivided or concomitantly collected and independently sealed in the presence of the donor. For urine, one void that is subdivided. For hair, one “harvest” that is subdivided by strands. For oral fluid, one specimen collected that is subdivided or two near simultaneously collected specimens. For sweat, a patch that is subdivided or two separate patches that are applied and removed simultaneously.

Standard Reference material of known purity or a solution containing a reference material at a known concentration.

Substituted A specimen that could not have been derived from the donor’s body at the time of collection.

Subpart B - Specimens

§2.1 What types of specimens may be collected?

A Federal agency may collect the following types of specimens as part of its workplace drug testing program:

- (a) Hair
- (b) Oral Fluid (Saliva)
- (c) Sweat
- (d) Urine

§2.2 Under what circumstances can the different types of specimens be collected?

Recommended reasons for specimen type selected are as follows:

<u>Type of Specimen</u>	<u>Reason For Test</u>
Hair	Pre-employment, random, return to duty, follow-up
Oral Fluid	Pre-employment, random, reasonable suspicion/cause, post accident, return to duty, follow-up
Sweat	Return to duty, follow-up
Urine	Pre-employment, random, reasonable suspicion/cause, post accident, return to duty, follow-up

§2.3 What is the minimum quantity of specimen to be collected?

(TO BE DETERMINED)

- (a) For Hair:
 - (1) 100 mg
- (b) For Oral Fluid: TBD
- (c) For Sweat: TBD
- (d) For Urine:
 - (1) 30 mL for a single specimen collection
 - (2) 45 mL for a split specimen collection (i.e., 30 mL for the primary specimen and 15 mL for the split specimen)

Subpart C - Drugs

§3.1 For which drugs can a specimen be tested?

The Executive Order 12564 defines "illegal drugs" as those included in Schedule I or II of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law. Federal agency drug testing programs must test all specimens for marijuana and cocaine use and may test for use of opiates, amphetamines, and phencyclidine.

§3.2 Can a specimen be tested for additional drugs?

(a) Reasonable suspicion/cause, or post accident specimens may be tested for any drug listed in Schedule I or II of the CSA.

(b) A Federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in section 3.1. Such approval shall be limited to the use of the appropriate science and technology and shall not otherwise limit agency discretion to test for any drug tested under paragraph (a) of this section.

§3.3 Can a specimen be used for other purposes?

(a) Specimens may be tested only for the drugs specified in these Guidelines and to determine specimen validity. They may not be used for any other analysis or test unless otherwise authorized by the Guidelines or by the Secretary.

(b) A specimen that tests negative by initial or confirmatory testing may, however, be pooled for use in a laboratory's internal quality control program.

(c) These Guidelines are not intended to prohibit any Federal agency specifically authorized by law to test for additional classes of drugs in its workplace drug testing program.

§3.4 What is the cutoff concentration for each drug by type of specimen collected?

NOTE: Cutoff concentrations are subject to change due to many factors that have yet to be resolved such as: laboratory analytical capability, MRO interpretation, and PT performance. These may or may not be the final cutoff concentrations for specific drug and/or drug metabolite for each specimen matrix.

Hair

Initial Test Cutoff Concentration (pg/mg)	
Marijuana metabolites.....	1.0
Cocaine metabolites.....	500
Opiate metabolites ¹	200
Phencyclidine.....	300
Amphetamines ²	500

¹ Labs are permitted to initial test all specimens for 6-AM at a 200 pg/mg cutoff

² Screening must significantly detect d-Methamphetamine, d-Amphetamine, MDMA, MDA & MDEA (~ 75 to125% cross-reactivity)

Confirmatory Test Cutoff Concentration (pg/mg)	
Marijuana metabolite ¹	0.05
Cocaine metabolite ²	100
Cocaine parent drug.....	1000
Opiates	
Morphine.....	200
Codeine.....	200
6-acetylmorphine	200
Hair 6-AM rule (TO BE DETERMINED)	
Phencyclidine.....	300
Amphetamines	
d-Amphetamine.....	300
d-Methamphetamine ³	300
MDMA.....	300
MDA.....	300
MDEA.....	300

¹ Delta-9-tetrahydrocannabinol-9-carboxylic acid

² Benzoylcegonine (BE/Cocaine ratio >= 0.1)

³ Specimen must also contain d-Amphetamine at a concentration ≥ 50 pg/m

Oral Fluid

Initial Test Cutoff Concentration (ng/mL)	
Marijuana metabolites.....	4
Cocaine metabolites.....	20

Opiate metabolites ¹	40
Phencyclidine.....	4
Amphetamines ²	160

¹ Labs are permitted to initial test all specimens for 6-AM at a 4 ng/mL cutoff

² Screening must significantly detect d-Methamphetamine, d-Amphetamine, MDMA, MDA & MDEA (~ 75 to 125% cross-reactivity)

Confirmatory Test Cutoff Concentration
(ng/mL)

THC Parent drug.....	2
Cocaine metabolite ²	8
Opiates	
Morphine.....	40
Codeine.....	40
6-acetylmorphine	4
Phencyclidine.....	2
Amphetamines	
d-Amphetamine.....	160
d-Methamphetamine ³	160
MDMA.....	160
MDA.....	160
MDEA.....	160

² Benzoylcegonine

³ Specimen must also contain Amphetamine at a concentration \geq (TO BE DETERMINED) ng/mL

Sweat

Initial Test Cutoff Concentration
(ng/ 2.5 mL eluate)

Marijuana metabolites.....	1.5
Cocaine metabolites.....	10
Opiate metabolites ¹	10
Phencyclidine.....	7.5
Amphetamines ²	10

¹ Labs are permitted to initial test all specimens for 6-AM at a 10 ng/2.5 mL

eluate cutoff

² Screening must significantly detect d-Methamphetamine, d-Amphetamine, MDMA, MDA & MDEA (~ 75 to 125% cross-reactivity)

Confirmatory Test Cutoff Concentration (ng/2.5 mL eluate)	
THC parent drug.....	0.5
Cocaine parent drug.....	10
Cocaine metabolite ²	10
Opiates	
Morphine.....	10
Codeine.....	10
6-acetylmorphine	10
Phencyclidine.....	7.5
Amphetamines	
d-Amphetamine.....	10
d-Methamphetamine ³	10
MDMA.....	10
MDA.....	10
MDEA.....	10

² Benzoylcegonine

³ Specimen must also contain Amphetamine at a concentration \geq (TO BE DETERMINED) ng/mL

Urine

Initial Test Cutoff Concentration (ng/mL)	
Marijuana metabolites.....	50
Cocaine metabolites.....	150
Opiate metabolites ¹	2000
Phencyclidine.....	25
Amphetamines ²	500

¹ Labs are permitted to initial test all specimens for 6-AM at a 10 ng/mL cutoff

² Screening must significantly detect d-Methamphetamine, d-Amphetamine, MDMA, MDA, & MDEA (~ 75 to 125% cross-reactivity)

Confirmatory Test Cutoff Concentration (ng/mL)	
Marijuana metabolite ¹	15

Cocaine metabolite ²	100
Opiates	
Morphine.....	2000
Codeine.....	2000
6-acetylmorphine ⁴	10
Phencyclidine.....	25
Amphetamines	
d-Amphetamine.....	250
d-Methamphetamine ³	250
MDMA.....	250
MDA.....	250
MDEA.....	250

¹ Delta-9-tetrahydrocannabinol-9-carboxylic acid

² Benzoylcegonine

³ Specimen must also contain d-Amphetamine at a concentration \geq 100 ng/mL

⁴ Labs are permitted to test for 6-AM concurrently with Morphine/Codeine and to report 6-AM alone at or above 10 ng/mL

Subpart D - Collectors

§4.1 Who may collect a specimen?

- (a) An individual certified to collect specimens.
- (b) The direct supervisor of a donor may not act as the collector when that donor is tested.

§4.2 What are the training requirements for a collector?

A collector must have training that includes:

- (a) Instruction on the collection procedure for each type of specimen;
- (b) Training on chain of custody and recordkeeping; and
- (c) A written examination covering the content of the training.

§4.3 What certification must a collector have?

A collector must be certified by an HHS-approved collector certification program for each type of specimen being collected and must be re-certified every three years.

§4.4 What are the requirements of an HHS-approved collector certification program?

The collection certification program must:

- (a) Submit an application to HHS to become an HHS-approved collector certification program.
- (b) Ensure that collector candidates for certification have attended a training program meeting the training requirements for a collector.
- (c) Require passing a written examination.
- (d) Ensure that certified collectors are kept current regarding any changes in the collection procedures for each type of specimen.
- (e) Annually audit the activities of at least 10% of the certified collectors on a random basis and submit a summary audit report to HHS within 60 days after the end of the calendar year.
- (f) Maintain a current list of individuals who have been certified as collectors. The list must be updated on a monthly basis. The list must be provided to HHS electronically for posting on the HHS website.

§4.5 Under what circumstances must a certified collector be retrained?

- (a) A collector must be retrained when:
 - (1) The collection procedure changes significantly (e.g., a new CCF is used); or
 - (2) The collector makes a mistake that causes a test to be canceled.
- (b) The required retraining:
 - (1) Must be focused in the specific area of collection procedures that changed or on the mistake that caused the test to be canceled; and
 - (2) Must be documented in writing by collection certification program.

§4.6 What must an organization do before a collector is permitted to collect specimens for Federal agencies?

An organization must:

- (a) Ensure that the collector has a current collector certification document issued by an HHS-approved collector certification program;
- (b) Retain a copy of collector's certification document as long as the person performs collector functions and for 2 years after the collector leaves the organization; and
- (c) Provide to the collector the name and telephone number of the employer's representative to contact about problems or issues that may arise during a specimen collection procedure.

Subpart E - Collection Sites

§5.1 Where can a collection for a drug test take place?

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.

(b) The selection of an appropriate collection site will depend on the type of specimen being collected.

§5.2 What are the requirements for a collection site?

A collection site must have the following:

- (a) A suitable clean surface for handling the specimen and completing the required paperwork;
- (b) A secure temporary storage capability to maintain a specimen until it is tested or shipped to the laboratory;
- (c) A facility to provide donor privacy appropriate to the specimen being collected;
- (d) A facility to restrict access to only authorized personnel during the collection;
- (e) Ability to restrict access to collection supplies; and
- (f) Ability to store records securely.

§5.3 How long must collection site records be stored?

Collection site records must be stored for a minimum of 2 years by the collector or the collector's employer.

§5.4 How does the certified collector ensure the security of a specimen at the collection site?

A certified collector must do the following to maintain the security of a specimen:

- (a) Do not allow unauthorized personnel to enter the collection site during the collection;
- (b) Perform only one specimen collection at a time;
- (c) Restrict access to collection supplies before and during the collection;
- (d) Ensure that you are the only person other than the donor to handle the unsealed specimen; and
- (e) Immediately seal the specimen in the presence of the donor.

§5.5 What are the privacy considerations when collecting a specimen?

The requirements for specimen collection are as follows depending on the type of specimen being collected:

- (a) For urine, the donor must have visual privacy while providing the specimen unless:
 - (1) There is a reason to believe that the donor may alter or substitute the specimen to be provided; or
 - (2) A direct observed collection was authorized.
- (b) For hair, head hair is collected unless it is not available. The policy for collection of hair from other areas of the body is described in the HHS Specimen Collection Handbook.
- (c) For sweat, the sweat patch will be applied by the collector to the donor's upper arm, chest, or back. The donor must be allowed privacy during the application and removal of the patch by the

collector.

(d) For oral fluid, the collection device must be inserted into and removed from the donor's mouth by the donor in the presence of the collector. The donor will be observed by the collector during this entire process.

(e) A complete description of collection procedures for each specimen are in the HHS Specimen Collection Handbook for Federal Workplace Drug Testing Programs.

§5.6 What supplies are needed at the collection site?

(a) A complete list of the supplies needed to collect each type of specimen is in the HHS Specimen Collection Handbook for Federal Workplace Drug Testing Programs.

(b) The handbook is available on the following website: www.health.org/workpl.htm

Subpart F - Federal Drug Testing Custody and Control Forms

§6.1 What form is used to document a specimen collection?

(a) An Office of Management and Budget (OMB)-approved Federal Drug Testing Custody and Control Form (CCF) must be used to document the collection of a specimen at the collection site.

(b) The form is used to document chain of custody from the time a donor gives the specimen to the collector until the specimen is received for testing.

(c) The Federal CCF used for each type of specimen collected is available from a number of different sources. A sample of the OMB-approved Federal CCF for each type of specimen is available at the following website: www.health.org/workpl.htm

(d) Federal agencies and employers regulated by the Department of Transportation (DOT) are required to use the OMB-approved Federal CCF for their workplace drug testing programs.

§6.2 What happens if an approved form is not available or is not used?

(a) When the collector either by mistake or as the only means to document a collection under difficult circumstances (e.g., post accident test with insufficient time to obtain the CCF) uses a non-Federal form for a regulated collection, the use of a non-Federal form is not a reason for the laboratory to reject the specimen for testing or for the MRO to cancel the test.

(b) If the testing facility or the MRO discovers the use of the incorrect form, a signed statement must be obtained from the collector stating the reason why the Federal CCF was not used for the regulated collection.

Subpart G - Collection Device

§7.1 What is a collection device?

- (a) A collection device is considered to be the following for each type of specimen collected:
 - (1) For urine, it is the single-use plastic specimen container and/or bottle.
 - (2) For hair, it is the foil and single-use plastic bag in which the hair sample is placed.
 - (3) For oral fluid, it is the applicator, pad, or aspirator placed in the mouth.
 - (4) For sweat, it is the patch that is placed on the skin.
- (b) A collection device must not affect or alter the specimen collected. The supplier of a collection device must evaluate the device to ensure that it does not affect the specimen collected.

§7.2 Must the collection device be cleared by the FDA?

- (a) If the collection device is a unique and integral part of the collection procedure and the analytical testing procedure, it must be cleared by the FDA as a medical device (e.g, the sweat patch and aspirator for oral fluid).
- (b) Single-use items (such as, plastic bottles, plastic bags, foil) are not unique collection devices and, therefore, are not required to be cleared by the FDA.

Subpart H - Specimen Collection Procedure

§8.1 What must the certified collector do before starting the collection procedure?

The certified collector must do the following before starting the collection procedure:

- (a) Verify the donor's identification;
- (b) Provide identification to the donor if the donor asks;
- (c) Explain the basic collection procedure to the donor;
- (d) Request the donor to read the instructions on the back of the CCF; and
- (e) Answer any reasonable and appropriate question the donor may have regarding the collection procedure.

§8.2 What are the basic requirements for collecting any type of specimen?

The basic requirements are:

- (a) The donor removes any unnecessary outer garments (such as, a coat or jacket).
- (b) The donor washes and dries his or her hands prior to handling the collection device, if such handling is part of the collection procedure. After washing hands, the donor must remain in the presence of the collector and must not have access to anything that could be used to affect the specimen.
- (c) The collector and donor observe the selection and opening of the collection device used to collect the specimen.
- (d) After a specimen is collected, the collector inspects the specimen for signs of tampering.
- (e) A specimen suspected of being tampered with is sent to the laboratory for testing and the collector documents the reason for suspicion on the Federal CCF.
- (f) The collector must get permission to immediately collect another specimen when a tampered specimen is collected. This second specimen must also be sent to the laboratory.
- (g) The collector and donor must keep the specimen in view at all times prior to sealing the specimen container.
- (h) A tamper-evident label/seal must be used to secure the specimen container.
- (i) The donor must initial the label and the collector must date the label after it is used to secure the specimen container.
- (j) The collector must complete the CCF and distribute each copy as required.

§8.3 Where can I find the collection procedure for each type of specimen?

- (a) A complete description of the collection procedure used to collect each type of specimen is in the HHS Specimen Collection Handbook for Federal Workplace Drug Testing Programs.
- (b) The handbook is available on the following website: www.health.org/workpl.htm

Subpart I - National Laboratory Certification Program

§9.1 What is the National Laboratory Certification Program (NLCP)?

(a) The HHS National Laboratory Certification Program (NLCP) is the program established to certify laboratories before they are permitted to test specimens that are collected for Federal agency or federally regulated workplace drug testing programs. The NLCP includes a performance testing (PT) program and a laboratory inspection program.

(b) An applicant laboratory is required to pass 3 consecutive sets of initial PT samples and an initial inspection before becoming HHS-certified.

(c) An HHS-certified laboratory is required to test quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections every 6 months thereafter.

(d) A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for and maintain certification. The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any laboratory suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any laboratory to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any laboratory to send specimens or specimen aliquots to another laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for Federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

§9.2 How does a laboratory apply to the NLCP?

(a) A laboratory interested in becoming an HHS certified laboratory must submit an NLCP application form.

(b) The application form requires the applicant laboratory to provide detailed information on both the administrative and analytical procedures the laboratory proposes to use for testing regulated specimens after it is certified.

(c) The NLCP application form is available at the following website: www.health.org/workpl.htm

§9.3 What are the qualitative and quantitative specifications of a performance test (PT) sample?

(a) A PT sample is a sample that may contain:

- (1) The drugs and/or metabolites in the drug classes that each laboratory must have the capability to test for; or
- (2) More than one drug class (but generally no more than two drug classes) to imitate real donor specimens.

(b) The concentration of the drugs and/or metabolites in a PT sample may be:

- (1) At least 20 percent above the cutoff concentration for either the initial test or the confirmatory test (depending on which is to be evaluated), but will not exceed 10 times the confirmatory cutoff;

- (2) As low as 40 percent of the cutoff concentration when the PT sample is designated as a retest sample; or
- (3) At another concentration for a special purpose.
- (c) A negative PT sample may not contain a measurable amount of a target drug and/or metabolite.
- (d) A PT sample may contain an interfering substance(s).
- (e) For each PT cycle, the set of PT samples going to each laboratory will vary but, within each calendar year, each laboratory will have analyzed the same total set of samples.
- (f) The laboratory must, to the greatest extent possible, handle, test, and report a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.

§9.4 What are the performance testing requirements for an applicant laboratory?

An applicant laboratory must satisfy the following criteria on 3 consecutive sets of initial PT samples:

- (a) No false positive results;
- (b) Correctly identify and confirm 90 percent of the total drug challenges on the 3 sets of samples;
- (c) The quantitative values for at least 80 percent of the total drug challenges must be within ± 20 percent of the calculated reference group mean;
- (d) No quantitative value on a drug concentration may differ by more than 50 percent from the calculated reference group mean; and
- (e) For an individual drug, correctly detect and quantify at least 50 percent of the total drug challenges.

§9.5 What are the performance testing requirements for a certified laboratory?

A certified laboratory must satisfy the following criteria on the maintenance PT samples to maintain its certification:

- (a) Correctly identify and confirm 90 percent of the total drug challenges over two consecutive PT cycles;
- (b) Correctly quantify 80 percent of the total drug challenges within ± 20 percent of the appropriate reference or peer group mean as measured over two consecutive PT cycles;
- (c) Have no more than one quantitative result differ more than 50 percent from the target value over two consecutive PT cycles; and
- (d) For any individual drug, correctly detect and quantify at least 50 percent of the total drug challenges.

§9.6 What are the inspection requirements for an applicant laboratory?

- (a) An applicant laboratory is inspected by a team of at least two inspectors.
- (b) Each inspector conducts an independent evaluation and review of all aspects of the laboratory's procedures and facilities using the guidance provided by the Secretary and the National Laboratory Certification Program inspection checklist.
- (c) To become certified, an applicant laboratory must satisfy the minimum requirements as stated in these Guidelines.
- (d) The applicant laboratory must be separately inspected for each specimen matrix for which it has applied. The inspection may be conducted concurrently, but the inspectors must review all appropriate data in distinct audits.

§9.7 What are the maintenance inspection requirements for a certified laboratory?

- (a) A certified laboratory must undergo an inspection 3 months after becoming certified and then inspected every 6 months thereafter.
- (b) A certified laboratory is inspected by a team of at least two inspectors. The number of inspectors required is dependent on the workload of the laboratory.
- (c) Each inspector conducts an independent evaluation and review of all aspects of the laboratory's procedures and facilities using the guidance provided by the Secretary and the National Laboratory Certification Program inspection checklist.
- (d) To remain certified, a laboratory must continue to satisfy the minimum requirements as stated in these Guidelines for that specimen matrix.

§9.8 Who may inspect a laboratory participating in the NLCP?

- (a) The Secretary, a Federal agency using a certified laboratory, or the contractor awarded the HHS NLCP contract may inspect a laboratory at any time.
- (b) An individual may serve as an NLCP inspector if he or she satisfies the following criteria:
 - (1) Has experience and an educational background similar to that required for either the responsible person or the certifying scientist as described in subpart K;
 - (2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other NLCP documents;
 - (3) Submits a resume and documentation of qualifications to HHS;
 - (4) Attends NLCP approved training; and
 - (5) Submits an acceptable inspection report and performs acceptably as a trainee inspector on an inspection.

§9.9 What happens if a laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

- (a) If an applicant laboratory fails to satisfy the requirements established for the initial certification process, the applicant laboratory must start the initial certification process from the beginning.
- (b) If a certified laboratory fails to satisfy the minimum requirements, the laboratory is given a period of time (e.g., 5 or 30 working days depending on the nature of the issue) to provide any explanation for its performance and evidence that any deficiency has been corrected.
- (c) A laboratory's certification may be revoked, suspended, or no further action taken depending on the seriousness of the errors and whether there is evidence that any deficiency has been corrected and that current performance meets the requirements for a certified laboratory.
- (d) A certified laboratory may be required to undergo a special inspection or to test additional PT samples, depending on the nature of the performance, to verify that any deficiency has been corrected.
- (e) If a laboratory's certification is revoked or suspended, the laboratory is not permitted to test specimens for Federal agencies or federally regulated employers until the suspension is lifted or the laboratory has successfully completed the certification requirements as a new applicant laboratory.

§9.10 Where is a list of certified laboratories published?

(a) A list of HHS-certified laboratories and the specimen matrix they are certified to perform, is published monthly in the **Federal Register** and is also available on the following website: www.health.org/workpl.htm.

(b) An applicant laboratory is not included on the list.

Subpart J - Blind Samples Submitted by an Agency

§10.1 What are the requirements for a blind sample?

- (a) A blind sample must be validated as to its content by the supplier using initial and confirmatory tests.
- (b) The supplier must provide information regarding the shelf life of the blind sample.
- (c) If the blind sample is positive, the concentration of the drug it contains must be between 1.5 and 2 times the initial drug test cutoff concentration.

§10.2 What are the requirements for Federal agencies to submit blind samples?

- (a) Each Federal agency is required to have both negative and positive blind samples submitted with its donor specimens.
- (b) During the initial 90-day period of any new Federal agency drug testing program, the agency must ensure that at least 5 percent of the total number of donor specimens submitted are blind samples.
- (c) After the initial 90-day period, the Federal agency must ensure that a minimum of 3 percent of the total number of donor specimens are blind samples.
- (d) Approximately 80 percent of the blind samples may be negative (i.e., certified to contain no drug) and the remaining positive for one or more drugs.
- (e) Each positive sample must be spiked only with those drugs for which the Federal agency is testing.

§10.3 How is a blind sample submitted to the laboratory?

- (a) A blind sample is either purchased by the Federal agency and given to the collector or the collector purchases the blind sample from a supplier and submits the blind sample with the Federal agency's donor specimens.
- (b) A blind sample is always submitted using the same OMB-approved Federal CCF as used for a donor specimen. The collector provides the required information to ensure that the CCF has been properly completed as well as providing fictitious initials on the specimen label/seal. The collector must indicate that the sample is a "blind sample" on the MRO copy where the donor would normally provide a signature.
- (c) Each Federal agency must ensure that the required blind samples are distributed throughout the total number of donor specimens rather than submitted as a single group of samples.

§10.4 What happens if an inconsistent result is reported on a blind sample?

If an inconsistent result is reported on a blind sample:

- (a) The MRO, individual, or group responsible for the oversight of the agency's blind sample program must notify both the Federal agency and the Federal office responsible for maintaining the NLCP; and
- (b) The Federal office responsible for the NLCP will initiate an investigation to determine the cause of the error and send a report to the MRO and the Federal agency describing the investigation and corrective action taken.

Subpart K - Laboratory Requirements

§11.1 What is a Standard Operating Procedure Manual?

- (a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all laboratory operations. When followed, it ensures that all specimens are tested using the same procedures and in a consistent manner.
- (b) The SOP manual must include, but is not limited to, a detailed description of the following:
 - (1) Chain-of-custody procedures;
 - (2) Accessioning;
 - (3) Security;
 - (4) Quality control/quality assurance programs;
 - (5) Analytical methods and procedures;
 - (6) Equipment and maintenance programs;
 - (7) Personnel training;
 - (8) Reporting procedures; and
 - (9) Computers, software, laboratory information management systems
- (c) All procedures in the SOP manual must be in compliance with these Guidelines and NLCP Program Documents.
- (d) A copy of all procedures that have been replaced or revised and the dates on which they were in effect must be maintained to allow the laboratory to retrieve the procedures that were used to test a specimen.

§11.2 What are the responsibilities of the responsible person (RP)?

- (a) Manage the day-to-day operations of the drug testing laboratory even where another individual has overall responsibility for an entire multi-specialty laboratory.
- (b) Ensure that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. The RP must ensure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.
- (c) Maintain a complete, current SOP manual that is available for personnel in the drug testing laboratory, and followed by those personnel. The SOP manual must be reviewed, signed, and dated by the RP(s) whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory.
- (d) Maintain a quality assurance program to assure the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and standards; monitor quality control testing; document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.
- (e) Implement all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results, and deficiencies identified during inspections. This individual must ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the results provided are accurate and reliable.
- (f) Qualify as a certifying scientist for positive, adulterated, and substituted test results.

§11.3 What qualifications must the RP have?

The RP must be:

- (a) Certified as a laboratory director by the State in forensic or clinical laboratory toxicology; or have a Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, pharmacology, or toxicology; or have training and experience comparable to a Ph.D. in one of the natural sciences with additional training and laboratory/research experience in biology, chemistry, pharmacology, or toxicology; and
- (b) Have appropriate experience in analytical forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse; and
- (c) Have appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

§11.4 What qualifications must an individual have to certify a result reported by a laboratory?

- (a) The certifying scientist (CS) who certifies a positive, adulterated, or substituted test result must have:
 - (1) A bachelor's degree in the chemical or biological sciences, medical technology, or similar field;
 - (2) Training and experience in the analytical methods and procedures used by the laboratory that are relevant to the results that the individual certifies; and
 - (3) Training and experience in reviewing and reporting test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.
- (b) The certifying scientist (CS) who certifies a negative test result must have:
 - (1) Training and experience in the analytical methods and procedures used by the laboratory that are relevant to the results that the individual certifies; and
 - (2) Training and experience in reviewing and reporting test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

§11.5 What qualifications and training must other laboratory personnel have?

- (a) All laboratory staff (e.g., technicians, administrative staff) must have the appropriate training and skills for the tasks assigned.
- (b) Each individual working in a certified laboratory must be properly trained before he or she is permitted to work independently in any area of the laboratory with regulated specimens.

§11.6 What security measures must a laboratory maintain?

- (a) A laboratory must control access to the drug testing facility and ensure that no unauthorized individual can gain access to specimens, aliquots, or records.
- (b) With the exception of personnel authorized to conduct inspections on behalf of Federal, state, or other accrediting agencies for which the laboratory is testing specimens or on behalf of the Secretary or emergency personnel (e.g., firefighters and medical rescue teams), all authorized visitors must be escorted at all times.
- (c) A laboratory must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized escorted visitors accessing secured areas.

§11.7 What are the laboratory chain of custody requirements for a specimen or an aliquot?

(a) A laboratory must use chain of custody procedures to document the receipt, handling, and transfer of a specimen or an aliquot throughout the testing process and until final disposition.

(b) Chain of custody must be documented by using either hard copy procedures or electronic procedures.

(c) Chain of custody documentation must be completed at the time of the transaction.

§11.8 What test(s) does an HHS-certified laboratory perform on a specimen received after a POCT?

The HHS-certified laboratory must test the specimen in the same manner as a regulated specimen that had not been previously tested.

§11.9 What test(s) does an HHS-certified laboratory perform on a specimen received from an IITF?

The HHS-certified laboratory conducts either:

(a) The confirmatory test only for the drug or metabolite identified in the specimen by the IITF; or

(b) A confirmatory test to verify the validity test result for an adulterated or substituted specimen.

§11.10 What is a laboratory initial test?

(a) A laboratory initial test is a test for drugs and/or for specimen validity. The data is generated by an instrument and is based on calibrators and controls registered by the instrument's detector.

(b) A laboratory initial test is a test used to differentiate a negative specimen from those that require further testing.

(c) A laboratory initial test may include, but is not limited to, the following techniques: immunoassay or chromatographic separation coupled with an appropriate detector.

(d) An initial test must be validated by the laboratory before it is used to test donor specimens.

(e) Commercially distributed reagents used for initial tests must have FDA clearance.

(f) A laboratory may conduct a second initial test prior to the confirmatory test. If the laboratory uses a second initial test, the second initial test is subject to the same requirements as the first initial test.

§11.11 What must a laboratory do to validate an initial test method?

(a) The laboratory must demonstrate and document:

(1) The ability to differentiate positive and negative samples;

(2) The performance of the test around the cutoff concentration; and

(3) The performance of the test results at several concentrations between 0 and 150 percent of the cutoff concentration.

(b) Performance of new lots must be verified prior to being placed into service.

§11.12 What are the quality control requirements when conducting an initial test?

- (a) Each batch of specimens must contain the following types of QC samples:
 - (1) At least one control certified to contain no drug or metabolite;
 - (2) At least one control that has the concentration of the drug or metabolite at 25 percent above the cutoff concentration; and
 - (3) At least one control that has the concentration of the drug or metabolite at 25 percent below the cutoff concentration.
- (b) At least 10 percent of the batch must be calibrators and controls.
- (c) A laboratory must document that any carryover that might occur between aliquots during the initial testing is detectable and corrected.

§11.13 What is a confirmatory drug test?

- (a) A confirmatory drug test is an analytical procedure performed on a separate aliquot of the specimen to identify the presence of a specific drug or metabolite.
- (b) The procedure used must combine chromatographic separation and mass spectrometric identification in the same procedure (e.g., GC/MS, LC/MS, GC/MS/MS, LC/MS/MS).
- (c) A confirmatory test must be validated before it can be used to test specimens.

§11.14 What must a laboratory do to validate a confirmatory drug test method?

The laboratory must demonstrate and document:

- (1) The linear range of the analysis;
- (2) The limit of detection;
- (3) The limit of quantitation;
- (4) The accuracy and precision at the cutoff concentration;
- (5) The accuracy and precision at 40 percent of the cutoff concentration; and
- (6) The potential for interfering substances.

§11.15 What are the quality control requirements when conducting a confirmatory drug test?

- (a) Each batch of specimens must contain the following types of QC samples:
 - (1) A single-point calibrator at the cutoff;
 - (2) At least one control certified to contain no drug or metabolite;
 - (3) At least one control that has the concentration of the drug or metabolite within 25 percent above the cutoff concentration;
 - (4) At least one control that has the concentration of the drug or metabolite at or below 40 percent of the cutoff concentration; and
 - (5) At least one control in every batch must be blind.
- (b) The linear range, limit of detection, and limit of quantitation must be documented and periodically re-evaluated for each confirmatory drug test.
- (c) A laboratory must document that any carryover that might occur between aliquots/extracts in the confirmatory batch is detectable and corrected.

§11.16 Is a laboratory allowed to conduct any additional tests on a specimen?

- (a) A laboratory is permitted to conduct additional tests to determine the validity of a specimen.
- (b) The validity tests that may be used will depend on the type of specimen being tested.
- (c) Specific guidance on conducting validity tests is described in NLCP program documents.
- (d) No further testing of a negative specimen for drugs is permitted and the specimen must either be discarded or pooled for use in the laboratory's internal quality control program.

§11.17 What are the laboratory reporting requirements for a specimen test results?

- (a) The laboratory must report the test result within 5 (on average) working days after receipt of the specimen.
- (b) A specimen identified as positive for a drug or metabolite on an initial test must be confirmed positive before a positive result can be reported to the MRO.
- (c) The laboratory may report only that a specimen is positive without including the concentration of the drug unless the MRO requests the concentration. The MRO may make a “blanket request” to automatically receive quantitative results on all positive drug results. This does not include results for specimen validity testing.
- (d) The laboratory can only report a test result to an MRO.
- (e) The laboratory may transmit results to the MRO electronically in a manner designed to ensure the confidentiality of the information and the security of the data transmission, and limit access to any data transmission, storage, and retrieval system.
- (f) A hard copy of the CCF must be sent to the MRO when the result is reported as either positive for a specific drug, adulterated, substituted, rejected for testing, or invalid result.
- (g) An electronic laboratory report containing the required information is sufficient to report a negative result to the MRO.
- (h) A test result may not be provided telephonically; however, the MRO may call the laboratory to discuss a result.
- (i) The laboratory may also send the MRO a separate laboratory report that gives additional information (e.g., cutoffs) for the specimen tested.
- (j) A laboratory must use its own form to report the results for the retesting of a single specimen.

§11.18 How long must a laboratory retain a specimen?

- (a) A laboratory must retain a specimen that was reported either positive, adulterated, substituted, or invalid result for a minimum of 1 year.
- (b) A retained specimen must be kept in a secured location that is appropriate for that type of specimen (e.g., frozen storage for urine) to ensure its availability for any necessary retesting during an administrative or judicial proceeding.
- (c) Within the 1-year storage period, a Federal agency may request a laboratory to retain a specimen for an additional period of time. If no such request is received, a specimen may be discarded.

§11.19 How long must a laboratory retain records?

- (a) A laboratory must retain all records generated to support test results for at least 2 years.
- (b) A Federal agency may request the laboratory to maintain records associated with a particular specimen under legal challenge for an indefinite period.

§11.20 Can a laboratory store records electronically?

Yes (Guidance will be developed at a later date)

§11.21 What summary report must a laboratory provide to a Federal agency?

(a) A laboratory must provide a summary report to a Federal agency for which it tests specimens when requested by the Federal agency.

(b) The report must not include any personal identifying information for the specimens tested.

(c) The laboratory is required to have statistical data available for the preceding 6 months and be able to provide this information within 5 working days of receipt of request.

(d) The summary report must contain the following information:

(1) Total number of specimens reported

(2) Number of specimens grouped by reason for test

A. Random

B. All others combined

(3) Number of specimens rejected for testing

(4) Number of specimens reported:

(a) Positive for each drug

(b) Adulterated

(c) Substituted

§11.22 What information is available to the donor?

(a) A Federal employee who is the subject of a drug test may, upon written request through the MRO and the Federal agency, have access to a documentation package.

(b) The documentation package is limited to copies of the analytical data for the donor's specimen and associated quality control samples, chain of custody records, and other administrative documents generated during the handling and testing of the donor's specimen that support the test result reported by the laboratory.

§11.23 What type of relationship is prohibited between a laboratory and an MRO?

Refer to Subpart N, §14.5

§11.24 What information must a certified laboratory provide to its private sector clients?

When a certified laboratory uses procedures to test private sector client specimens that are different from those for which it is certified, it must inform the private sector client that its specimens are not being tested under the Guidelines and the procedures are not subject to review by the NLCP.

Subpart L - Point of Collection Test (POCT)

§12.1 What is a Point of Collection Test?

A point of collection test (POCT) is an initial test conducted at the collection site to determine either the presence of drugs or to determine the validity of a specimen.

§12.2 What types of POCT devices are there?

POCT devices are:

- (a) Non-instrumented for which the endpoint result is obtained by visual evaluation (i.e., read by human eye); or
- (b) Instrumented for which the endpoint result is obtained by instrumental evaluation (e.g., densitometer, spectrophotometer).

§12.3 What are the requirements for a POCT device?

- (a) The POCT device must be cleared by the FDA.
- (b) The POCT device must be included on the HHS Conforming Products List.

§12.4 Where is the list of HHS Conforming Products published?

The list is published monthly in the Federal Register and is also available on the following website:

§12.5 Which types of specimens may be tested using a POCT?

- (a) Oral fluid (Saliva)
- (b) Urine

§12.6 What are the cutoff concentrations when using a POCT?

The cutoff concentrations for POCTs are the same as those for laboratory based initial tests. The cutoff concentrations for drugs/metabolites are listed in Subpart C of these Guidelines.

§12.7 What are the collector and the collection site requirements to conduct a POCT?

The following requirements must be present at a location before a POCT can be performed:

- (a) The collector must be certified to collect the type of specimen being collected;
- (b) The individual conducting the POCT (a.k.a. the tester; may also be the collector) must be certified to conduct the POCT by an HHS-recognized POCT certification program (e.g., POCT manufacturer, private sector organization);
- (c) The collection site (mobile or permanent) must satisfy all the requirements for a collection site; and
- (d) Appropriate supplies and manuals must be available.

§12.8 What are the requirements to become an HHS-approved POCT certification program?

(a) The manufacturer/organization managing the POCT certification program must apply to HHS to become an HHS-approved POCT Certification Program.

(b) The organization must:

(1) Provide a training program that includes:

(a) Instruction on the use of the POCT;

(b) Interpretation of results;

(c) Training on chain of custody, reporting, and recordkeeping; and

(d) A written examination covering the content of the training.

(2) Ensure that certified testers are kept current regarding any changes in the POCT.

(3) Audit annually the activities of at least 10% of the certified testers on a random basis and submit the audit report to HHS within 60 days after the end of the calendar year.

(4) Maintain a current list of individuals who have been trained to use the POCT. The list must be updated on a monthly basis. The list must be provided to HHS electronically for posting on the HHS website.

§12.9 May the donor observe the POCT being performed?

No, the donor must leave prior to the POCT.

§12.10 What are the procedures for conducting a POCT?

There are two types of POCT devices:

1) Integrated specimen collection container/testing device; and

2) Separate specimen collection container and testing device.

(a) The donor must not have access to the testing device (that is, in the case of an integrated specimen container and testing device, a separate collection device must be used).

(b) A POCT may be performed on an aliquot of the specimen that has been separated from the specimen, or the entire specimen is transferred to an integrated specimen collection container/testing device.

(c) Chain of custody must be maintained and documented for the specimen and any aliquot used for the POCT.

(d) A specimen that tests negative must be discarded unless it is submitted as part of the quality assurance program.

(e) The certified tester must report a negative test result to the MRO and forward a presumptive positive, adulterated, or substituted specimen to an HHS-certified laboratory for testing.

(f) The certified tester must complete a POCT before beginning another POCT.

§12.11 What are the quality control requirements when conducting POCTs?

(a) The following QC samples must be analyzed:

(1) Each day testing is performed, at least one negative control (i.e., certified to contain no drug or drug metabolite) and one positive control (i.e., the concentration of the drugs or metabolites are at least or within 25 percent above the cutoff concentration) must be

tested;

or

- (2) A positive QC sample must be tested immediately after each presumptive positive, adulterated, or substituted donor specimen.
- (b) At least 1 specimen out of every twenty specimens that are tested negative must be submitted to an HHS-certified laboratory as part of a Quality Assurance Program.

§12.12 What action must be taken when a POCT quality control sample fails?

(a) For option (a)(1) in section 12.11, the failed quality control sample must be sent to an HHS-certified laboratory. The POCT tester must continue testing QC samples until acceptable results are obtained before testing donor specimens. If acceptable QC results cannot be obtained, donor specimens must be sent directly to the HHS-certified laboratory.

(b) For option (a)(2) in section 12.11, the POCT tester must send both the failed QC sample and the presumptive positive, adulterated, or substituted donor specimen to the HHS-certified laboratory. The POCT tester must immediately test a negative QC sample before any donor specimens are tested.

§12.13 What are the qualitative and quantitative specifications for PT samples that are used to evaluate a POCT manufacturer?

- (a) A PT sample is a sample that may contain:
 - (1) The drugs and/or metabolites in the drug classes that each POCT must have the capability to test for; or
 - (2) More than one drug class (but generally no more than two drug classes) to imitate real donor specimens.
- (b) The concentration of the drugs and/or metabolites in a PT sample may be:
 - (1) At least 50 percent above the cutoff concentration for the initial test; or
 - (2) At another concentration for a special purpose.
- (c) A negative PT sample may not contain a measurable amount of a target drug and/or metabolite.
- (d) A PT sample may contain an interfering substance(s).
- (e) For each PT cycle, the set of PT samples going to each POCT manufacturer will vary but, within each calendar year, each POCT manufacturer will have analyzed the same total set of samples.

§12.14 Who may inspect a POCT manufacturer?

The Secretary, a Federal agency using a POCT, or the contractor awarded the HHS inspection contract may inspect a POCT manufacturer at any time.

§12.15 What are the inspection requirements for a POCT manufacturer?

(a) Each POCT manufacturer is inspected annually by at least one inspector under the HHS National Laboratory Certification Program.

(b) The inspector conducts an evaluation and review of all aspects of the POCT manufacturer's procedures and facilities using NLCP guidance.

§12.16 What happens if a POCT manufacturer does not satisfy the minimum inspection requirements?

(a) The NLCP will give the POCT manufacturer thirty days to complete appropriate corrective action.

(b) If corrective action has not been completed within 30 days, the POCT will be removed from the SAMHSA/HHS Conforming Products List until the manufacturer can return the POCT to compliance.

§12.17 Is a POCT tester allowed to conduct any additional tests on a specimen?

(a) A certified tester is permitted to conduct any additional test to determine the validity of a specimen.

(b) The validity test(s) used will depend on the type of specimen being tested.

(c) Specific guidance on conducting validity tests is described in program documents.

(d) No further testing of a negative specimen for drugs is permitted and the specimen must either be discarded or pooled for use in the point of collection provider's internal quality control program.

§12.18 How long must a POCT tester retain a specimen?

(a) Each presumptive positive, adulterated, or substituted specimen must be sent to an HHS-certified laboratory for additional testing.

(b) A POCT tester must send 1 of every 20 negative specimens to an HHS-certified laboratory to be tested.

§12.19 How long must POCT records be retained?

All POCT records must be retained for at least 2 years by the POCT tester or the tester's employer.

§12.20 Can the POCT records be stored electronically?

Yes (Guidance will be developed at a later date)

§12.21 What summary report must a POCT tester provide to a Federal agency?

(a) A POCT tester must provide a summary report to a Federal agency for which it tests specimens using a POCT when requested by the Federal agency.

(b) The report must not include any personal identifying information for the specimens tested.

(c) The report is required to have statistical data available for the preceding 6 months and the collection site must provide this information within 5 working days of receipt of request.

(d) The summary report must contain the following information:

(1) Total number of specimens tested

(2) Number of specimens grouped by reason for test

(a) Random

(b) All others combined

- (3) Number of specimens rejected for testing for the following reasons:
 - (a) Fatal flaw, unsuitable (e.g. color, foreign objects, unusual odor)
 - (b) Insufficient quantity
- (4) Number of specimens screened negative
- (5) Number of specimens screened positive, adulterated, or substituted

§12.22 What type of relationship is prohibited between a POCT tester and a Medical Review Officer?

Refer to Subpart N, §14.5

§12.23 What type of relationship can exist between a POCT tester and an HHS-certified laboratory?

A POCT tester can freely enter into any relationship with an HHS-certified laboratory.

§12.24 What POCT information is available to the donor?

- (a) A Federal employee who is the subject of a drug test may, upon written request through the Agency and the MRO, have access to a documentation package.
- (b) The documentation package is limited to copies of the analytical data for the donor's specimen and associated quality control samples, chain of custody records, and other administrative documents generated during the handling and testing of the donor's specimen that support the test result reported by the POCT location.

§12.25 How is a POCT result reported?

- (a) Negative results are reported to an MRO.
- (b) Each presumptive positive, adulterated, or substituted specimen and a copy of the POCT result are sent to an HHS-certified laboratory.

Subpart M - Instrumented Initial Test Facility

§13.1 What is an Instrumented Initial Test Facility (IITF)?

- (a) An instrumented initial test facility (IITF) may be a remote site that meets all the laboratory requirements to perform screening only testing;
- (b) It must be a permanent location; and
- (c) A full-time responsible technician (RT) must have day-to-day responsibility for the IITF.

§13.2 What is an instrumented initial test?

See §11.10

§13.3 What types of initial tests may be used at an IITF?

The same FDA cleared initial tests used in the HHS-certified laboratories may be used at an IITF.

§13.4 What must be included in the IITF's Standard Operating Procedure Manual?

(a) An HHS-certified IITF must have a standard operating procedure (SOP) manual that describes, in detail, all IITF operations. When followed, it ensures that all specimens are tested using the same procedures and in a consistent manner.

(b) The SOP manual must include, but is not limited to, a detailed description of the following:

- (1) Chain-of-custody procedures;
- (2) Accessioning;
- (3) Security;
- (4) Quality control/quality assurance programs;
- (5) Analytical methods and procedures;
- (6) Equipment and maintenance programs;
- (7) Personnel training;
- (8) Reporting procedures; and
- (9) Computers, software, laboratory information management systems

(c) All procedures in the SOP manual must be in compliance with these Guidelines and NLCP Program Documents.

(d) A copy of all procedures that have been replaced or revised and the dates on which they were in effect must be maintained to allow the IITF to retrieve the procedures that were used to test a specimen.

§13.5 What must the IITF do to validate an initial test?

(a) The validation of an instrumented initial test must demonstrate:

- (1) The ability to differentiate positive and negative samples;
- (2) The performance of the test around the cutoff concentration; and
- (3) The performance of the test results at several concentrations between 0 and 150 percent of the cutoff concentration;

(b) Performance of new lots must be verified prior to being placed into service.

(c) An IITF may conduct a second initial test. If the IITF uses a second initial test, the second initial test is subject to the same requirements as the first initial test.

§13.6 What qualifications must the Responsible Technician (RT) have?

- (a) A Responsible Technician (RT) must have the following qualifications:
- (1) A bachelor's degree in the chemical or biological sciences, medical technology, or similar field;
 - (2) Training and experience in the analytical methods and procedures used by the IITF that are relevant to the results; and
 - (3) Training and experience in reviewing and reporting test results, maintenance of chain of custody, recordkeeping, and understanding proper remedial action in response to problems that may arise.

§13.7 What are the responsibilities of an RT?

The RT must:

- (a) Manage the day-to-day operations of the IITF.
- (b) Ensure that there are enough personnel with adequate training and experience to conduct and operate the work of the IITF. The RT must ensure the continued competency of testing facility personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.
- (c) Maintain a complete, current SOP manual that is available for personnel at the IITF, and followed by those personnel. The SOP manual must be reviewed, signed, and dated by the RT whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the IITF.
- (d) Verify and maintain a quality assurance program to assure the proper performance and reporting of all test results; monitor acceptable analytical performance for all controls and standards; monitor quality control testing; document the validity, reliability, accuracy, precision, and performance characteristics of each device/system used at that testing facility.
- (e) Implement all remedial actions necessary to maintain satisfactory operation and performance of the testing facility in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual must ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the results provided are accurate and reliable.
- (f) Qualify as an operator of the initial test analyzers used at the IITF.

§13.8 What qualifications must an individual have to certify a test result reported by an IITF?

The individual who certifies a negative test result must have:

- (1) Training and experience in the analytical methods and procedures used by the IITF that are relevant to the results that the individual certifies; and
- (2) Training and experience in reviewing and reporting test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

§13.9 What qualifications and training must other IITF personnel have?

(a) All IITF staff (e.g., technicians, administrative staff) must have the appropriate training and skills for the tasks assigned.

(b) Each individual working in a certified IITF must be properly trained before he or she is permitted to work independently in any area of the facility with regulated specimens.

(c) The training file for each individual must include, at a minimum, resumes, documentation of training provided, and any applicable professional certifications/licenses. Training files may be maintained separate from personnel files.

§13.10 What security measures must an IITF maintain?

(a) An IITF must control access to the facility and ensure that no unauthorized individual can gain access to specimens, aliquots, or records.

(b) With the exception of personnel authorized to conduct inspections on behalf of Federal, state, or other accrediting agencies for which the IITF is testing specimens or on behalf of the Secretary or emergency personnel (e.g., firefighters and medical rescue teams), all authorized visitors must be escorted at all times.

(c) An IITF must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized visitors and authorized escorts to accessing secured areas.

§13.11 What are the chain of custody requirements for an IITF specimen or an aliquot?

(a) An IITF must use chain of custody procedures to document the receipt, handling, and transfer of a specimen or an aliquot throughout the testing process and until final disposition.

(b) Chain of custody must be documented by using either hard copy procedures or electronic procedures.

(c) Chain of custody documentation must be completed at the time of the transaction.

§13.12 Which specimen types may be tested at an IITF?

- (a) Hair
- (b) Oral fluid (saliva)
- (c) Sweat
- (d) Urine

§13.13 What are the cutoff concentrations when using an instrumented initial test?

The cutoff concentrations are the same as those for laboratory based tests. The cutoff concentrations are listed in Subpart C of these Guidelines.

§13.14 What are the quality control requirements when conducting an IIT?

(a) Each batch of specimens must contain the following types of QC samples:

- (1) At least one control certified to contain no drug or metabolite;
- (2) At least one control that has the concentration of the drug or metabolite at 25 percent above the cutoff concentration; and

- (3) At least one control that has the concentration of the drug or metabolite at 25 percent below the cutoff concentration.
- (b) At least 10 percent of the batch must be calibrators and controls.
- (c) The initial test analyzers must be evaluated to document that any carryover that might occur between aliquots during the initial testing is detectable and corrected.

§13.15 What are the application requirements for an IITF?

- (a) An initial test facility must submit an application to become an HHS-certified IITF.
- (b) The applicant IITF must furnish detailed information on both the administrative and analytical procedures the facility proposes to use for testing regulated specimens after it is certified.
- (c) The application form is available at the following website: www.health.org/workpl.htm.

§13.16 What are the qualitative and quantitative specifications for PT samples that are used to evaluate an IITF?

- (a) A PT sample is a sample that may contain:
 - (1) The drugs and/or metabolites in the drug classes that each laboratory must have the capability to test for;
 - (2) Both the parent drug and/or its major metabolite(s); or
 - (3) More than one drug class (but generally no more than two drug classes) to imitate real donor specimens.
- (b) The concentration of the drugs and/or metabolites in a PT sample may be:
 - (1) At least 50 percent above the cutoff concentration for the initial test; or
 - (2) At another concentration for a special purpose.
- (c) A negative PT sample may not contain a measurable amount of a target drug and/or metabolite.
- (d) A PT sample may contain an interfering substance(s).
- (e) For each PT cycle, the set of PT samples going to each initial test facility will vary but, within each calendar year, each initial test facility will have analyzed the same total set of samples.
- (f) The IITF must, to the greatest extent possible, handle and test a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.
- (g) The IITF must report the result for a PT sample to the certifying organization in the same manner as specified for a donor specimen.

§13.17 What are the inspection requirements for an IITF?

- (a) An applicant IITF is inspected by at least one inspector.
- (b) The inspector conducts an evaluation and review of all aspects of the IITF.
- (c) An IITF becomes certified after satisfying the minimum requirements as stated in these Guidelines.
- (d) Maintenance inspections of certified IITFs will be conducted by at least one inspector every 6 months.

§13.18 Who may inspect an IITF?

- (a) The Secretary, a Federal agency using a certified IITF, or the contractor awarded the HHS NLCP contract may inspect an IITF at any time.
- (b) An individual may serve as an inspector if he or she satisfies the following criteria:
- (1) Has experience and an educational background similar to that required for the Responsible Technician;
 - (2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other program documents;
 - (3) Submits a resume and documentation of qualifications to HHS;
 - (4) Attends an HHS-approved inspector training program; and
 - (5) Submits an acceptable inspection report and has acceptable performance as a trainee on an inspection.

§13.19 What happens if an IITF does not satisfy the minimum inspection requirements?

- (a) If an applicant IITF fails to satisfy the requirements established for the initial certification process, the applicant IITF must start the initial certification process from the beginning.
- (b) If a certified IITF fails to satisfy the minimum requirements, the IITF is given a period of time (e.g., 5 or 30 working days depending on the nature of the issue) to furnish any explanation for its performance and evidence that any deficiency has been corrected.
- (c) An IITF's certification may be revoked, suspended, or no further action taken depending on the seriousness of the errors and whether there is evidence that any deficiency has been corrected and that current performance meets the requirements for a certified instrumented initial test facility.
- (d) A certified IITF may be required to undergo a special inspection or to test additional PT samples, depending on the nature of the performance, to verify that any deficiency has been corrected.
- (e) If an IITF's certification is revoked or suspended, the IITF is not permitted to test specimens for Federal agencies or federally regulated employers until the suspension is lifted or the instrumented initial test facility has successfully completed the certification requirements as a new applicant.

§13.20 Where is a list of certified IITFs published?

- (a) A list of current HHS-certified IITFs is published monthly in the Federal Register.
- (b) A list of current HHS-certified IITFs is available at the following website:
www.health.org/workpl.htm.
- (c) An applicant IITF is not included on the list.

§13.21 Is an IITF allowed to conduct any additional tests on a specimen?

- (a) An IITF is permitted to conduct any additional test to determine the validity of a specimen.
- (b) The validity tests that may be used will depend on the type of specimen being tested.
- (c) Specific guidance on conducting validity tests is described in program documents.
- (d) No further testing of a negative specimen for drugs is permitted and the specimen must either be discarded or pooled for use in the IITF's internal quality control program.

§13.22 How long must an IITF retain a specimen?

- (a) Specimens that are negative by the initial tests may be discarded after batch requirements are

met as specified in §13.14.

(b) A retained specimen must be kept in a secured location that is appropriate for that type of specimen (e.g., refrigerated storage for urine) to ensure its availability for any necessary retesting.

§13.23 How long must an IITF retain records?

(a) An IITF must retain all records generated to support test results for at least 2 years.

(b) A Federal agency may request the IITF to maintain records associated with a particular specimen under legal challenge for an indefinite period.

§13.24 Can an IITF store records electronically?

Yes (Guidance will be developed at a later date)

§13.25 What summary report must an IITF provide to a Federal agency?

(a) An IITF must provide a summary report to a Federal agency for which it tests specimens when requested by the Federal agency.

(b) The report must not include any personal identifying information for the specimens tested.

(c) The IITF is required to have statistical data available for the preceding 6 months and be able to provide this information within 5 business days of receipt of request.

(d) The summary report must contain the following information:

(1) Total number of specimens reported.

(2) Number of specimens grouped by reason for test:

(a) Random

(b) All others combined

(3) Number of specimens rejected for testing grouped by the following reasons:

(a) Fatal flaw, uncorrected flaw, or unsuitable(e.g. color, foreign objects, unusual odor)

(b) Insufficient quantity

(c) Adulterated

(d) Substituted

(4) Number of specimens screened negative

(5) Number of specimens screened positive

§13.26 What type of relationship is prohibited between an IITF and a Medical Review Officer?

Refer to Subpart N, §14.5

§13.27 What type of relationship can exist between an IITF and an HHS-certified laboratory?

An IITF can freely enter into any relationship with an HHS-certified laboratory.

§13.28 What is the minimum specimen volume collected for an instrumented initial test?

(TO BE DETERMINED)

§13.29 How do IITFs report results?

- (a) A certified negative result on a specimen is reported directly to an MRO.
- (b) A presumptive positive, adulterated, or substituted result on a specimen and the specimen are sent under chain of custody to the HHS-certified laboratory for confirmatory testing.

Subpart N - Medical Review Officer (MRO)

§14.1 Who may serve as an MRO?

- (a) A licensed physician holding either a Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree.
- (b) The physician must be certified by an HHS-approved MRO Certification Program.
- (c) The MRO may be either an employee of the Federal agency or a contractor for the Federal agency.

§14.2 What are the training requirements for an MRO?

An MRO must have training that includes:

- (a) Instruction on the collection procedures for each type of specimen;
- (b) Training on chain of custody, reporting, and recordkeeping;
- (c) Interpretation of test results; and
- (d) Federal workplace regulations policies.

§14.3 What are the requirements to be an HHS-approved MRO certification board?

The MRO certification board must:

- (a) Submit an application to HHS to become an HHS-approved MRO certification board.
- (b) Ensure that MRO candidates for certification have attended a training program meeting the training requirements for an MRO.
- (c) Require passing a written examination.
- (d) Ensure that certified MROs are kept current regarding changes in federal workplace regulations and procedures for each type of specimen.
- (e) Audit annually the activities of at least 10% of the certified MROs on a random basis and submit a summary audit report to HHS within 60 days after the end of the calendar year.
- (f) Maintain a current list of individuals who have been certified as MROs. The list must be updated on a monthly basis. The list must be provided to HHS electronically for posting on the HHS website.

§14.4 What are the responsibilities of an MRO?

- (a) The MRO must:
 - (1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the laboratory, IITF, or POCT site;
 - (2) Interview the donor when required;
 - (3) Make a determination regarding the test result;
 - (4) Report the verified result to the Federal agency; and
 - (5) Maintain the records (for a minimum of 2 years) and the confidentiality of the information.
- (b) The MRO is authorized to order a retest of a single specimen or a test of the primary specimen from a split specimen collection. The MRO may request that the retest be performed by the same certified laboratory or a different certified laboratory.
- (d) Before an MRO verifies a specimen positive for opiates, the MRO must determine that there is

clinical evidence of illegal use by the donor of an opium, opiate, or opium derivative (e.g., morphine/codeine) listed in Schedule I or II of the Controlled Substances Act. This requirement does not apply if the confirmatory procedure for opiates confirms the presence of 6-acetylmorphine since the presence of this metabolite is proof of heroin use.

(e) The MRO review process is described in the HHS MRO Manual for Federal Workplace Drug Testing programs. It may be found at the following website: www.health.org/workpl.htm

§14.5 What must an organization/employer do before an MRO is permitted to review results for a Federal agency?

An organization/employer must:

(a) Ensure that the physician has a current MRO certificate issued by an HHS-approved MRO certification board; and

(b) Retain a copy of the certificate as long as the physician performs MRO functions and for 2 years after the MRO ceases to perform services for the organization/employer.

§14.6 What type of relationship is prohibited between an MRO and a laboratory, POCT tester, or IITF?

(a) An MRO must not be an employee, agent of, or have any financial interest in a laboratory, POCT tester, or IITF for which the MRO is reviewing drug test results.

(b) An MRO must not derive any financial benefit by having an agency use a specific drug testing laboratory, POCT tester, or instrumented initial test facility or have any agreement with the laboratory, POCT tester, or IITF that may be construed as a potential conflict of interest.

Subpart O - Single Specimen Retests and Split Specimen Tests

§15.1 When may a single specimen or primary specimen be retested?

Before an MRO makes a determination, the MRO may order a retest of a single or a primary specimen if there is reason to believe that the test result reported by the laboratory is incorrect.

§15.2 When may a split specimen be tested?

(a) After a primary specimen has been reported to the agency, a donor has the right to request through the MRO that the split specimen be tested at an HHS-certified laboratory to confirm the same positive, adulterated, or substituted result that was reported by the laboratory for the primary specimen.

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The donor must document this request in writing to the MRO.

§15.3 How does a laboratory handle the retesting of a single specimen or the testing of a split specimen for drug(s) or metabolite(s)?

The retesting of a single specimen or the testing of a split specimen for drug(s) or metabolite(s) is not subject to the testing cutoff concentrations established for the original testing of a specimen. The laboratory is only required to provide data that is sufficient to confirm the presence of the drug or metabolite that was reported present in the original testing of a single specimen or the primary specimen for a split specimen collection.

§15.4 How does a laboratory handle the retesting of a single specimen or the testing of a split specimen for validity?

(a) The retesting of a single specimen or the testing of a split specimen for adulteration or substitution is permitted.

(b) This testing shall be sufficient to confirm the original adulteration or substitution result.

§15.5 Who receives the single specimen retest result or the split specimen result?

A laboratory must transmit the result directly to the MRO.

§15.6 What happens when a single specimen retest or split specimen result does not reconfirm the original test result?

(a) The MRO must cancel the test and inform the agency that an immediate collection of another specimen is permitted in order to obtain a valid test result.

(b) The MRO or Agency contacts the appropriate regulatory office with details of the failure to reconfirm that are needed by the regulatory office to conduct an investigation into the cause of the failure to reconfirm.

§15.7 How long must a laboratory retain a split specimen?

A split specimen is retained for the same period of time that a primary specimen is retained and under the same storage conditions.

Subpart P - Problems with Drug Tests

§16.1 What problems will always result in a specimen not being tested?

- (a) The following problems are considered to be fatal flaws:
 - (1) The specimen ID number on the specimen received by the laboratory does not match the number on the CCF;
 - (2) There is no specimen ID number on the specimen received by the laboratory;
 - (3) There is no printed collector's name and no collector's signature on the CCF;
 - (4) The tamper-evident seal on the specimen is received broken; or
 - (5) There is insufficient specimen to conduct the required analyses.
- (b) The specimen received with a fatal flaw will not be tested and the reason will be reported to the MRO.

§16.2 What problems will result in a drug test result not being reported unless the problem is corrected?

- (a) The following problems are considered to be correctable errors:
 - (1) The collector fails to complete the chain of custody step (e.g., no signature or no printed name, no date or time of collection);
 - (2) All information on the CCF is not properly provided (e.g., a phone number is missing); or
 - (3) A required box is not marked (e.g., the reason for test is not marked).
- (b) When this type of error occurs, the collector must be contacted, and requested to provide a written memorandum attesting to the fact that he or she did actually carry out the required action but inadvertently forgot to properly document the CCF.
- (c) If the discrepancy or error of omission cannot be corrected, the drug test result must not be reported.

Subpart Q - Laboratory/POCT/IITF Suspension/Revocation Procedures

(This subpart will be expanded to address issues related to the POCT and IITF)

§17.1 When may a certified laboratory be suspended?

(a) When there is reason to believe that immediate action is necessary to protect the interests of the United States and its employees (i.e, imminent harm).

(b) The existence of imminent harm may be identified through the NLCP PT and inspection programs, blind samples, or information obtained by an MRO.

§17.2 When may a laboratory's certification be revoked?

(a) When there is evidence that the laboratory is unable to ensure either the reliability and accuracy of drug tests or the accurate reporting of test results.

(b) The following reasons may be considered in revoking a laboratory's certification:

- (1) Unsatisfactory performance in analyzing and reporting a donor drug test result;
- (2) Unsatisfactory participation in the NLCP;
- (3) Violation of a Federal agency contract;
- (4) Conviction of a criminal offense; or
- (5) Any other cause which affects the ability of the laboratory to ensure the full reliability and accuracy of donor drug test results.

§17.3 What is the procedure when a laboratory is suspended?

(a) The Administrator, SAMHSA, or the Administrator's designee (e.g., Director, Division of Workplace Programs) notifies a laboratory in writing that its certification is suspended and it must cease testing regulated specimens.

(b) The laboratory has 5 calendar days from the date of the notification to respond in writing with a plan to take corrective action to prevent the recurrence of the error that caused the laboratory to be suspended.

(c) The laboratory's plan of corrective action will be reviewed and a determination made as to its acceptability in correcting the problem.

(d) The laboratory will be required to submit revised plans of corrective action until a plan is determined to be acceptable.

(e) After the approved corrective action plan has been completed, the laboratory must submit in writing a letter, including appropriate supporting documents.

(f) If the supporting documents and corrective action are complete, the Administrator's designee will recommend lifting the laboratory's suspension.

§17.4 What is the procedure when there is a proposal to revoke a laboratory's certification?

(a) The Administrator, SAMHSA, or the Administrator's designee (e.g., Director, Division of Workplace Programs) notifies a laboratory in writing that there is a proposal to revoke its certification.

(b) The laboratory has 30 calendar days from the date of the notification to respond in writing with a plan to take corrective action to prevent the recurrence of the error(s) that caused the proposal to revoke the laboratory's certification.

(c) The laboratory's plan of corrective action will be reviewed and a determination made as to its acceptability in correcting the error(s).

(d) The laboratory will be required to submit revised plans of corrective action until a plan is determined to be acceptable.

(e) After the approved corrective action plan has been completed, the laboratory must submit in writing a letter, including appropriate supporting documents.

(f) If the supporting documents and corrective action are complete, the Administrator's designee will recommend removing the proposal to revoke the laboratory's certification.

§17.5 Where are notices of laboratory actions published?

(a) A notice is published in the **Federal Register** listing the name and address of any certified laboratory that has its certification suspended or revoked.

(b) The notice will state the reason for the immediate suspension or revocation.

(c) A notice is published in the Federal Register when the suspension is lifted.