NOTE: *This draft document represents a joint effort by the SAMHSA/CSAP Division of Workplace Programs and members of the SAMHSA Drug Testing Advisory Board (DTAB). It has not been reviewed by all members of the DTAB, by industry working groups, or by other Federal agencies. This draft document is the first release to a wider audience. It will serve as the basis for developing the guidelines for Federal Workplace Drug Testing Programs.*

All interested parties are invited to comment on the draft document. Comments may be mailed to the Division of Workplace Programs, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, by fax (301-443-3031), or by email: wvogl@samhsa.gov or clodico@samhsa.gov

Please submit your comments by July 12, 2000, to ensure they are considered prior to the September Drug Testing Advisory Board meeting.

MANDATORY GUIDELINES
for
FEDERAL WORKPLACE DRUG TESTING PROGRAMS

17.4 What is the procedure when there is a proposal to revoke a laboratory's certification?
17.5 Where are notices of laboratory actions published?

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;

(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 of 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. These interpretations are the only official and authoritative interpretations that are valid and binding.

§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 is considered to be adulterated if it either contains a substance that is not a normal constituent for that type of specimen or contains 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 blind sample is 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 that is used to define 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 or the POCT provider cannot support reporting either a positive nor a negative test to the employer.

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

Chain of Custody 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.

Chain of Custody Document The form(s) used by the laboratory to document the security of the specimen and all aliquots of the specimens during testing and storage by the laboratory. The form, which may account for an entire test batch, shall include the names and signatures of all individuals who accessed 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 to be analyzed for the presence of drugs.

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

Confirmatory Test An analytical procedure performed on a separate aliquot of the specimen to identify the presence of a specific drug or metabolite.

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

Cut-off The concentration used to report a specimen as negative or positive.

Dilute Refers to a specimen with less than normal constituents.
(TO BE DETERMINED FOR EACH SPECIMEN)

Donor The individual from whom a specimen is collected.

Failed to Reconfirm The result reported when a laboratory is unable to detect the drug or metabolite that was previously reported from the original analysis.

Federal Custody and Control Form An OMB approved form used to document the collection, 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 returned to a testing designated position.

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

Initial Test The test used to differentiate a negative specimen from one that requires further testing.

Invalid Result The result reported when a laboratory is unable to obtain a scientifically supportable drug test result.

HHS Certified Instrumented Initial Test Facility A location where initial testing, reporting of results, and recordkeeping is performed under the supervision of a responsible technical (RT).

HHS Certified Laboratory A location where initial and confirmation testing is performed under the supervision of an RP and Certifying Scientists are used for final review and release of drug testing results.

HHS Certified Point of Collection Test Facility A location where specimen collection, initial testing, reporting of results, and record keeping is performed under the supervision of a responsible technician (RT).

Medical Review Officer (MRO) A licensed physician who receives, reviews, verifies, and reports the drug test results.

Negative Result Result for a specimen that either contains no drug or the concentration of the drug is less than the cutoff concentration for that drug or drug class.

Non-Negative Result Result for a specimen from an initial test that must go to confirmation for a final report.

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

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

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

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

Random Test A test performed on a specimen collected from a donor who is selected at random from the individuals working in testing designated positions.

Reasonable Suspicion/Cause Test (TO BE DETERMINED)

Reconfirmed The result reported when a laboratory is able to detect the drug or metabolite that was previously reported from the original analysis.

Rejected for Testing Result for a specimen for which the laboratory or the point of

collection test device provider does not perform any tests on the specimen.

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 point of collection test facility or the HHS certified instrumented initial test facility.

Return to Duty Test A test performed on a specimen collected from a donor 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 simultaneously collected specimens. For sweat, a sweat 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 provided by a donor.

Testing Designated Position An employment position within a Federal agency that has been designated for random testing.

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

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

Recommended reasons for specimen type selected are as follows:

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

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 collected pursuant to these Guidelines may be used to test only for those drugs included in the Agency workplace drug testing program. They may not be used to conduct any other analysis or test unless otherwise authorized by the Guidelines.

(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?

Urine

	Initial Test Cutoff Concentration (ng/mL)	
Marijuana metabolites.....	50	
Cocaine metabolites.....	150	
Opiate metabolites.....	2000	
Phencyclidine.....	25	
Amphetamines.....	500	Screening must significantly cross-react w/MDMA (Roughly equal cross-reactivity)

Confirmatory Test Cutoff Concentration (ng/mL)

Marijuana metabolite[1]	15
Cocaine metabolite[2]	100
Opiates	
Morphine	2000
Codeine	2000
6-acetylmorphine	10
Phencyclidine	25
Amphetamines	
d-Amphetamine	150 - 250
d-Methamphetamine[3]	150 - 250
MDMA	150 - 250
MDA	150 - 250
MDEA	150 - 250

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid
[2] Benzoylecgonine
[3] Specimen must also contain Amphetamine at a concentration $\geq$ 100 ng/mL

Hair

	Initial Test Cutoff Concentration (pg/mg)	
Marijuana metabolites	1.0	
Cocaine metabolites	500	
Opiate metabolites	200	
Phencyclidine	300	
Amphetamines	500	Screening must cross-react w/MDMA

	Confirmatory Test Cutoff Concentration (pg/mg)
Marijuana metabolite[1]	0.05
Cocaine metabolite[2]	100
Cocaine	1000
BE/COC ratio >= 0.1	
Opiates	
Morphine	200
Codeine	200
6-acetylmorphine	200
Hair 6-AM rule (TO BE DETERMINED)	
Phencyclidine	300
Amphetamines	
d-Amphetamine	300

d-Methamphetamine.....	300
Hair amp rule.....	50
MDMA	
MDA	
MDEA	

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid
[2] Benzoylecgonine

Sweat

	Initial Test Cutoff Concentration (ng/ 2.5 mL eluate)	Target Analyte
Marijuana metabolites.....	1.5	THC
Cocaine metabolites.....	10	Benzoylecgonine
Opiate metabolites.....	10	Morphine
Phencyclidine.....	7.5	Phencyclidine
Amphetamines.....	10	d-Methamphetamine
(Amp screening must cross-react w/MDMA)		

	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	
MDA	
MDEA	

[2] Benzoylecgonine
[3] Specimen must also contain Amphetamine at a concentration $\geq$ (TO BE DETERMINED) ng/mL

Oral Fluid

	Initial Test Cutoff Concentration (ng/mL)	
Marijuana metabolites.....	4	
Cocaine metabolites.....	20	
Opiate metabolites.....	40	
Phencyclidine.....	4	
Amphetamines.....	160	Screening must cross-react w/MDMA

	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	
MDA	
MDEA	

[2] Benzoylecgonine

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

Subpart D - Collectors

§4.1 Who may collect a specimen?

(a) An individual trained or certified to collect specimens.

(b) The direct supervisor of donor may not act as the collector when that donor is tested, unless no other collector is available.

§4.2 What training and certification must a collector have?

(a) HHS has not established a formal certification program for collectors. However, private sector organizations are encouraged to develop the required certification program. This will help to ensure that collectors have, in fact, been properly trained and certified to collect specimens as required by the Guidelines.

(b) To be a collector, you must do the following:

(1) Read and become familiar with the collection procedures in these Guidelines;

(2) Read and become familiar with the HHS Specimen Collection Handbook for the specimen being collected; and

(3) Attain certification through a recognized collector certification program for the type(s) of specimen(s) you are going to collect.

(c) As a collector, you must be recertified once every two years to ensure that you are familiar with current HHS specimen collection policies and procedures.

(d) As a collector, you must maintain all documentation of certification/recertification as long as you serve as a collector.

§4.3 Who can train and certify collectors?

(TO BE DETERMINED)

§4.4 Under what circumstances must a collector be retrained?

(a) A collector needs to be retrained when:

(1) The collection procedure changes significantly (e.g., a new CCF is used); or

(2) The collector makes mistakes that cause tests to be canceled. This will lead to a "collector's cancellation rate" being an index of performance.

(b) The required retraining:

(1) Must be focused in the specific area of collection procedures that caused the tests to be canceled; and

(2) Be documented in writing by a trainer.

§4.5 What are the collector monitoring and support requirements for organizations employing collectors?

An organization (e.g., Federal agency, contractor, health clinic) employing the collector must do the following:

(a) Have an official certification statement documenting that the collector is certified;

(b) Retain these official certification statements as long as the person performs collector functions and for 2 years after the collector leaves the organization; and

(c) Provide to a collector the name and telephone number of the Federal agency'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) Ability to restrict access to only authorized personnel during the collection;

(d) Ability to restrict access to collection supplies; and

(e) 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.

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

A 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 specimen; and

(e) Immediately seal the specimen.

§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. Collection of hair from other areas of the body must be approved in accordance with Agency procedures before the collection and must be collected using appropriate privacy.

(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 CCF used for each type of specimen collected is available from a number of different sources. A sample of the OMB approved 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 conduct a test 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 oral cavity.

(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.

(c) A collection device must have the capability of being sealed by the collector to prevent unauthorized access to the specimen while at the collection site.

§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.

(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.

(c) The sweat patch (sweat) and applicator, pad, or aspirator (oral fluid) are unique and integral to collecting a valid specimen and must be FDA cleared.

Subpart H - Specimen Collection Procedure

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

The collector must do the following before starting the collection procedure:
(a) Verify the donor's identification;
(b) Provide your 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 questions 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 as follows:
(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. 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.
(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 collection device.
(h) A tamper-evident label/seal must be used to secure the collection device.
(i) The donor must initial the label and the collector must date the label after it is used to secure the collection device.
(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 National Laboratory Certification Program (NLCP) is the program established by HHS 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 semiannual maintenance inspections 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 proficiency testing; ordering any laboratory to send aliquots of specimens 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 is a 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;

(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 20 percent above the cutoff concentration for either the initial test or the confirmatory test (depending on which is to be evaluated);

(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.

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

(a) It must undergo an inspection 3 months after becoming certified and then inspected semiannually 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.

§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 has acceptable performance as a trainee 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 is published monthly in the **Federal Register**.

(b) Applicant laboratories are <u>not</u> included in 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 at least 25 percent above the cutoff concentration for that drug.

§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 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 bottle label/seal. Since there is no donor, 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?

The Medical Review Officer (MRO) is generally the individual who finds that a laboratory has reported an inconsistent result on a blind sample. When such a result is identified:

(a) The MRO 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. 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

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

(c) 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 qualifications must the laboratory's responsible person (RP) have?

A certified laboratory must have at least one individual who can assume the professional, organizational, educational, and administrative responsibilities for the entire drug testing facility. The minimum qualifications for the RP are as follows:

(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.

§11.3 What are the responsibilities of the RP?

The RP must fulfill the following responsibilities:

(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 performing tests, and followed by those personnel. The SOP manual must be reviewed, signed, and dated by the RP 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; 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. 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 both initial and confirmatory test results.

§11.4 What qualifications and training must an individual have to certify a drug test result that is reported by a laboratory?

(a) A certifying scientist (CS) must have the following qualifications:

(1) A bachelor's degree in the chemical or biological sciences, medical technology, or equivalent;

(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) A laboratory must have at least one individual who is designated as a CS.

(c) There are two types of certifying scientists:

(1) A negative CS who is qualified to certify only results that are negative on the initial test; and

(2) A CS who is qualified to certify results for both initial and confirmatory test results.

§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.

(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.

§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) A laboratory must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized visitors accessing secured areas.

(c) 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.

§11.7 How must a laboratory handle 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 is an initial test?

(a) An initial test is a test used to differentiate a "negative" specimen from those that require further testing.

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

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

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

(a) The validation procedure 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) 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.

§11.10 Why must the initial test be calibrated?

The initial test must be calibrated to ensure and document the linearity of the assay method over time in the concentration area of the cutoff.

§11.11 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;

(3) At least one control that has the concentration of the drug or metabolite at 25 percent below the cutoff concentration; and

(4) At least one blind control (or a minimum of 1 percent) inserted to appear as a donor specimen to the laboratory analysts.

(b) At least 10 percent of the batch must be calibrators and controls.

(c) A laboratory must establish a procedure to ensure that any carryover that might occur between aliquots during the initial testing is detectable and corrected.

§11.12 What is a confirmatory test?

(a) A confirmatory 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.

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

To validate a confirmatory test, the laboratory must demonstrate:

(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.

§11.14 Why must the confirmatory test be calibrated?

The confirmatory test must be calibrated to ensure and document the linearity of the assay method over time in the concentration area of the cutoff.

§11.15 What are the quality control requirements when conducting a confirmatory 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 at 25 percent above the cutoff concentration;

(4) At least one control that has the concentration of the drug or metabolite at 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 test.

(c) A laboratory must establish a procedure to ensure that any carryover that might occur between aliquots 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 requirements for a laboratory to report the test result for a specimen?

(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 specifically requests the concentration.

(d) The laboratory can only report a test result to an MRO.

(e) The laboratory may transmit results to the MRO by various electronic means (e.g., facsimile, computer) in a manner designed to ensure the confidentiality of the information, 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) A facsimile or electronic report is sufficient to report a negative result.

(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, diluted, rejected for testing, 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?

(TO BE DETERMINED)

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

(a) A laboratory must provide a semi-annual summary report to a Federal agency for which it tests specimens, but must not include any personal identifying information for the specimens tested.

(b) 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

NOTE: We are currently evaluating the need for this report.

§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 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 laboratory.

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

Refer to Subpart N, §14.3

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

When a certified laboratory uses procedures that are different from those for which it is certified to test private sector client specimens, it must inform the private sector client that its specimens are not being tested under the Guidelines and 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 for either the presence of drugs or to determine specimen validity.

§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) Validation studies must be completed prior to placing a new lot in service.

(c) The POCT device must be included on the SAMHSA/HHS Conforming Products List.

§12.4 Who may conduct the POCT?

(a) A certified collector must collect the specimen. The specimen may be transferred under chain of custody if the specimen is going to be tested by another individual.

(b) A trained tester under the supervision of a Responsible Technician must perform the test.

§12.5 What are the qualifications for the person who performs a POCT?

(a) The person who performs the POCT must be a certified collector.

(b) Additionally, this person must be trained in the use of the specific device/system used to perform the POCT.

(c) This training must be documented in the tester's personnel file.

§12.6 What are the responsibilities of a Responsible Technician?

The Responsible Technician (RT) must fulfill the following responsibilities:

(a) Manage the day-to-day operations of the POCT facility 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 conduct the work of the POCT facility. 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 performing tests, 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 POCT facility.

(d) 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 a certified collector and tester for the POCT devices used at that testing facility.

§12.7 Which specimen types may be tested using a POCT?

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

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

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

§12.9 May the donor observe the POCT being performed?

No, the donor must leave prior to performing the test.

§12.10 What are the requirements for conducting a POCT?

(a) A POCT is performed on an aliquot of the specimen that has been separated from the specimen.

(b) The POCT is performed after the specimen is sealed.

(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 collector/tester under the supervision of a Responsible Technician must report the test result to the MRO.

§12.11 What are the quality control requirements when conducting a POCT?

(a) Each day testing is performed, the following types of QC samples must be analyzed:

(1) At least one control certified to contain no drug or metabolite; and

(2) At least one control that has the concentration of the drugs or metabolites at 25 percent above the cutoff concentration.

(b) Minimum of 1 specimen out of every twenty specimens screened negative (5%) must be submitted to an HHS certified laboratory as part of a Quality Assurance Program.

§12.12 What are the application requirements for a POCT Provider?

(a) An individual must submit an application to become an HHS certified POCT provider.

(b) The application form requires the applicant to furnish detailed information on both the administrative and analytical procedures that will be used for testing regulated specimens after becoming certified.

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

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

(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 POCT provider will vary but, within each calendar year, each POCT provider will have analyzed the same total set of samples.

(f) The POCT provider 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 POCT provider must report the result for PT sample to the certifying organization in the same manner as specified for a donor specimen.

§12.14 What are the inspection requirements for a POCT provider?

(a) An applicant POCT provider is inspected by at least one inspector.

(b) The inspector conducts an evaluation and review of all aspects of the POCT provider procedures and collection facilities using the guidance provided by the Secretary.

(c) To become certified, an applicant POCT provider must satisfy the minimum requirements as stated in these Guidelines.

§12.15 Who may inspect a POCT provider?

(a) The Secretary, a Federal agency using a certified POCT provider, or the contractor awarded the HHS inspection contract may inspect a POCT provider 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 either the Responsible Technician as described in subpart L;

(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 approved training; and

(5) Submits an acceptable inspection report and has acceptable performance as a trainee on an inspection.

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

(a) If an applicant POCT provider fails to satisfy the requirements established for the initial certification process, the applicant POCT provider must start the initial certification process from the beginning.

(b) If a certified POCT provider fails to satisfy the minimum requirements, the POCT provider 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 POCT provider'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 POCT provider.

(d) A certified POCT provider 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 POCT provider's certification is revoked or suspended, the POCT provider is not permitted to test specimens for Federal agencies or federally regulated employers until the suspension is lifted or the POCT provider has successfully completed the certification requirements as a new applicant.

§12.17 Where is a list of "recognized" POCT providers published?

(a) A list of HHS certified POCT providers is published quarterly in the Federal Register.

(b) The list of current HHS certified POCT providers is available at the following website: www.health.org/workpl.htm.

(c) Applicant POCT provider are not included on the list.

§12.18 Is a POCT provider allowed to conduct any additional tests on a specimen?

(a) A POCT provider 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 point of collection provider's internal quality control program.

§12.19 How long must a POCT provider retain a specimen?

(a) All non-negative specimens will be sent to a certified laboratory for any necessary additional testing.

(b) A POCT provider must retain negative specimens for a minimum of time needed to accumulate a total of 20 specimens tested negative (5% of the specimens must be submitted to an HHS certified laboratory to be tested). Must perform quality assurance (subpart L, §12.11) before discard of patient specimens.

(c) 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.

§12.20 How long must a POCT provider retain records?

(a) A POCT provider must retain all records generated to support test results for at least 2 years.

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

§12.21 Can a POCT provider store records electronically?

(TO BE DETERMINED)

§12.22 What summary report must a Federal agency receive from a POCT provider?

(a) A POCT provider must submit a semi-annual summary report to a Federal agency for which it tests specimens, but must not include any personal identifying information for the specimens tested.

(b) 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 non-negative

NOTE: We are currently evaluating the need for this report.

§12.23 What type of relationship is prohibited between a POCT provider and a Medical Review Officer?

Refer to Subpart N, §14.3

§12.24 What type of relationship can exist between a POCT provider and an HHS certified laboratory?

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

§12.25 What security measures must a POCT provider maintain?

(a) A POCT provider must control access to the drug testing facility and ensure that no unauthorized individual can gain access to specimens, aliquots, or records.

(b) The collector/tester must maintain visual control of the specimen at all times during the collection and POCT procedure.

§12.26 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 Agency and the MRO, may 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 provider.

§12.27 What is the minimum specimen volume collected for a POCT?

(TO BE DETERMINED)

§12.28 What action may a Federal agency take when a POCT is non-negative?

(TO BE DETERMINED)

§12.29 How is a POCT result reported to the Medical Review Officer?

(TO BE DETERMINED)

Subpart M - Instrumented Initial Test Facility

§13.1 What is an Instrumented Initial Test Facility

An initial test facility is a remote site that meets all the laboratory requirements to perform screen only testing.

§13.2 Are Laboratories that perform only initial tests allowed?

Yes

§13.3 What is an instrumented initial test?

(a) An instrumented initial test is a device that is used to conduct initial tests for drugs or for determining specimen validity. The data generated by the instrument is based on calibrators and controls registered by the instruments detector.

(b) An instrumented initial test is a device that may include, but is not limited to, the following techniques: immunoassay or chromatographic separation coupled with an appropriate detector.

(c) An instrumented initial test is a device that must be validated with calibrators and controls before it is used to test donor specimens.

§13.4 What types of initial test are there?

(a) POCT Device (either non-instrumented or instrumented). The endpoint result from this device is obtained by visual evaluation (i.e., read by human eye or by instrumental evaluation of an output).

(b) Instrumented initial test. The endpoint result from this device is obtained by instrumental evaluation (e.g., densitometer, spectrophotometer)

§13.5 What are the requirements for an Instrumented Initial Test Facility?

(a) The instrumented initial test device must be cleared by the FDA.

(b) Validation studies must be completed prior to placing a new lot in service.

(c) The validation procedure 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;

(d) An initial test facility may conduct a second initial test prior to the confirmatory test. If

the initial test facility uses a second initial test, the second initial test is subject to the same requirements as the first initial test.

§13.6 Why must the instrumented initial test device be calibrated?

The instrumented initial test device must be calibrated to ensure and document the linearity of the assay method over time in the concentration area of the cutoff.

§13.7 Who may conduct an instrumented initial test?

A trained tester under the supervision of a Responsible Technician must perform the test.

§13.8 What are the qualifications for the person who operates an instrumented initial test?

(a) The person who operates an instrumented initial test must be trained in the use of the specific device/system used to perform an initial test.

(b) This training must be documented in the tester's personnel file.

§13.9 What are the responsibilities of a Responsible Technician?

The Responsible Technician (RT) must fulfill the following responsibilities:

(a) Manage the day-to-day operations of the instrumented initial test device facility 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 conduct and operate the work of the instrumented initial test device facility. 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 performing tests, 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 instrumented initial test device facility.

(d) 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 an instrumented initial test device used at that testing facility.

§13.10 Which specimen types may be tested using an instrumented initial test?

(a) Urine
(b) Oral fluid (saliva)

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

The cutoff concentrations when using an instrumented initial test device are the same as those for laboratory based tests. The cutoff concentrations are listed in Subpart C of these Guidelines.

§13.12 What are the quality control requirements when conducting an instrumented 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;
(3) At least one control that has the concentration of the drug or metabolite at 25 percent below the cutoff concentration; and
(4) At least one blind control (or a minimum of 1 percent) inserted to appear as a donor specimen to the laboratory analysts.

(b) At least 10 percent of the batch must be calibrators and controls.

(c) An instrumented initial test device provider must establish a procedure to ensure that any carryover that might occur between aliquots during the initial testing is detectable and corrected.

§13.13 What is the application requirements for an Instrumented Initial Test Facility?

(a) An initial test facility must submit an application in becoming an HHS certified instrumented initial test facility.

(b) The application form requires the applicant initial test facility to furnish detailed information on both the administrative and analytical procedures the initial test 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.

§13.14 What are the qualitative and quantitative specifications for PT samples that are used to evaluate an instrumented initial test facility?

(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 initial test facility 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 initial test facility must report the result for PT sample to the certifying organization in the same manner as specified for a donor specimen.

§13.15 What are the inspection requirements for an instrumented initial test facility?

(a) An applicant instrumented initial test facility is inspected by at least one inspector.

(b) The inspector conducts an evaluation and review of all aspects of the instrumented initial test facility procedures and collection facilities using the guidance provided by the Secretary.

(c) To become certified, an applicant instrumented initial test facility must satisfy the minimum requirements as stated in these Guidelines.

§13.16 Who may inspect an instrumented initial test facility?

(a) The Secretary, a Federal agency using a certified instrumented initial test facility, or the contractor awarded the HHS program contract may inspect an instrumented initial test facility 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 either the Responsible Technician as described in subpart L;

(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 program approved training; and
(5) Submits an acceptable inspection report and has acceptable performance as a trainee on an inspection.

§13.17 What happens if an instrumented initial test facility does not satisfy the minimum inspection requirements?

a) If an applicant instrumented initial test facility fails to satisfy the requirements established for the initial certification process, the applicant instrumented initial test facility must start the initial certification process from the beginning.

(b) If a certified instrumented initial test facility fails to satisfy the minimum requirements, the instrumented initial test facility 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 instrumented initial test facility'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 instrumented initial test facility 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 instrumented initial test facility's certification is revoked or suspended, the instrumented initial test facility 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.

§13.18 Where is a list of recognized instrumented initial test facilities published?

(a) A list of current HHS certified instrumented initial test facilities is published monthly in the Federal Register.

(b) A list of current HHS certified instrumented initial test facilities is available at the following website: www.health.org/workpl.htm.

(c) Applicant instrumented initial test facilities are not included on the list.

§13.19 Is an instrumented initial test facility allowed to conduct any additional tests on a specimen?

(a) An instrumented initial test facility 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 instrumented initial test facility's internal quality control program.

§13.20 How long must an instrumented initial test facility retain a specimen?

(a) Specimens that are negative by initial test may be discarded after batch requirements are met as specified in §13.10.

(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.

§13.21 How long must an instrumented initial test facility retain records?

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

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

§13.22 Can an instrumented initial test device provider store records electronically?

(TO BE DETERMINED)

§13.23 What summary report must a Federal agency receive from an instrumented initial test facility?

(a) An instrumented initial test facility must furnish a semi-annual summary report to a Federal agency for which it tests specimens, but must not include any personal identifying information for the specimens tested.

(b) 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 non-negative

NOTE: We are currently evaluating the need for this report.

§13.24 What type of relationship is prohibited between an instrumented initial test facility and a Medical Review Officer?

Refer to Subpart N, §14.3

§13.25 What type of relationship can exist between an instrumented initial test facility and an HHS certified laboratory?

An instrumented initial test facility can freely enter into any relationship with an HHS certified laboratory.

§13.26 What security measures must an instrumented initial test facility maintain?

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

(b) An instrumented initial test facility must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized visitors accessing secured areas.

(c) With the exception of personnel authorized to conduct inspections on behalf of Federal, state, or other accrediting agencies for which the POCT provider 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(e.g. instrument service representatives, house cleaning crews).

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

(TO BE DETERMINED)

§13.28 What action may a Federal agency take when an instrumented initial test is reported as a non-negative?

(TO BE DETERMINED)

§13.29 How is the instrumented initial test result reported to the Medical Review Officer?

(TO BE DETERMINED)

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 with knowledge of substance abuse disorders.

(b) The MRO may be either an employee of the Federal agency or a contractor for the Federal agency.

§14.2 What are the responsibilities of an MRO?

(a) After receiving the result from the laboratory, an 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;

(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) An MRO must become familiar with current Federal polices and procedures to ensure that he or she is properly fulfilling the role of an MRO.

(c) If there is any question as to the validity of a positive test result, only the MRO is authorized to order a retest of a single specimen or 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

§14.3 What type of relationship is prohibited between an MRO and a laboratory, POCT provider, or an instrumented initial test facility?

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

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

Subpart O - Single Specimen Retests and Split Specimen Tests

(This section needs to be expanded to address all types of specimens)

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

Before an MRO makes a determination, the MRO is authorized to 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 making a determination for a primary specimen and reporting the result to the Agency, a donor has the right to request through the MRO that the split specimen be tested for the same result as was reported by the laboratory for the primary specimen.

(b) A donor has 72 hours to initiate the request after being informed by the MRO that a non-negative result was reported to the Agency.

§15.3 How does a laboratory handle the retesting of a single specimen or the testing of a split specimen?

The retesting of a single specimen or the testing of a split specimen is not subject to using 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 drug metabolite that was reported present in the original testing of a single specimen or the primary specimen for a split specimen collection.

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

A laboratory must transmit the result directly to the MRO.

§15.5 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 an/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.

§15.6 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

(This section needs to be expanded to address all types of specimens)

§16.1 What problems will always result in a laboratory not testing a specimen?

(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) The tamper-evident seal on the specimen is received broken; or

(4) There is insufficient specimen to conduct the required analyses.

(b) A laboratory receiving such a specimen with a fatal flaw will not test the specimen and will report the reason to the MRO.

§16.2 What problems will result in a laboratory not reporting a drug test result 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, 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 laboratory must contact the collector to determine if the collector can 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 laboratory must not report a drug test result.

Subpart Q - Laboratory Suspension/Revocation Procedures
(This section needs to be expanded to address all types of facilities)

§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.

(b) The laboratory has 5 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 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.