105684

105684

Alcohol, Drug Abuse, and Mental Health Administration

Department of Health and Human Services

SCIENTIFIC AND TECHNICAL GUIDELINES FOR DRUG TESTING PROGRAMS

February 13, 1987

TABLE OF CONTENTS

INTRODUCTION

This document represents the Department of Health and Human Services "Scientific and Technical Guidelines for Drug Testing Programs" as directed in the President's Executive Order No. 12564 dated 15 September 1986.

Part 1 of these guidelines addresses the mandatory scientific and technical requirements of agency drug testing protocols, including: collection of specimens, laboratory analysis, and the transmittal and interpretation of results.

Part 2 is for information purposes and includes the recommended model language for developing Requests for Proposals (RFP's) to procure the required services (i.e., collection and laboratory analysis).

Agencies may not deviate from the provisions of these guidelines without the written approval of the Secretary, Health and Human Services or his designee.

These guidelines are effective immediately, however, agencies currently operating drug testing programs may take up to 180 days to bring their programs into compliance.

The Secretary, Health and Human Services or his designee may routinely update these guidelines for the purpose of conforming them to advances in technology or to provide additional guidance.

Information, technical assistance, and further clarification may be obtained by contacting the Alcohol Drug Abuse and Mental Health Administration (ADAMHA)

PART I

SCIENTIFIC AND TECHNICAL REQUIREMENTS

THE DRUGS

As part of the Executive Order, each Executive Agency will determine which drugs will be included in each category of the testing program (e.g., pre-employment, reasonable suspicion, random). The Order defines "illegal drugs" as those included in Schedule I or II of the Controlled Substances Act (CSA), unless the use is authorized by a legal prescription or other exemption as permitted under appropriate laws. These schedules cover hundreds of drugs, but it is obviously not practical to test for all of them.

Agency drug testing programs shall at a minimum test for marijuana and cocaine. Furthermore, agencies may also test for opiates, amphetamines, and phencyclidine (PCP). When conducting reasonable suspicion testing, an agency may test for any drug identified in Schedule I or II of the Controlled Substances Act. The above provisions are not intended to limit agencies specifically authorized by law to include additional categories of drugs in the drug testing of their own employees or employees in their regulated industries.

This document presents specific information on the drugs most likely to be included in agency drug testing programs (i.e. marijuana, cocaine, opiates, amphetamines, and PCP). An agency may petition the Secretary of Health and Human Services or his designee for approval to include any additional drugs (or classes of drugs) in its testing protocols.

SPECIMEN COLLECTION PROCEDURES

COLLECTION SITE

The collection site is a place where individuals present themselves for the purpose of providing urine specimens to be analyzed for drugs of abuse. The site must possess all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and transportation (shipping) of urine specimens to a drug testing laboratory.

Procedures must provide for the collection site to be secure. Chain of custody forms must be properly executed by authorized collection site personnel upon receipt of specimens. The handling and transportation of urine specimens from one authorized individual or place to another must always be accomplished through the use of chain of custody procedures. No unauthorized personnel shall be permitted in any part of the collection site where urine specimens are collected or stored.

COLLECTION PROCEDURES

Procedures for providing urine specimens must allow individual privacy unless the agency has reason to believe that a particular individual may alter or substitute the specimen to be provided. Agencies must take precautions to ensure that a urine specimen has not been adulterated or diluted during the collection procedure and that all information on the urine bottle and in the log book can be identified as belonging to a given individual. To ensure that unadulterated specimens are obtained, the following procedures outline the minimum precautions that shall be taken during the collection of urine specimens:

1. At the collection site, toilet bluing agents shall be placed in the toilet tanks, wherever possible, so the reservoir of water in the toilet bowl always remains blue. There should not be any other source of water (e.g. shower, sink, etc.) in the enclosure where urination occurs.

2. Upon arrival at the collection site, the collection site person shall request the individual to present some type of photo identification. If the individual does not have proper identification, this shall be noted on the chain of custody form. If the individual fails to appear at the assigned time, collection site personnel shall contact appropriate authority to obtain guidance on action to be taken.

3. The collection site person shall ask the individual to remove any unnecessary outer garments (e.g., coat, jacket) that might conceal items or substances that could be used to tamper with or adulterate his/her urine specimen. Also, all personal belongings (e.g. purse, briefcase) must remain with the outer garments; the individual may, however, retain his/her wallet. The collection site person shall note any unusual behavior or appearance.

4. The individual shall be instructed to wash and dry his/her hands prior to urination.

5. After washing hands, the individual shall remain in the presence of the collection site person and not have access to water fountains, faucets, soap dispensers, or cleaning agents.

6. The individual may provide his/her specimen in the privacy of a stall, or otherwise partitioned area that allows for individual privacy. The collection site person shall note any unusual behavior by the individual.

7. If the collection site uses a public restroom the following procedures should be followed:

   Females: A female collection site person should accompany the individual into the public restroom. Toilet bluing should be placed into the toilet bowl. The individual should be asked to void into the disposable specimen container, and asked not to flush the toilet. A disposable collection container with a wider mouth may be used to collect the urine. The sample is then transferred to the collection container by the individual. The collection site person remains in the restroom but outside the stall until the urine specimen is collected and handed to the collection site person by the individual. The collection site person should flush the toilet and continue on with the chain of custody procedures.

   Males: A male collection site person should accompany the individual into the public restroom. Toilet bluing should be placed into the urinal or the toilet bowl (whichever is being used). The individual should be asked to void into the disposable specimen container and asked not to flush the toilet. The collection site person remains in the restroom but outside the stall until the urine specimen is collected and handed to the collection site person by the individual. The collection site person should flush the toilet and continue on with the chain of custody procedures.

8. Upon receiving the specimen from the individual, the collection site person will determine that it contains at least 60 milliliters of urine. If there is not sufficient urine in the container, additional urine should be collected. The individual may be given reasonable amounts of liquid (e.g., a glass of water). If an individual fails, for any reason, to provide the necessary specimen, collection site personnel shall contact appropriate authority to obtain guidance on action to be taken.

9. After the specimen has been provided and submitted to the collection site person the individual should be allowed to wash his/her hands.

10. Immediately after collection, collection site personnel shall measure the temperature of the specimen and conduct an inspection to determine the specimen's color, and signs of contaminants. Any unusual findings resulting from the inspection must be included on the chain of custody form. The time from urination to delivery of the sample for temperature measurement is critical and in no case should exceed four (4) minutes. If the temperature of the specimen is outside the range of 32.5 - 37.7°C / 90.5 - 99.8°F this gives rise to reasonable suspicion of adulteration/substitution, and another specimen should be collected under direct observation and both specimens forwarded to the laboratory. Any specimen suspected to be adulterated should always be forwarded for testing. When reasonable suspicion is established, the second specimen must be obtained under direct observation.

11. Both the individual being tested and the collection site person should keep the specimen in view at all times prior to its being sealed and labeled. If the specimen is transferred to a second container, the collection site person shall request the individual to observe the transfer of the specimen and the placement of the tamperproof seal over the bottle cap and down the sides of the bottle. The collection site person will place the identification label securely on the bottle.

12. The identification label should contain the date, individual's specimen number, and any other identifying information provided/required by the Agency. The individual shall initial the label on the specimen bottle.

13. The collection site person will enter the identifying information in a ledger. Both the collection site person and the individual shall sign the ledger next to the identifying information.

14. The individual shall be asked to read and sign a certification statement regarding his/her urine specimen.

15. The collection site person shall complete the appropriate chain of custody form.

16. The urine specimen and chain of custody form are now ready for shipment. If the specimen is not immediately prepared for shipment, it must be appropriately secured during temporary storage.

NOTE: While performing any part of the chain of custody procedures it is essential that the urine specimen and custody documents be under the control of the involved collection site person. If the involved Collection Site person must leave his/her work station momentarily, the specimen and custody form must be taken with him/her or must be secured. After the collection site person returns to the work station the custody process will continue. If the site person is leaving for an extended period of time, prior to leaving the site the specimen should be packaged for mailing.

Collection Control

Collection site personnel shall always attempt to have the container or specimen bottle within sight before and after the individual has urinated. The containers shall be tightly capped, properly sealed, and labeled. A chain of custody form approved by the Agency shall be utilized for maintaining control and accountability from point of collection to final disposition of specimens. With each transfer of possession, the chain of custody form shall be dated, signed by the individual releasing the specimen, signed by the individual accepting the specimen, and the purpose for transferring possession noted. Every effort should be made to minimize the number of persons handling specimens.

Transportation to Laboratory

After collection of urine specimens, collection site personnel shall arrange to ship the specimens to the drug testing laboratory. The specimens shall be placed in appropriate containers (specimen boxes or padded mailers) that are securely sealed to eliminate the possibility of tampering. Collection site personnel shall sign and date across the tape sealing the container and ensure that the chain of custody documentation is attached to each sealed container. An outer mailing wrapper is placed around each sealed container. Specimens may be delivered to the drug testing laboratory using either the United States Postal Service, commercial air freight, air express, or may be handcarried. It is not necessary to send specimens by registered mail.

LABORATORY ANALYSIS PROCEDURES

DEFINITIONS

INTRALABORATORY CHAIN OF CUSTODY: Procedures used by the laboratory to maintain control and accountability from the receipt of urine specimens until testing is completed, results reported, and while specimens are in storage.

INITIAL TEST: A sensitive, rapid, and inexpensive immunoassay screen to eliminate "true negative" specimens from further consideration.

CONFIRMATORY TEST: A second analytical procedure used to identify the presence of a specific drug or metabolite in a urine specimen. The confirmatory test must be different in technique and chemical principle from that of the initial test procedure to ensure reliability and accuracy (At this time gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method).

ALIQUOT: A portion of a specimen used for testing. An appropriate amount is transferred into a labeled test tube.

RECEIVING/PREPARATION

The laboratory must be secure at all times; no unauthorized personnel shall be permitted. Upon receipt of specimens, accession personnel shall inspect packages for evidence of possible tampering and compare information on specimen bottles with that on chain of custody forms. Any discrepancies shall be properly noted and described. Any direct evidence of tampering shall be reported immediately to the Agency, and shall also be noted on the chain-of-custody form which must accompany all specimens during laboratory possession.

Specimen bottles and original chain of custody forms will normally be retained within the accession area until all analyses have been completed. Aliquots and intralaboratory chain of custody forms shall be used by laboratory personnel for conducting the initial and confirmatory tests.

SHORT-TERM REFRIGERATED STORAGE

Specimens shall be refrigerated upon arrival if initial testing is not to be completed within 2 days.

SPECIMEN PROCESSING

Drug testing laboratories will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory testing, every batch shall contain an appropriate

number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both internal and external blind proficiency test samples should appear as ordinary samples to laboratory personnel.

INITIAL TEST

The initial testing shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether negative or positive for these five drugs or classes of drugs:

	Initial Test Level (ng/ml)
Marijuana metabolites	100
Cocaine metabolites	300
Opiates	300
Phencyclidine	25
Amphetamines	1000

These test levels are subject to change by HHS as advances in technology or other considerations may permit identification and quantification of these substances at lower concentrations.

Some specimens may be subjected to initial testing by methods other than immunoassays, where the latter are unavailable for the detection of specific drugs of special concern. These methods are thin layer, high pressure liquid, and/or gas chromatography. Alternate initial test methods and testing levels shall be submitted for written approval to the Secretary of Health and Human Services or his designee.

CONFIRMATORY TEST

All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques. Quantitative GC/MS confirmation procedures at the following cutoff values shall be used for the following drugs:

	Confirmatory Test Level (ng/ml)
Marijuana metabolite*	20
Cocaine metabolite**	150
Opiates	300
Phencyclidine	25
Amphetamines	300

*Delta-9-tetrahydrocannabinol-9-carboxylic acid
**Benzoylecgonine

These test levels are subject to change by HHS as advances in technology or other considerations may permit identification and quantification of these substances at lower concentrations.

Confirmation methods and levels for other drugs tested shall be submitted by the Agency to the Secretary of Health and Human Services or his designee for approval. In the absence of an accepted quantitative GC/MS assay procedure, preference will be given to a confirmation of qualitative identification by means of full-scan GC/MS analysis and quantification by an alternate chromatographic method. All methods shall meet commonly accepted analytical standards.

Proper chain of custody controls shall always be enforced during confirmation testing. Authorized confirmation technicians shall sign the chain of custody forms and be responsible for each urine specimen to be tested. The laboratory shall include sufficient safeguards to ensure that unauthorized personnel are prevented from gaining access to the confirmation laboratory.

REPORTING RESULTS

Test results shall be reported to the agencys designated Medical Review Official within an average of 5 working days of receipt of the specimens. The report should contain the specimen number assigned by the submitting agency, the drug testing laboratory accession number, and results of the drug tests. All specimens negative on the initial test or negative on the confirmatory test shall be reported as negative. Only specimens confirmed positive shall be reported positive for a specific drug. Results may be transmitted to the Medical Review Officer (see pg. 15) by various electronic means (e.g., teleprinters, facsimile, or computer) in a manner consistent with the privacy act. It is not permitted to provide results verbally by telephone. A certified copy of the original chain of custody form, signed by the laboratory director or laboratory certifying official, shall be sent to the Medical Review Officer. Certified copies of all analytical results shall be available from the laboratory when requested by appropriate authority.

All records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

LONG-TERM STORAGE

Specimens confirmed positive shall be retained and placed in properly secured long-term frozen storage for at least 365 days. Within this 365 day period an Agency may request the laboratory to retain the specimen for an additional period of time. This ensures that the urine specimen will be available for a possible retest during any administrative or disciplinary proceeding. If the laboratory does not receive a request to retain the specimen during the initial 365 day period, the specimen may be discarded.

RETESTING SPECIMENS

Should specimen reanalysis be required, the quantitation of a drug or metabolite in a specimen may not be subject to the same testing level criteria that were used during the original analysis. Some analytes deteriorate or are lost during freezing and/or storage.

SECURITY

The laboratory facilities shall use appropriate security measures to ensure limited and/or controlled access.

SUBCONTRACTING

The drug testing laboratory shall perform all work with its own personnel and equipment, unless otherwise authorized by the Agency.

LABORATORY FACILITIES

Laboratories must comply with applicable provisions of any State licensure requirements. Accredited laboratories must have the facility and capability, at the same laboratory, of performing screening and confirmation tests for each drug or metabolite for which service is offered.

LABORATORY PERSONNEL

The scientific director of the drug testing laboratory shall meet three criteria. He or she must: (1) be [A] certified as a Laboratory Director by the State in forensic/toxicological analysis, or [b] hold a Ph.D. in pharmacology, toxicology, or analytical chemistry; (2) have at least two years experience in analytic toxicology (the analysis of biological materials for drugs of abuse) and appropriate training and/or forensic applications of analytic toxicology (court testimony, research and publications in analytic toxicology of drugs of abuse, etc.); and, (3) have documented scientific qualifications comparable to those of a person certified by the American Board of Forensic Toxicology or the American Board of Clinical Chemistry in Toxicological Chemistry. The director is responsible for ensuring that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the urine drug testing laboratory.

A key individual in the laboratory is the certifying scientist; (who may be the Laboratory Scientific Director); this individual reviews the standards, control specimens, and quality control data together with the screening and confirmation test results. After having assured that all results are acceptable, this individual certifies the test result. The certifying scientist must have sound training in the sciences, specific training in the theory and practice of the procedures used, including the recognition of aberrant results, and familiarity with quality control procedures.

Supervisors of analysts must possess a B.S. degree in chemistry or at least the education and experience comparable to a Medical Technologist certified by the American Society of Clinical Pathologists, MT(ASCP), or its equivalent. These individuals also must have training in the theory and practice of the procedures used, and understanding of quality control concepts. Periodic verification of their skills must be documented. Other technicians or nontechnical staff must possess the necessary training and skills for the task assigned. Inservice continuing education programs to meet the needs of all laboratory personnel are desirable. Personnel files must include: resume of training and experience, certification or license, if any, references, job descriptions, health records, records of performance evaluation and advancement, incident reports, and results of tests for color blindness.

QUALITY ASSURANCE AND QUALITY CONTROL

Urine drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process: specimen acquisition, chain of custody, security, and reporting of results, in addition to the screening and confirmation of analytical procedures. Quality control procedures will be designed, implemented, and reviewed to monitor the conduct of each step of the process.

a. Requirement of Internal Laboratory Quality Control

Laboratories are responsible for assuring that Quality Control (QC) urine specimens containing no drug and specimens fortified with known standards be analyzed with each run of specimens screened: some of these will be blind to the analyst. In addition, some of these QC specimens will contain drug or metabolite at or near the threshold (cutoff) levels. Implementation of procedures must be documented to ensure that carry-over does not contaminate the testing of a subject's specimen. A minimum of 10 percent of all test samples must be QC specimens. The known standards shall be the first specimens processed in each run. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Internal proficiency test samples, prepared from spiked urine samples of determined concentration shall be included in the run and will appear as normal samples to laboratory personnel. Each run must include at least two (2) blind control samples (one positive and one negative) per 200 specimens. Similar standards, positive and negative controls will be analyzed in parallel with confirmation tests.

b. Agency External Laboratory Quality Control Procedures

Participation in proficiency testing surveys, by which the laboratory performance is compared with peers and reference laboratories, is encouraged. Participation in a ADAMHA/National Institute on Drug Abuse (NIDA)-recognized accreditation and proficiency testing program for drugs of abuse is mandatory. (Criteria for such recognition will be available from ADAMHA in March 1987.)

During the initial 90 day period of any new drug testing program a minimum of 1000 samples of which at least 800 are blank (i.e. certified to contain no drug) must be submitted to the contract laboratory as external blind proficiency test specimens. Subsequent to the initial 90 day period, a minimum of 250 specimens per quarter shall be submitted to the contract laboratory as external blind proficiency test specimens. Any unsatisfactory proficiency testing result must be investigated by the Agency and corrective actions must be taken. A report of the investigative findings, together with subsequent corrective actions, should be recorded, dated, signed by the responsible supervisor and laboratory director and sent to the agency contracting officer. Should a false-positive error occur on a blind proficiency test specimen, retesting of all specimens submitted to that lab for the period two weeks prior to the detected error and two weeks after is required. Unsatisfactory performance on proficiency test samples is sufficient cause for the Agency to revoke laboratory accreditation.

c. Interim External Laboratory Quality Control Procedures

Prior to the existence of ADAMHA/NIDA recognized accreditation and proficiency testing programs, agencies must ensure laboratory proficiency by one of the following methods:

1. Agencies may use contract laboratories that have been certified for urinalysis testing by the Department of Defense.

2. Agencies may develop interim self-accreditation procedures by establishing pre-award inspections and proficiency testing plans approved by HHS.

DOCUMENTATION

Documentation of all aspects of the testing process must be available. This documentation will be maintained for at least 2 years and will include: personnel files on analysts, supervisors, directors, and all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; all test data; reports; performance records on proficiency testing; performance on accreditation inspections; and hard copies of computer-generated data.

REPORTS

All test results, including screening, confirmation, and quality control data must be reviewed by the certifying scientist or laboratory director before a test result is certified as accurate. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the threshold concentration for each.

INSPECTIONS

The Agency shall reserve the right to inspect the laboratory at any time. Contracts with laboratories, as well as for collection site services, shall permit unannounced inspections. Preaward inspections and evaluation of the procedural aspects of the program must be accomplished prior to the award of any contract.

JUDICIAL PROCEEDINGS

The laboratory must have qualified personnel available to testify in an administrative or disciplinary proceeding against a Federal employee that is based on a positive urinalysis result reported by its laboratory.

REPORTING AND REVIEW OF RESULTS

An essential part of the drug testing program is the final review of results. A positive test result does not automatically identify an employee/applicant as an illegal drug user. An individual with a detailed knowledge of possible alternate medical explanations must be involved in the review process. This review will be performed by the Medical Review Official (MRO) prior to the transmission of results to Agency administrative officials.

The MRO may be an Agency or contract employee who is a licensed physician with knowledge of substance abuse disorders. The role of the MRO is to review and interpret positive test results obtained through the Agency's testing program. In the conduct of this responsibility, the MRO should undertake the examination of alternate medical explanations for a positive test result. This action could include the conduct of employee medical interviews, review of employee medical history, or the review of any other relevant biomedical factors. The MRO is required to review all medical records made available by the tested employee when a confirmed positive test could have resulted from legally prescribed medication. After the MRO has reviewed the pertinent information and the laboratory assessment is verified, the case will be referred as determined by Agency policy to the Agency Employee Assistance Program, Personnel, or Administrative Offices for disposition. Should any question arise as to the veracity of a positive test result, the MRO is authorized to order a reanalysis of the original sample. If the MRO determines there is a legitimate medical explanation for the positive test result, the MRO may deem that the result is consistent with legal drug use, and take no further action. Additionally, the MRO, based on review of inspection reports, QC data, multiple samples, and other pertinent results may deem the result scientifically insufficient for further action and declare the individual as negative. The contract laboratory must be able to provide information to assist in this review process by employing or having available a forensic toxicologist or someone with equivalent forensic experience in urine drug testing who can be called on when specific consultation is required by the Agency. [Note. Before the MRO certifies a confirmed positive result for opiates, he/she must verify that there is clinical evidence (in addition to the urine test) of illegal use of any opium, opiate or opium derivative listed in Schedules I and II. This requirement does not apply if the Agency's GC/MS confirmation testing for opiates verifies the presence of 6-O-monoacetylmorphine.]

PROTECTION OF EMPLOYEE RECORDS

Any laboratory contract shall provide that the contractor's records are subject to the Privacy Act, 5 U.S.C. 552a. The Agency shall establish a Privacy Act System of Records (or modify an existing system) to cover both the Agency's and the contractor's records of employee urinalysis results. The contract and the Privacy Act System must have specific provisions that require that employee records are maintained and used with the highest regard for employee privacy.

PART II

MODEL LANGUAGE FOR CONTRACT RFP'S

The following model language is recommended to Agencies for use in the development of contract statements of work for the services required for drug testing programs. Section A details the recommended "Collection Site Specifications." Section B details the recommended "Laboratory and Testing Specifications."

A. COLLECTION SITE SPECIFICATIONS

COLLECTION SITE: The collection site is a place for specified Federal employees to present themselves for the purpose of providing their urine specimens under controlled conditions for the detection of drugs of abuse. The collection site may be at the Agency's place of business or at a contractor's facility.

The collection site must possess all necessary personnel, materials, equipment, facilities, and supervision to provide collection, security, storage, and transportation (shipping) of urine specimens to the testing laboratories.

The collection site, although serving a separate function, may be on laboratory property or at other locations approved by the Agency. The collection site must have restroom facilities which are clean, well-lighted, and sufficiently secure to prevent compromise during the collection of urine specimens.

If the Agency decides that samples are to be provided at a contractor's facility away from the employee's place of work, the collection site should be reasonably accessible to employees so as to provide minimum disruption of the Agency's business, and shall have the capacity to collect a minimum of 80 urine specimens per day. The Agency will furnish the collection site with an advance listing of Federal employees scheduled for testing. During non working hours, the collection site shall provide emergency collection services within four (4) hours following notification from individuals authorized by the Agency or its designated contractors.

A collection site facility dedicated solely to urine collection shall be secure at all times. In cases where a facility cannot be dedicated solely for the purpose of drug testing the portion of the facility being used for testing shall be secured during drug testing operations. Chain of custody forms must be properly executed by authorized collection site personnel upon receipt of specimens. The handling and transportation of urine specimens from one authorized individual or place to another must always be accomplished through the use of chain of custody format. No unauthorized personnel shall be permitted in any part of the collection site where urine specimens are collected or stored.

COLLECTION PROCEDURE: Federal employees or applicants required to submit to testing for drug abuse must provide urine specimens under the supervision of testing personnel, but not under direct observation, under conditions that provide an opportunity for individual privacy. However, in order to assure that proper and unadulterated specimens are obtained, procedures at least equivalent to those described in Part I must be used.

All Federal employees must wash and dry their hands thoroughly prior to urination. Specimens shall be collected under the supervision of authorized collection site personnel. Collection site personnel must ensure that disposable specimen containers are sealed in the presence of the employee. Federal employees providing urine specimens should not let the containers out of their sight until they are sealed.

Immediately after collection, collection site personnel shall measure temperature (avoiding cross contamination of specimens) and conduct an inspection of each specimen in order to determine the specimen's warmth, color, and signs of contaminants. Any unusual findings resulting from the inspection must be included on the chain of custody form. A specimen suspected to be adulterated should always be forwarded for testing. When reasonable suspicion of specimen adulteration is established, collection site personnel should obtain a second specimen under direct observation.

Following inspection, the container will be capped and the cap sealed with approved security tape or sealable bag. The Federal employee must then initial the tape or sealed bag to protect the chain of custody.

If an employee fails, for any reason, to provide the necessary specimen, or if an employee fails to appear at the collection site at his/her assigned time, such failure shall be noted on the chain of custody form.

COLLECTION CONTROL: In cases where samples are provided without direct observation, collection site personnel shall always have the urine disposable specimen container within sight before and after but not during urination. The containers shall be tightly capped, sealed, and labeled. The labeling shall include: (1) a secure numbering system, (2) The Agency name or code number, (3) the Federal employee's initials, and (4) time and date of collection. The site must maintain a logbook containing this information and the signatures of the employee and collection person.

Chain of custody forms approved by the Agency shall be utilized for the purpose of maintaining control and accountability from initial collection to final disposition of all specimens, and these forms shall always accompany the specimens. The form will identify the specimens through use of information which matches label items and a sequential number which is assigned to each urine specimen obtained. With each transfer of possession, the chain of custody form must be signed and dated, (including the time), by individuals charged with possession of the specimens. Every effort must be made to minimize the number of persons handling the specimens in order to maximize the overall security of the specimens.

Transportation to Laboratory

After collection of urine specimens, collection site personnel shall arrange to ship the specimens to the drug testing laboratory. The specimens shall be placed in appropriate containers (specimen boxes or padded mailers) that are securely sealed to eliminate the possibility of tampering. Collection site personnel shall sign and date across the tape sealing the container and ensure that the chain of custody documentation is attached to each sealed container. An outer mailing wrapper is placed around each sealed container. Specimens may be delivered to the drug testing laboratory using either the United States Postal Service, commercial air freight, air express, or may be handcarried. It is not necessary to send specimens by registered mail.

B. LABORATORY AND TESTING SPECIFICATIONS

DEFINITIONS

AUTHORIZED PERSONNEL: Individuals determined by the laboratory to have a need for access to areas used for the receiving, testing, and storage of urine specimens; further, this definition shall include laboratory supervisors with the authority to sign for and take control of urine specimens through the use of the chain of custody format.

CHAIN OF CUSTODY: Refers to the methodology of tracking specified materials and/or substances for the purpose of maintaining control and accountability from initial collection to final disposition for all such materials and/or substances and must provide for accountability at each stage in handling, testing, storing specimens, and reporting test results.

CONFIRMATION TESTING: A second procedure (test) used to demonstrate the presence of specified drugs of abuse in given urine specimens. This test (gas chromatography/mass spectrometry is currently the only acceptable method), must be different in format and chemical theory from that of the initial testing procedure utilized.

MEDICAL REVIEW OFFICIAL: The medical review official (MRO) is responsible for receiving laboratory results generated from the Agency drug testing program. This officer will be a licensed physician with knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate all positive test results together with the employee's medical history and any other relevant biomedical information.

INITIAL TESTING: The initial assay of urine specimens for presence of specified drugs of abuse or their metabolites.

LABORATORY: Physical plant where specimens are received, inspected, numbered, screened, confirmed, and stored.

SAMPLE RUN: An analytical run is a group of specimens consisting of standards, quality control specimens, and unknowns which are processed and measured sequentially or simultaneously under a standard set of conditions. The analytical run is designed in such a way that quality control specimens can be related to a defined group of unknown specimens.

SPECIMEN: A sample of human urine, at least 60 ml in volume, to be confined in a shatter-resistent, sealed, and marked container.

REQUIREMENTS

RECEIVING/ACCESSION: This area of the laboratory must be secure at all times; no unauthorized personnel shall be permitted. If any specimen becomes lost, misplaced, or is improperly delivered, the Agency shall be notified immediately. If a package of specimens is received and the outer wrapping is found to be damaged, the laboratory shall note and describe this damage on a chain of custody form.

Specimens shall not leave the presence and control of authorized receiving/accession personnel until the specimens are released to testing personnel or placed in temporary refrigerated storage. Personnel in receiving/accession areas shall examine outer wrappings and contents of every specimen for signs of tampering. Any direct evidence of tampering shall be reported immediately to the Agency, and shall also be noted on the chain of custody form which must accompany all specimens during laboratory possession.

SHORT-TERM REFRIGERATED STORAGE: Specimens that do not receive an initial testing within two (2) days of arrival at the laboratory shall be placed in secure, temporary refrigeration units. Temperatures shall not exceed six (6) degrees centigrade. Emergency power equipment shall be available in case of prolonged power failure.

INITIAL TEST

The initial testing shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether negative or positive for these five drugs or classes of drugs:

	Initial Test Level (ng/ml)
Marijuana metabolites	100
Cocaine metabolites	300
Opiates	300
Phencyclidine	25
Amphetamines	1000

These test levels are subject to change by HHS as advances in technology may permit identification and quantitation of these substances at lower concentrations.

Some specimens may be subjected to initial testing by methods other than immunoassays, where the latter are unavailable for the detection of specific drugs of special concern. These methods include thin layer, high pressure liquid, and/or gas chromatography. Alternate initial test methods and testing levels shall be submitted for approval to the Secretary of Health and Human Services or his designee.

CONFIRMATORY TEST

All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques. Quantitative GC/MS confirmation procedures at the following cutoff values shall be used for the following drugs:

	Confirmatory Test Level (ng/ml)
Marijuana metabolite*	20
Cocaine metabolite**	150
Opiates	300
Phencyclidline	25
Amphetamines	300

*Delta-9-tetrahydrocannabinol-9-carboxylic acid
**Benzoylecgonine

These test levels are subject to change by HHS as advances in technology may permit identification and quantitation of these substances at lower concentrations.

Confirmation methods and cutoff values for any other drug designated for testing shall be approved during contract review and negotiation in consultation with HHS. In the absence of an accepted quantitative GC/MS assay procedure, preference will be given to the combination of qualitative identification by means of full-scan GC/MS analysis and quantification by an alternate chromatographic method. All methods must meet commonly accepted analytical standards. For all confirmation test results, quantitative values shall be reported.

Proper chain of custody controls shall always be enforced during confirmation testing. Authorized confirmation technicians shall sign the chain of custody forms and be responsible for each urine specimen to be tested. The laboratory shall include sufficient safeguards to ensure that unauthorized personnel are prevented from gaining access to the confirmation laboratory.

TESTING CONTROLS: Every sample run for initial and confirmation testing shall contain at least 10 percent known standards and quality control samples. The known standards shall be the first specimens processed in each run. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Known and blind quality control samples, prepared from spiked urine samples of determined concentration shall be included in the run and will appear as normal samples to laboratory personnel. Each run must include at least two blind control samples (one positive and one negative) per 200 specimens. A minimum of 250 blind samples per quarter should be submitted for testing.

LONG-TERM STORAGE: All specimens initially tested negative need not be retained. Specimens tested positive shall be confirmed as described above. All confirmed positive specimens shall then be placed in long-term frozen storage for a period of 365 days. All nonconfirmed positive specimens shall be disposed of. If, at the end of this 365-day period, the laboratory has not been notified by the Agency to retain certain confirmed positive specimens indefinitely, the laboratory shall dispose of these specimens.

Should reanalysis or retest be required as a result of challenge or litigation, it is important to note that the quantitation of the drug or metabolite may not be required to meet the same initial cutoff criteria, since some analytes deteriorate or are lost during freezing and/or storage.

Long-term storage facilities shall be equipped with secure locks. Emergency power equipment shall be available in case of prolonged power failure.

Access to the long-term storage facility shall be limited to authorized personnel only.

TEST RESULTS: Test results shall be transmitted electronically or by registered mail to the Agency Medical Review Official ordinarily within an average of 5 working days of receipt of the specimen(s). Appropriate safeguards must be adopted to ensure confidentiality of records by limiting access to authorized individuals.

REPORTING REQUIREMENTS: The laboratory shall provide the Medical Review Official with a monthly statistical summary of urinalysis testing of Federal employees. Screening and confirmation data should only be included from results reported within that period. This summary normally should be forwarded by registered mail within 2 weeks (14 calendar days) after the end of the month covered by the summary and shall contain the following information:

INITIAL TESTING

a) Number of specimens received
b) Number reported out
c) Number of specimens screened positive for:

marijuana metabolites	cocaine metabolites
opiates (morphine/codeine)	phencyclidine
amphetamines	
any other drugs requested	

CONFIRMATION TESTING

a) Number of specimens received
b) Number of specimens confirmed positive for:

marijuana metabolite	cocaine metabolites
morphine and/or codeine	phencyclidine
amphetamine	methamphetamine
any other drug requested	

NOTE: ALL RECORDS, INCLUDING INITIAL TEST RECORDS AND CHROMATOGRAPHIC TRACINGS, SHALL BE RETAINED BY THE LABORATORY IN SUCH A MANNER AS TO ALLOW RETRIEVAL OF ALL INFORMATION PERTAINING TO THE INDIVIDUAL URINE SPECIMENS FOR A MINIMUM PERIOD OF TWO (2) YEARS AFTER COMPLETION OF TESTING OF ANY GIVEN SPECIMEN.

SECURITY: The degree to which locks, doors, walls, storage facilities, testing laboratories, and buildings must be resistant to unauthorized entry, tampering, and compromise; keyed locks must be "tamper-proof" and all cipher locks should be subject to periodic combination changes. All testing and storage areas shall have limited access. In properly established accession, storage and testing facilities, the construction and physical security protection must be designed either to prevent or detect attempted, forced, or surreptitious entry.

SUBCONTRACTING: The laboratory shall perform all work required under these Guidelines with its own personnel and equipment, unless otherwise authorized by the Agency.

LABORATORY FACILITIES

Laboratories must comply with applicable provisions of any State licensure requirements. Accredited laboratories must have the facility and capability, at the same laboratory, of performing screening and confirmation tests for each drug or metabolite for which service is offered.

LABORATORY PERSONNEL

The scientific director of the drug testing laboratory shall meet three criteria. He or she must: (1) be [A] certified as a Laboratory Director by the State in forensic/toxicological analysis, or [b] hold a Ph.D. in pharmacology, toxicology, or analytical chemistry; (2) have at least two years experience in analytic toxicology (the analysis of biological materials for drugs of abuse) and appropriate training and/or forensic applications of analytic toxicology (court testimony, research and publications in analytic toxicology of drugs of abuse, etc.); and, (3) have documented scientific qualifications comparable to those of a person certified by the American Board of Forensic Toxicology or the American Board of Clinical Chemistry in Toxicological Chemistry. The director is responsible for ensuring that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the urine drug testing laboratory.

A key individual in the laboratory is the certifying scientist; (who may be the Laboratory Scientific Director); this individual reviews the standards, control specimens, and quality control data together with the screening and confirmation test results. After having assured that all results are acceptable, this individual certifies the test result. The certifying scientist must have sound training in the sciences, specific training in the theory and practice of the procedures used, including the recognition of aberrant results, and familiarity with quality control procedures.

Supervisors of analysts must possess a B.S. degree in chemistry or at least the education and experience comparable to a Medical Technologist certified by the American Society of Clinical Pathologists, MT(ASCP), or its equivalent. These individuals also must have training in the theory and practice of the procedures used, and understanding of quality control concepts. Periodic verification of their skills must be documented. Other technicians or nontechnical staff must possess the necessary training and skills for the task assigned. Inservice continuing education programs to meet the needs of all laboratory personnel are desirable. Personnel files must include: resume of training and experience, certification or license, if any, references, job descriptions, health records, records of performance evaluation and advancement, incident reports, and results of tests for color blindness.

QUALITY ASSURANCE AND QUALITY CONTROL

Urine drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process: specimen acquisition, chain of custody, security, and reporting of results, in addition to the screening and confirmation of analytical procedures. Quality control procedures will be designed, implemented, and reviewed to monitor the conduct of each step of the process.

a. Requirement of Internal Laboratory Quality Control

Laboratories are responsible for assuring that Quality Control (QC) urine specimens containing no drug and specimens fortified with known standards be analyzed with each run of specimens screened: some of these will be blind to the analyst. In addition, some of these QC specimens will contain drug or metabolite at or near the threshold (cutoff) levels. Implementation of procedures must be documented to ensure that carry-over does not contaminate the testing of a subject's specimen. A minimum of 10 percent of all test samples must be QC specimens. The known standards shall be the first specimens processed in each run. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Internal proficiency test samples, prepared from spiked urine samples of determined concentration shall be included in the run and will appear as normal samples to laboratory personnel. Each run must include at least two (2) blind control samples (one positive and one negative) per 200 specimens. Similar standards, positive and negative controls will be analyzed in parallel with confirmation tests.

b. Agency External Laboratory Quality Control Procedures

Participation in proficiency testing surveys, by which the laboratory performance is compared with peers and reference laboratories, is encouraged. Participation in a ADAMHA/National Institute on Drug Abuse (NIDA)-recognized accreditation and proficiency testing program for drugs of abuse is mandatory. (Criteria for such recognition will be available from ADAMHA in March 1987.)

During the initial 90 day period of any new drug testing program a minimum of 1000 samples of which at least 800 are blank (i.e. certified to contain no drug) must be submitted to the contract laboratory as external blind proficiency test specimens. Subsequent to the initial 90 day period, a minimum of 250 specimens per quarter shall be submitted to the contract laboratory as external blind proficiency test specimens. Any unsatisfactory proficiency testing result must be investigated by the Agency and corrective actions must be taken. A report of the investigative findings, together with subsequent corrective actions, should be recorded, dated, signed by the responsible supervisor and laboratory director and sent to the agency contracting officer. Should a false-positive error occur on a blind proficiency test specimen, retesting of all specimens submitted to that lab for the period two weeks prior to the detected error and two weeks after is required. Unsatisfactory performance on proficiency test samples is sufficient cause for the Agency to revoke laboratory accreditation.

DOCUMENTATION

Documentation of all aspects of the testing process must be available. This documentation will be maintained for at least 2 years, and will include: personnel files on analysts, supervisors, directors and all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; all test data; reports; performance records on proficiency testing; performance on accreditation inspections, and hard copies of computer-generated data.

REPORTS

All test results, including screening, confirmation and quality control data must be reviewed by the certifying scientist or laboratory director before certifying that a test result is accurate. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the threshold concentration for each.

INSPECTIONs: The Agency reserves the right to conduct pre- and post-award inspections and/or to require other evidence of technical, managerial, financial, and similar abilities to perform the work described in these Specifications. These inspections may include testing proficiency samples.

JUDICIAL PROCEEDINGS: The laboratory shall provide all services and testing in such a manner that all results and reports shall be developed so as to maximize the likelihood that they will be admissible evidence in any administrative or civil judicial proceeding. The laboratory must also have processing technicians (and collection site personnel, if under laboratory contract) available for testimony.

PAYMENT OF POSTAGE AND FEES: All postage and fees related to information submitted to the Agency, including forms, reports, etc., shall be prepaid by the laboratory.

SUPPLIES AND MATERIALS: All bottles, forms, labels, sealing tape or bags, and supplies must be furnished by the laboratory.

STAFFING: An Agency may conduct a survey of the laboratory buildings, facilities, security, critical personnel, and the overall capacity to conform to all of these Guidelines before the contract is awarded. Additionally, the laboratory should submit to the Agency a complete resume of employees whom the laboratory believes are most likely to be called as witnesses in any judicial defense of the the Agency drug detection program.

FACILITIES: The laboratory must be made available for inspection by Agency officials at any time during normal working hours.

OTHER TESTS: The specific gravity and pH shall be determined on every specimen submitted to the laboratory for testing. The laboratory will also examine every specimen for any other evidence of adulteration or substitution. Any abnormal findings shall be reported to the Agency. In addition to the drugs specifically mandated in the laboratory contract, the laboratory must also have the capability to measure creatinine. Creatinine is an endogenous compound excreted in human urine at a relatively constant rate which can be used as an indicator to determine whether a specimen has been diluted.

EVALUATION FACTORS FOR APPROVAL

EVALUATION CRITERIA: The Agency must consider the following elements when evaluating laboratories.

(1) OPERATING PLANS - to be evaluated on the basis of work, as demonstrated by internal control and execution of assigned work, including proper receiving, storage, internal chain of custody, testing, supervision, security, and plans for reporting test results to the Agency as required.

(2) COMPANY EXPERIENCE - to be evaluated on the basis of total years of relevant laboratory experience in providing similar services as verified through references of past and present performance.

(3) TEST METHODS - to be evaluated on the basis of the scientific acceptability of the actual methods to be employed, the proper inclusion of standards, and evaluation of previous test records.

(4) KEY PERSONNEL - to be evaluated on the basis of the appropriateness of positions and skills designated by the laboratory, the qualifications proposed, the certifications obtained, and the submission of specific nominations for key personnel.

(5) QUALITY ASSURANCE AND CONTROL PROGRAM - to be evaluated on the basis of the proposed methods and techniques for the detection and correction of deficiencies with regard to receiving, chain of custody, preliminary/confirmation testing and storage.

(6) FACILITIES - to be evaluated on the basis of laboratory facilities and equipment for receiving, testing, security, and storage of urine specimens.