National Institute on Drug Abuse

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Model Plan for a Comprehensive Drug-Free Workplace Program

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Alcohol, Drug Abuse, and Mental Health Administration

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National Institute on Drug Abuse
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Rockville, MD 20857

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This model plan was developed by a Federal Interagency Coordinating Group composed of representatives from the Department of Health and Human Services, the Office of Personnel Management, and the Department of Justice and distributed to Federal agencies by the National Drug Policy Board.

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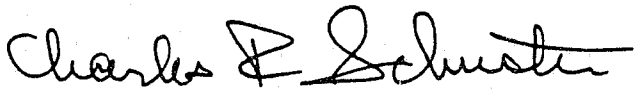
by the uniqueness of each Federal agency, its application outside the Federal context must be flexible enough to accommodate the needs of the great variety of employers, work sites, and workforce characteristics which constitute the private and non-Federal public American workplace.

This model plan was developed by a Federal interagency coordinating group composed of representatives of the Department of Health and Human Services, Office of Personnel Management, and Department of Justice and distributed to Federal agencies by the National Drug Policy Board to provide a prototype for developing a drug-free workplace plan appropriate to each agency's own mission and work force.

There has been very little editing of the plan as distributed to Federal agencies. For the Federal audience, the use of the term "Agency" throughout invited substitution of the specific agency name. Private sector employers should substitute the name of their business in most instances. The model plan contains references to Federal authorities which do not impose requirements on private employers. While those references are retained for the purpose of reflecting the policies behind provisions of the Federal model plan, it is expected that private sector employers will modify the plan when they intend to preserve the principle without referencing Federal law or regulations.

Selected source documents for the Federal Drug-Free Workplace Program are published as Appendices: Appendix A is Executive Order 12564; Appendix B is section 503 of Pub. L. 100-71; and Appendix C is the Mandatory Guidelines for Federal Workplace Drug Testing Programs which include scientific and technical requirements and provisions for certification of laboratories engaged in urine drug testing for Federal agencies. They are published along with the model in order to provide a framework for the existing application of the model.

The National Institute on Drug Abuse is making this model available, both for employers just initiating a program and for those who may be re-examining provisions of an on-going program, in the belief that the fight against illegal drugs in the workplace is critical to the Nation's war against drug use. This model, with its five essential elements, is worthy of careful consideration as employers chart or alter their course.



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I. INTRODUCTION

A. Background

On September 15, 1986, President Reagan signed Executive Order 12564, establishing the goal of a Drug-Free Federal Workplace. The Order made it a condition of employment for all Federal employees to refrain from using illegal drugs on or off-duty. In a letter to all executive branch employees dated October 4, 1986, the President reiterated his goal of ensuring a safe and drug-free workplace for all Federal workers.

The Executive Order recognized that illegal drug use is seriously impairing a portion of the national work force, resulting in the loss of billions of dollars each year. As the largest employer in the Nation, the Federal Government has a compelling proprietary interest in establishing reasonable conditions of employment. Prohibiting employee drug use is one such condition. The [Agency] is concerned with the well-being of its employees, the successful accomplishment of agency missions, and the need to maintain employee productivity. The intent of the policy is to offer a helping hand to those who need it, while sending a clear message that any illegal drug use is, quite simply, incompatible with Federal service.

On July 11, 1987, Congress passed legislation affecting implementation of the Executive Order under Section 503 of the Supplemental Appropriations Act of 1987, Pub. L. 100-71, 101 Stat. 391, 468-471, codified at 5 U.S.C. §7301 note (1987), (hereafter, the "Act"), in an attempt to establish uniformity among Federal agencies' drug testing plans, reliable and accurate drug testing, employee access to drug testing records, confidentiality of drug test results, and centralized oversight of the Federal Government's drug testing program.*

*NOTE TO PRIVATE SECTOR USERS OF THIS MODEL PLAN: Since section 503 of Pub. L. 100-71 places most attention on the drug testing component (the most sensitive aspect) of a comprehensive drug-free workplace program, compliance with its requirements stimulates in the Federal model plan an initial focus on the drug testing component of the Drug-Free Federal Workplace Program. Nevertheless, all Federal agencies' drug-free workplace plans implementing Executive Order 12564 are comprehensive and should be viewed as a whole; i.e., each agency has a written policy, provides for education of employees, training for supervisors, access to an employee assistance program, and for identification of illegal drug use.

The purpose of the [Agency] Drug-Free Workplace Plan is to set forth objectives, policies, procedures, and implementation guidelines, to achieve a drug-free Federal workplace, consistent with the Executive Order and Section 503 of the Act.

B. Statement of Policy

The [Agency], as a result of its [describe type of] responsibilities, as well as the sensitive nature of its work, has a compelling obligation to eliminate illegal drug use from its workplace.

[Insert a one page summary that describes the two or three most significant aspects of your agency's mission. The summary should convey to the uninitiated reader, why drug testing is necessary at your agency. The purpose of the summary is to explicitly describe your agency's mission, and how illegal drug use would impact the accomplishment of that mission. In preparing this summary, a review of the following documents from your agency may help in identifying examples of the adverse impact which illegal drug use has had or could have on your agency mission: (1) personnel records; (2) security clearance revocations; (3) EAP records; (4) Merit Systems Protection Board actions; and any other relevant agency records to glean effective examples regarding public health, safety or security risks which have occurred in the past. Large numbers are neither necessary nor essential. The preamble focuses on the magnitude of risk of even one employee using illegal drugs.]

The mark of a successful drug-free workplace program also depends on how well the [Agency] can inform its employees of the hazards of drug use, and on how much assistance it can provide drug users. Equally important is the assurance to employees that personal dignity and privacy will be respected in reaching the [Agency's] goal of a drug-free workplace. Therefore, this plan includes policies and procedures for: (1) employee assistance; (2) supervisory training; (3) employee education; and (4) identification of illegal drug use through drug testing on a carefully controlled and monitored basis.

C. Nature, Frequency, and Type of Drug Testing to be Instituted

Section 503 of the Act requires the [Agency] Plan to specify the nature, frequency, and type of drug testing to be instituted. The [Agency] Plan includes the following types of drug testing: (1) Applicant testing; (2) Random testing of those employees in sensitive positions that have been designated as testing designated positions; (3) Reasonable suspicion testing; (4) Accident or unsafe practice testing; (5) Voluntary testing, and (6) Testing as part of or as a follow-up to counseling or rehabilitation.

The frequency of testing for random testing, voluntary testing, and follow-up testing is specified in Section XV, Section XII(B), and Section XII(C), respectively. The [Agency Head] reserves the right to increase or decrease the frequency of testing based on the Agency's mission, need, availability of resources, and experience in the program, consistent with the duty to achieve a drug-free workplace under the Executive Order.

D. Drugs for Which Individuals Are Tested

Section 503 of the Act requires the [Agency] to specify the drugs for which individuals shall be tested. The [Agency] will test for the following drugs: Marijuana, Cocaine. [Agency may also add Amphetamines, Opiates, and Phencyclidine (PCP). If the Agency desires to test for any other drug, advance written approval from the Secretary, Department of Health and Human Services is required.]

E. Scope

Upon certification by the Department of Health and Human Services in accordance with Section 503 of the Act, this order shall be effective immediately for all [list divisions of the agency which will be affected by the order].

F. Union Cooperation

The active participation and support of labor organizations can contribute to the success of this program. Management will seek ways in which recognized bargaining unit representatives might assist in program implementation, such as in acquainting employees with rehabilitation facilities and by enhancing employee confidence in the program. Management will continue to observe agreements already reached, will include union representatives in general orientation programs, and will continue to meet its obligations under Title VII of the Civil Service Reform Act of 1978.

G. References

1. Authorities

a. Executive Order 12564;

b. Executive Order 10450;

c. Executive Order 12356;

d. Section 503 of the Supplemental Appropriations Act of 1987, Pub. L. 100-71, 101 Stat. 391, 468-471, codified at 5 U.S.C. §7301 note (1987);

e. Mandatory Guidelines for Federal Workplace Drug Testing Programs, which includes Scientific and Technical Requirements and Certification of Laboratories Engaged in Urine Drug Testing, 53 FR 11970 (1988);

f. Civil Service Reform Act of 1978, Pub. L. 95-454;

g. Sections 523 and 527 of the Public Health Service Act and implementing regulations at 42 CFR Part 2, Confidentiality of Alcohol and Drug-Abuse Patient Treatment Records;

h. The Privacy Act of 1974 (5 U.S.C. §552a), prescribing requirements governing the maintenance of records by agencies pertaining to individuals and access to these records by the individual(s) to whom they pertain;

i. Regulations implementing the Privacy Act of 1974 for the [Agency];

j. Federal Employees Substance Abuse Education and Treatment Act of 1986, Pub. L. 99-570;

k. [Add any relevant Agency orders, including appropriate personnel orders.]

2. Guidance

a. Office of Personnel Management (OPM), Federal Personnel Manual (FPM) Letters 792-16 (November 28, 1986), and 792-17 (March 9, 1987), and any subsequent FPM letters setting forth guidelines for Federal civilian agencies in establishing a drug-free workplace pursuant to Executive Order 12564;

b. FPM Chapter 792, Federal Health and Counseling Programs, providing guidance to Federal agencies in establishing alcoholism and drug abuse programs (subchapter 5) and employee counseling services programs (subchapter 6) for Federal employees with alcohol or drug problems;

c. FPM Supplement, Chapter 792-2, providing guidance for developing and maintaining appropriate prevention, treatment and rehabilitation programs and services for alcoholism and drug abuse among Federal employees;

d. **[Appropriate Agency personnel manual implementing FPM Chapter 792 and FPM Supplement, Chapter 792-2 within the Agency.]**

II. DEFINITIONS

A. Applicant means any individual tentatively selected--

1. For employment with the [Agency]; or
2. For a Testing Designated Position, and who has not, immediately prior to the selection, been subject to random testing.

B. **Employee Assistance Program (EAP)** means the [Agency]-based counseling program that offers assessment, short-term counseling, and referral services to employees for a wide range of drug, alcohol, and mental health problems, and monitors the progress of employees while in treatment.

C. **Employee Assistance Program Administrator** means the individual responsible for ensuring the development, implementation and review of the agency EAP.

D. **Employee Assistance Program Coordinator** means the individual designated by the EAP Administrator to be responsible for implementing and operating the EAP within the [Agency] component assigned to the coordinator, by providing counseling, treatment, and education services to employees and supervisors regarding the [component] EAP.

E. **Medical Review Officer** means the individual responsible for receiving laboratory results generated from the [Agency] Drug-Free Workplace Program who is a licensed physician with knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate all positive test results together with an individual's medical history and any other relevant biomedical information.

F. **Illegal Drugs** means a controlled substance included in Schedule I or II, as defined by section 802(6) of Title 21 of the United States Code, the possession of which is unlawful under chapter 13 of that Title. The term "illegal drugs" does not mean the use of a controlled substance pursuant to a valid prescription or other uses authorized by law.

G. **Random Testing** means a system of drug testing imposed without individualized suspicion that a particular individual is using illegal drugs, and may either be:

1. Uniform-unannounced testing of testing designated employees occupying a specified area, element or position; or
2. A statistically random sampling of such employees based on a neutral criterion, such as social security numbers.

H. Employees in Sensitive Positions means:

1. Employees in positions designated by the [Agency head] as Special Sensitive, Critical Sensitive, or Noncritical-Sensitive under Chapter 731 of the Federal Personnel Manual, or employees in positions designated by the [Agency head] as sensitive in accordance with Executive Order No. 10450, as amended;

2. Employees granted access to classified information or who may be granted access to classified information pursuant to a determination of trustworthiness by the [Agency head] under Section 4 of Executive Order No. 12356;

3. Individuals serving under Presidential appointments;

4. Law enforcement officers as defined in 5 U.S.C. §8331(20) and 8401(17); or

5. Other positions that the [Agency head] determines involve law enforcement, national security, the protection of life and property, public health or safety, or other functions requiring a high degree of trust and confidence.

I. **Supervisor** means an employee having authority to hire, direct, assign, promote, reward, transfer, furlough, layoff, recall, suspend, discipline, or remove other employees, to adjust their grievances, or to effectively recommend such action, if the exercise of the authority is not merely routine or clerical in nature, but requires the consistent exercise of independent judgement. 5 U.S.C. §7103 (a)(10).

J. **Testing Designated Positions (TDPs)** means employment positions within the [Agency] which have been designated for random testing under Section IX(B) of this plan.

K. **Verified Positive Test Result** means a test result that was positive on an initial FDA-approved immunoassay test, confirmed by a Gas Chromatography/Mass Spectrometry assay, (or other confirmatory tests approved by the Department of Health and Human Services), and reviewed and verified by the Medical Review Officer in accordance with this plan and the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

III. EMPLOYEE ASSISTANCE PROGRAMS

A. Function

The [Agency] EAP plays an important role in preventing and resolving employee drug use by: demonstrating the [Agency's] commitment to eliminating illegal drug use; providing employees an opportunity, with appropriate assistance, to discontinue their drug use; providing educational materials to supervisors and employees on drug use issues; assisting supervisors in confronting employees who have performance and/or conduct problems and making referrals to appropriate treatment and rehabilitative facilities; and follow-up with individuals during the rehabilitation period to track their progress and encourage successful completion of the program. The EAP, however, shall not be involved in the collection of urine samples or the initial reporting of test results. Specifically, the EAP shall--

1. Provide counseling and assistance to employees who self-refer for treatment or whose drug tests have been verified positive, and monitor the employees' progress through treatment and rehabilitation;

2. Provide needed education and training to all levels of the [Agency] on types and effects of drugs, symptoms of drug use and its impact on performance and conduct, relationship of the EAP to drug testing, and related treatment, rehabilitation, and confidentiality issues;

3. Ensure that confidentiality of test results and related medical treatment and rehabilitation records is maintained in accordance with Section XIV.

B. Referral and Availability

Any employee found to be using drugs shall be referred to the EAP. The EAP shall be administered separately from the testing program, and shall be available to all employees without regard to a finding of drug use. The EAP shall provide counseling or rehabilitation for all referrals, as well as education and training regarding illegal drug use. The EAP is available not only to [Agency] employees, but, when feasible, to the families of employees with drug problems, and to employees with family members who have drug problems.

In the event the employee is not satisfied with the program of treatment or rehabilitation, such employee may seek review of the EAP Counselor's referral by notifying the EAP Administrator prior to completion of the program. The decision of the EAP Administrator shall be final and shall not be subject to further administrative review. Regardless of the treatment program chosen, the employee remains responsible for successful completion of the treatment, and assertions that the counselor failed to consider one or more of the factors in Section VI(D)(5) in making a referral shall not constitute either an excuse for continuing to use illegal drugs or a defense to disciplinary action if the employee does not complete treatment.

C. Leave Allowance

Employees shall be allowed up to one hour (or more as necessitated by travel time) of excused absence for each counseling session, up to a maximum of **[state limit here]**, during the assessment/referral phase of rehabilitation. Absences during duty hours for rehabilitation or treatment must be charged to the appropriate leave category in accordance with law and leave regulations.

D. Records and Confidentiality

All EAP operations shall be confidential in accordance with Section XIV of this plan relating to records and confidentiality.

E. Structure

The [appropriate division of the agency] shall be responsible for oversight and implementation of the [Agency] EAP, and will provide, with the support of the [Agency head], high level direction and promotion of the EAP.

[Describe more fully the structure of the agency's EAP -- in-house, contracted, regional locations, etc.]

IV. SUPERVISORY TRAINING

A. Objectives

As supervisors have a key role in establishing and monitoring a drug-free workplace, the [Agency] shall provide training to assist supervisors and managers in recognizing and addressing illegal drug use by agency employees. The purpose of supervisory training is to understand--

1. Agency policies relevant to work performance problems, drug use, and [the Agency] EAP;

2. The responsibilities of offering EAP services;

3. How employee performance and behavioral changes should be recognized and documented;

4. The roles of the Medical Review Officer, medical staff, supervisors, personnel, and EAP personnel;

5. The ways to use [the Agency] EAP;

6. How the EAP is linked to the performance appraisal and the disciplinary process; and

7. The process of reintegrating employees into the workforce.

B. Implementation

The [appropriate division of the agency] shall be responsible for implementing supervisory training, and shall develop a training package to ensure that all employees and supervisors are fully informed of the [Agency] Drug-Free Workplace Plan.

C. Training Package

Supervisory training shall be required of all supervisors and may be presented as a separate course, or be included as part of an ongoing supervisory training program. Training shall be provided as soon as possible after a person assumes supervisory responsibility. Training courses should include--

1. Overall Agency policy;

2. The prevalence of various employee problems with respect to drugs and alcohol;

3. The EAP approach to handling problems including the supervisor's role and relationship to EAP;

4. How to recognize employees with possible problems;

5. Documentation of employee performance or behavior;

6. Skills in confronting employees with possible problems;

7. Agency procedures for referring employees to EAP;

8. Disciplinary action, and removals from sensitive positions as required by Section 5(c) of the Executive Order;

9. Reintegration of employees into the workforce; and

10. Written materials which the supervisor can use at the work site.

V. EMPLOYEE EDUCATION

A. Objectives

The EAP Administrator shall offer drug education to all [Agency] employees. Drug education should include education and training to all levels of the [Agency] on--

1. Types and effects of drugs;

2. Symptoms of drug use, and the effects on performance and conduct;

3. The relationship of the EAP to drug testing; and

4. Other relevant treatment, rehabilitation, and confidentiality issues.

B. Means of Education

Drug education activities may include:

1. Distribution of written materials;

2. Videotapes;

3. Lunchtime employee forums; and

4. Employee drug awareness days.

VI. SPECIAL DUTIES AND RESPONSIBILITIES

[Smaller agencies may choose to combine several of the duties listed into a single position upon advice from the Department of Health and Human Services.]

A. Drug Program Coordinator

Each [operating or other appropriate element] shall have a Drug Program Coordinator assigned to carry out the purposes of this plan. The Drug Program Coordinator shall be responsible for implementing, directing, administering, and managing the drug program within the [operating element]. The Drug Program Coordinator shall serve as the principal contact with the laboratory and for collection activities in assuring the effective operation of the testing portion of the program. In carrying out his responsibilities, the Drug Program Coordinator shall, among other duties:

1. Arrange for all testing authorized under this order;

2. Ensure that all employees subject to random testing receive individual notice as described in Section VII(B) of this plan, prior to implementation of the program, and that such employees return a signed acknowledgment of receipt form;

3. Document, through written inspection reports, all results of laboratory inspections conducted;

4. Coordinate with and report to the [Agency head] on Drug Program Coordinator activities and findings that may affect the reliability or accuracy of laboratory results;

5. In coordination with the EAP Administrator, publicize and disseminate drug program educational materials, and oversee training and education sessions regarding drug use and rehabilitation; and

6. Coordinate all Drug Program Coordinator duties in field offices wherever possible to conserve resources and to efficiently and speedily accomplish reliable and accurate testing objectives.

B. Employee Assistance Program Administrator

The EAP Administrator shall:

1. Receive verified positive test results from the Medical Review Officer;

2. Assume the lead role in the development, implementation, and evaluation of the EAP;

3. Supervise and designate the headquarters EAP Coordinator and counselors, and assist them in establishing field office EAPs; and

4. Advise [Agency] components on the submission of annual statistical reports, and prepare consolidated reports on the [Agency's] EAP activity.

C. Employee Assistance Program Coordinator

The EAP Coordinator shall:

1. Implement and operate the EAP within the [Agency] component assigned to the coordinator;

2. Provide counseling and treatment services to all employees referred to the EAP by their supervisors or on self-referral, and otherwise offer employees the opportunity for counseling and rehabilitation;

3. Coordinate with the [Agency Head], the Medical Review Officer and supervisors, as appropriate;

4. Work with the Drug Program Coordinator to provide educational materials and training to managers, supervisors, and employees on illegal drugs in the workplace;

5. Assist supervisors with performance and/or personnel problems that may be related to illegal drug use;

6. Monitor the progress of referred employees during and after the rehabilitation period, and provide feedback to supervisors in accordance with 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records;

7. Ensure that training is provided to assist supervisors in the recognition and documentation of facts and circumstances that support a reasonable suspicion that an employee may be using illegal drugs;

8. Maintain a list of rehabilitation or treatment organizations which provide counseling and rehabilitative programs, and include the following information on each such organization:

   a. Name, address, and phone number;

   b. Types of services provided;

   c. Hours of operation, including emergency hours;

   d. The contact person's name and phone number;

   e. Fee structure, including insurance coverage;

   f. Client specialization; and

   g. Other pertinent information; and

9. Periodically visit rehabilitative or treatment organizations to meet administrative and staff members, tour the site, and ascertain the experience, certification and educational level of staff, and the organization's policy concerning progress reports on clients and post-treatment follow-up.

D. **Employee Assistance Counselors**

The Employee Assistance Counselors shall--

1. Serve as the initial point of contact for employees who ask or are referred for counseling;

2. Be familiar with all applicable law and regulations, including drug treatment and rehabilitation insurance coverage available to employees through the Federal Employee Health Benefits Program;

3. Meet the qualifications as determined by the EAP Administrator and be trained in counseling employees in the occupational setting, and in identifying drug use;

4. Document and sign the treatment plan prescribed for all employees referred for treatment, after obtaining the employee's signature on this document; and

5. In making referrals, consider the--

   a. Nature and severity of the problem;

   b. Location of the treatment;

   c. Cost of the treatment;

   d. Intensity of the treatment environment;

   e. Availability of inpatient/outpatient care;

   f. Other special needs, such as transportation and child care; and

   g. The preferences of the employee.

E. Medical Review Officer Each [Agency or other appropriate element] shall have an Medical Review Officer assigned to carry out the purposes of this Order. The Medical Review Officer shall, among other duties:

1. Receive all laboratory test results;

2. Assure that an individual who has tested positive has been afforded an opportunity to discuss the test result in accordance with Section XIII(D) of this plan;

3. Consistent with confidentiality requirements, refer written determinations regarding all verified positive test results to the EAP Administrator, and the [appropriate official], including a positive drug test result form indicating that the positive result has been verified, together with all relevant documentation and a summary of findings;

4. Confirm with the appropriate personnel official whether an individual who has been tentatively selected for employment with the [Agency] has obtained a verified positive test result;

5. Coordinate with and report to the [Agency head] on all activities and findings on a regular basis;

6. Coordinate all Medical Review Officer duties in field offices wherever possible to conserve resources and to efficiently and speedily accomplish reliable and accurate testing objectives.

F. Supervisors

Supervisors will be trained to recognize and address illegal drug use by employees, and will be provided information regarding referral of employees to the EAP, procedures and requirements for drug testing, and behavioral patterns that give rise to a reasonable suspicion that an employee may be using illegal drugs. Except as modified by the [Agency head] to suit specific program responsibilities, first-line supervisors shall:

1. Attend training sessions on illegal drug-use in the workplace;

2. Initiate a drug test based on reasonable suspicion as described in Section X;

3. Refer employees to the EAP for assistance in obtaining counseling and rehabilitation, upon a finding of illegal drug use;

4. Initiate appropriate disciplinary action upon a finding of illegal drug use; and

5. In conjunction with personnel specialists, assist higher-level supervisors and the EAP Administrator in evaluating employee performance and or personnel problems that may be related to illegal drug use.

A higher-level supervisor shall review and concur, in advance, with all tests ordered on the basis of a reasonable suspicion in accordance with Section X.

G. Implementation

At the direction of the [appropriate agency official], each [operating unit head] shall implement the Drug-Free Workplace Plan within [the operating unit head's division], and ensure that the Plan is efficiently and effectively accomplished in accordance with this order and all other applicable regulations.

H. General Program/Structural Provisions

The [appropriate agency official] shall develop implementation procedures to enable [Agency field offices] efficiently and swiftly to implement all aspects of this order, taking into account the unique geographical, personnel, budgetary and other relevant factors of the field offices. Such procedures will permit field office implementation to proceed independently of headquarters implementation, and of any field office situs implementation. Testing may proceed under this order as soon as any field office or operating site is prepared to commence testing, and without regard to whether any other field office or operating site or headquarters is prepared to commence with testing. Such procedures shall also encourage cooperation and coordination among components so as to conserve resources and efficiently implement this order. [Agencies should give careful consideration to overall structures and determine whether additional management analysis provisions should be added.]

I. Government Contractors

Wherever existing facilities are inadequate to implement this order, the [appropriate agency official] shall:

1. Act as Contracting Officer for the administration of all related contracts;

2. Ensure that contract laboratories chosen to perform the drug screening tests are duly certified according to subpart C of the Mandatory Guidelines for Federal Workplace Drug Testing Programs and that any other contracts to implement this Order conform to the technical specifications of the Mandatory Guidelines; and

3. Establish, by contract or with [Agency] employees as deemed appropriate, the positions and specific responsibilities of the Drug Program Coordinator and the Medical Review Officer as required by the Mandatory Guidelines.

VII. NOTICE

A. General Notice

A general notice from the [Agency head] announcing the testing program, as required by the Executive Order Section 4(a), will be provided to all employees no later than sixty (60) days prior to the implementation date of the Plan. The notices shall be provided immediately upon completion of the congressional certification procedures pursuant to Section 503 of the Act, and shall explain:

1. The purpose of the Drug-Free Workplace Plan;

2. That the Plan will include both voluntary and mandatory testing;

3. That those who hold positions selected for random testing will also receive an individual notice, prior to the commencement of testing, indicating that their position has been designated a Testing Designated Position;

4. The availability and procedures necessary to obtain counseling and rehabilitation through the EAP;

5. The circumstances under which testing may occur;

6. That opportunity will be afforded to submit medical documentation of lawful use of an otherwise illegal drug;

7. That the laboratory assessment is a series of tests which are highly accurate and reliable, and that, as an added safeguard, laboratory results are reviewed by the Medical Review Officer;

8. That positive test results verified by the Medical Review Officer may only be disclosed to the employee, the appropriate EAP administrator, the appropriate management officials necessary to process an adverse action against the employee, or a court of law or administrative tribunal in any adverse personnel action;

9. That all medical and rehabilitation records in an EAP will be deemed confidential "patient" records and may not be disclosed without the prior written consent of the patient, an authorizing court order, or otherwise as permitted by Federal law implemented at 42 CFR Part 2.

B. Individual Notice

In addition to the information provided in the general notice, an individual notice will be distributed to all employees in testing designated positions explaining:

1. That the employee's position has been designated a "testing designated position;"

2. That the employee will have the opportunity to voluntarily admit to being a user of illegal drugs and to receive counseling or rehabilitation, [If there is no safe harbor*, add: "in which case disciplinary action is not required;" If there is a safe harbor, add: "and shall not be subject to disciplinary action."];

*Refer to Section VIII(F) for safe harbor option to create an absolute bar to disciplinary action for certain volunteers.

3. That the employee's position will be subject to random testing no sooner than thirty days following the notice.

C. Signed Acknowledgement

Each employee in a Testing Designated Position shall be asked to acknowledge in writing that the employee has received and read the notice which states that the employee's position has been designated for random drug testing, and that refusal to submit to testing will result in initiation of disciplinary action, up to and including dismissal. If the employee refuses to sign the acknowledgement, the employee's supervisor shall note on the acknowledgement form that the employee received the notice. This acknowledgement, which is advisory only, shall be centrally collected for easy retrieval by the [operating unit head]. An employee's failure to sign the notice shall not preclude testing that employee, or otherwise affect the implementation of this order since the general sixty-day notice will previously have notified all agency employees of the requirement to be drug-free.

D. Administrative Relief

If an employee believes his or her position has been wrongly designated a Testing Designated Position, that employee may file an administrative appeal to [specify the designated official] who has authority to remove the employee from the Testing Designated Position list. The appeal must be submitted by the employee, in writing, to [the designated official] within 15 days of notification, setting forth all relevant information. The [designated official] shall review the appeal based upon the criteria applied in designating that employee's position as a Testing Designated Position. The [official's] decision is final and is not subject to further administrative review.

VIII. FINDING OF DRUG USE AND DISCIPLINARY CONSEQUENCES

A. Determination

An employee may be found to use illegal drugs on the basis of any appropriate evidence including, but not limited to:

1. Direct observation;

2. Evidence obtained from an arrest or criminal conviction;

3. A verified positive test result; or

4. An employee's voluntary admission.

B. Mandatory Administrative Actions

The [Agency] shall refer an employee found to use illegal drugs to the EAP, and, if the employee occupies a sensitive position, immediately remove the employee from that position without regard to whether it is a Testing Designated Position. At the discretion of the [Agency head], however, and as part of an EAP, an employee may return to duty in a sensitive position if the employee's return would not endanger public health or safety or national security.

C. Range of Consequences

Disciplinary action taken against an employee found to use illegal drugs may include the full range of disciplinary actions, including removal. The severity of the action chosen will depend on the circumstances of each case, and will be consistent with the Executive Order. The [Agency] shall initiate disciplinary action against any employee found to use illegal drugs.

[Insert either:]

a. provided that such action is not required for an employee who voluntarily admits to illegal drug use, and obtains counseling or rehabilitation and thereafter refrains from using illegal drugs.

[or if a safe harbor exists, add:]

b. but shall not discipline an employee who voluntarily admits to illegal drug use in accordance with subsection VIII(F) of this plan.

[In either case, add:]

Such disciplinary action, consistent with the requirements of any governing collective bargaining agreement and the Civil Service Reform Act and other statutes, [Agency] orders, and regulations, may include any of the following measures but some disciplinary action must be initiated:

1. Reprimanding the employee in writing;

2. Placing the employee in an enforced leave status;

3. Suspending the employee for 14 days or less;

4. Suspending the employee for 15 days or more;

5. Suspending the employee until the employee successfully completes the EAP or until the [Agency] determines that action other than suspension is more appropriate;

6. Removing the employee from service.

D. Initiation of Mandatory Removal From Service

The [Agency] shall initiate action to remove an employee for:

1. Refusing to obtain counseling or rehabilitation through an EAP as required by the Executive Order after having been found to use illegal drugs;

2. Not refraining from illegal drug use after a first finding of such use.

All letters to propose and decide on a separation action should be worked out in consultation with the [appropriate servicing personnel office].

E. Refusal to Take Drug Test When Required

An employee who refuses to be tested when so required will be subject to the full range of disciplinary action, including dismissal. No applicant who refuses to be tested shall be extended an offer of employment. Attempts to alter or substitute the specimen provided will be deemed a refusal to take the drug test when required.

F. Voluntary Referral

Under Executive Order 12564, the [Agency] is required to initiate action to discipline any employee found to use illegal drugs in every circumstance except that such discipline is not required for an employee who (1) voluntarily admits his or her drug use; (2) completes counseling or an EAP; and (3) thereafter refrains from drug use.

[If you do not wish to create an absolute bar to discipline for individuals who voluntarily come forward, insert the following language:]

The decision whether to discipline a voluntary referral will be made by the agency head on a case by case basis depending upon the facts and circumstances. Although an absolute bar to discipline cannot be provided for certain positions because of their extreme sensitivity, the [Agency], in determining whether to discipline, shall consider that the employee has come forward voluntarily. In coming forward voluntarily, and consistent with Section XII(B), an employee may volunteer for a drug test as a means of identification. The results of this test, however, shall not constitute a second finding of illegal drug use under subsection (D).

[If you wish to create an absolute bar to discipline for individuals who voluntarily come forward, insert the following language:]

1. Because the Order permits an agency to create a "safe harbor" for an employee who meets all three of these conditions, the [Agency] has decided to create such a "safe harbor" and will not initiate disciplinary action against employees who satisfy the provisions of this Section.

2. A fundamental purpose of the [Agency's] Drug-Free Workplace Plan is to assist employees who themselves are seeking treatment for drug use. For this reason, the [Agency] will not initiate disciplinary action against any employee who meets all three of these conditions:

a. Voluntarily identifies him/herself as a user of illegal drugs prior to being identified through other means;

b. Obtains counseling or rehabilitation through an EAP; and

c. Thereafter refrains from using illegal drugs.

This self-referral option allows any employee to step forward and identify him/herself as an illegal drug user for the purpose of entering a drug treatment program under the EAP. In stepping forward, and consistent with Section XII(B), an employee may volunteer for a drug test as a means of identification. Although this self-identification test may yield a verified positive test result, such result shall not subject an employee to discipline assuming the three safe harbor requirements are met.

3. Since the key to this provision's rehabilitative effectiveness is an employee's willingness to admit his or her problem, this provision is not available to an employee who requests protection under this provision after:

a. Being asked to provide a urine sample in accordance with this plan; or

b. Having been found to have used illegal drugs pursuant to Section VIII(A)(1) or VIII(A)(2).

IX. RANDOM TESTING

A. Sensitive Positions Designated for Random Testing

The Executive Order requires random testing for employees in sensitive positions, subject to agency criteria. As specified in Section XV of this plan, the **[Agency head]** has determined that some of these sensitive positions are testing designated positions subject to random testing. The position titles designated for random drug testing are listed in Section XV, along with the criteria and procedures applied in designating such positions for drug testing, including the justification for such criteria and procedures. **[Section XV must list those positions designated for random testing and contain "drug impact statements" describing the duties of each Testing Designated Position and the risks of harm arising from illegal drug use by an employee occupying that position.]**

B. Determining The Testing Designated Position

Among the factors the **[Agency head]** has considered in designating a Testing Designated Position, are the extent to which the **[Agency]**--

[Omit any factors which do not apply]

1. Considers its mission inconsistent with illegal drug use;

2. Is engaged in law enforcement;

3. Must foster public trust by preserving employee reputation for integrity, honesty and responsibility;

4. Has national security responsibilities;

5. Has drug interdiction responsibilities; or

6. Has positions which--

   a. Authorize employees to carry firearms;

   b. Give employees access to sensitive information;

   c. Authorize employees to engage in law enforcement;

   d. Require employees, as a condition of employment, to obtain a security clearance; or

   e. Require employees to engage in activities affecting public health or safety.

These positions are characterized by critical safety or security responsibilities as related to the mission of the [Agency]. The job functions associated with these positions directly and immediately relate to public health and safety, the protection of life and property, law enforcement, or national security. These positions are identified for random testing because they require the highest degree of trust and confidence. The [agency head] reserves the right to add or delete positions determined to be testing designated positions pursuant to the criteria established in the Executive Order and this plan. Moreover, the **[Agency head]** has determined, pursuant to 42 U.S.C. 290ee-1(b)(2)(B), that all positions which have been or will be designated as testing designated positions under this plan are "sensitive positions" and are therefore exempted from coverage under 42 U.S.C. 290ee-1(b).

C. Implementing Random Testing

In implementing the program of random testing the Drug Program Coordinator shall--

1. Ensure that the means of random selection remains confidential; and

2. Evaluate periodically whether the numbers of employees tested and the frequency with which those tests will be administered satisfy the **[Agency's]** duty to achieve a drug-free work force.

The number of sensitive employees occupying testing designated positions and the frequency with which random tests will be administered are specified in Section XV.

D. Notification of Selection

An individual selected for random testing, and the individual's first-line supervisor, shall be notified the same day the test is scheduled, preferably, within two hours of the scheduled testing. The supervisor shall explain to the employee that the employee is under no suspicion of taking drugs and that the employee's name was selected randomly.

E. Deferral of Testing

An employee selected for random drug testing may obtain a deferral of testing if the employee's first-line and higher-level supervisors concur that a compelling need necessitates a deferral on the grounds that the employee is:

1. In a leave status (sick, annual, administrative or leave without pay); or

2. In official travel status away from the test site or is about to embark on official travel scheduled prior to testing notification.

An employee whose random drug test is deferred will be subject to an unannounced test within the following 60 days.

X. REASONABLE SUSPICION TESTING

A. Grounds

Reasonable suspicion testing may be based upon, among other things:

1. Observable phenomena, such as direct observation of drug use or possession and/or the physical symptoms of being under the influence of a drug;

2. A pattern of abnormal conduct or erratic behavior;

3. Arrest or conviction for a drug-related offense, or the identification of an employee as the focus of a criminal investigation into illegal drug possession, use, or trafficking;

4. Information provided either by reliable and credible sources or independently corroborated; or

5. Newly discovered evidence that the employee has tampered with a previous drug test.

Although reasonable suspicion testing does not require certainty, mere "hunches" are not sufficient to meet this standard.

B. Procedures

If an employee is suspected of using illegal drugs, the appropriate supervisor will gather all information, facts, and circumstances leading to and supporting this suspicion. **[Agencies should insert a higher-level approval requirement that is consistent with their organizational structure. In some agencies, this may be the next level supervisor or a higher-level individual above the supervisor making the finding that a reasonable suspicion of illegal drug use exists.]**

When higher-level concurrence of a reasonable suspicion determination has been made, the appropriate supervisor will promptly prepare a written report detailing the circumstances which formed the basis to warrant the testing. This report should include the appropriate dates and times of reported drug related incidents, reliable/credible sources of information, rationale leading to the test, and the action taken.

C. Obtaining the Sample

The employee may be asked to provide the urine sample under observation in accordance with the criteria in Section XIII(B).

D. Supervisory Training

In accordance with Section IV, supervisors will be trained to address illegal drug use by employees, to recognize facts that give rise to a reasonable suspicion, and to document facts and circumstances to support a finding of reasonable suspicion. Failure to receive such training, however, shall not invalidate otherwise proper reasonable suspicion testing.

XI. APPLICANT TESTING

A. Objectives

To maintain the high professional standards of the [Agency's] workforce, it is imperative that individuals who use illegal drugs be screened out during the initial employment process before they are placed on the employment rolls of the [Agency]. This procedure will have a positive effect on reducing instances of illegal drug use by employees working within the [Agency], and will provide for a safer work environment. For these reasons, drug testing shall be required of all applicants as defined in Section II.

B. Vacancy Announcements

Every vacancy announcement for positions designated for applicant testing shall state:

> "All applicants tentatively selected for this position will be required to submit to urinalysis to screen for illegal drug use prior to appointment."

In addition, each applicant will be notified that appointment to the position will be contingent upon a negative drug test result. Failure of the vacancy announcement to contain this statement notice will not preclude applicant testing if advance written notice is provided applicants in some other manner.

C. Procedures

The Drug Program Coordinator shall direct applicants to an appropriate collection facility. The drug test must be undertaken as soon after notification as possible, and no later than 48 hours after notice to the applicant. Where appropriate, applicants may be reimbursed for reasonable travel expenses.

Applicants shall be advised of the opportunity to submit medical documentation that may support a legitimate use for a specific drug and that such information will be reviewed only by the Medical Review Officer to determine whether the individual is licitly using an otherwise illegal drug.

D. Personnel Officials

Upon notification that an individual has been tentatively selected for employment with the [Agency], the [Manager of the Personnel Division] shall assure, after consultation with the Medical Review Officer, that a drug test has been conducted on that individual and determine whether the test result is a verified positive result.

E. Consequences

The [Agency] will decline to extend a final offer of employment to any applicant with a verified positive test result, and such applicant may not reapply to the [Agency] for a period of six months. The Personnel Officer working on the applicant's certificate shall be directed to object to the applicant on the basis of failure to pass the physical, a lack of personal characteristics necessary to relate to public employment or failure to support the goals of the [Agency]. The [Agency] shall inform such applicant that a confirmed presence of an illegal drug in the applicant's urine precludes the [Agency] from hiring the applicant.

XII. ADDITIONAL TYPES OF DRUG TESTING

A. Accident or Unsafe Practice Testing

The [Agency] is committed to providing a safe and secure work environment. Employees involved in on-the-job accidents or who engage in unsafe on-duty job-related activities that pose a danger to others or the overall operation of the [Agency], may be subject to testing. Based on the circumstances of the accident or unsafe act, the [operating unit head] may initiate testing when such circumstances involve:

[State criteria here. Consider the following example of appropriate criteria:]

1. A death or personal injury requiring immediate hospitalization, or

2. Damage to government or private property in excess of $_____.]

B. Voluntary Testing

In order to demonstrate their commitment to the [Agency's] goal of a drug-free workplace and to set an example for other Federal employees, employees not in testing designated positions may volunteer for unannounced random testing by notifying the Drug Program Coordinator. These employees will then be included in the pool of testing designated positions subject to random testing, and be subject to the same conditions and procedures, including the provisions of Section VIII(F). Volunteers shall remain in the testing designated positions pool until they withdraw from participation by notifying the Drug Program Coordinator of such intent at least 48 hours prior to a scheduled test.

C. Follow-up Testing

All employees referred through administrative channels who undergo a counseling or rehabilitation program for illegal drug use through the EAP will be subject to unannounced testing following completion of such a program for a period of one year. Such employees shall be tested at the frequency stipulated in the abeyance contract, or, in the alternative, at an increased frequency of [state frequency: e.g. once a month]. Such testing is distinct from testing which may be imposed as a component of the EAP.

XIII. TEST PROCEDURES IN GENERAL

A. Mandatory Guidelines for Federal Workplace Drug Testing

The [Agency] shall adhere to the Mandatory Guidelines for Federal Workplace Drug Testing Programs promulgated by the Department of Health and Human Services consistent with the authority granted by Executive Order 12564, and to the requirements of Section 503 of the Act. The [Agency's] drug testing component shall have professionally trained collection personnel, quality assurance requirements for urinalysis procedures, and strict confidentiality requirements.

B. Privacy Assured

Any individual subject to testing under this plan, shall be permitted to provide urine specimens in private, and in a rest room stall or similar enclosure so that the employee is not observed while providing the sample. Collection site personnel of the same gender as the individual tested, however, may observe the individual provide the urine specimen when such personnel have reason to believe the individual may alter or substitute the specimen to be provided. Collection site personnel may have reason to believe that a particular individual may alter or substitute the specimen to be provided when --

1. The individual--

   a. Is being tested pursuant to Section X relating to reasonable suspicion testing;

   b. Has previously been found by the [Agency] to be an illegal drug user; or

   c. Has previously tampered with a sample; or

2. Facts and circumstances suggest that the individual--

   a. Is an illegal drug user;

   b. Is under the influence of drugs at the time of the test; or

   c. Has equipment or implements capable of tampering with or altering urine samples; or

3. The specimen--

   a. Has a temperature outside the range of 32.5-37.7 degrees C / 90.5-99.8 degrees F; or

   b. Shows signs of contaminants.

C. Failure to Appear for Testing

Failure to appear for testing without a deferral will be considered refusal to participate in testing, and will subject an employee to the range of disciplinary actions, including dismissal, and an applicant to the cancellation of an offer of employment. If an individual fails to appear at the collection site at the assigned time, the collector shall contact the Drug Program Coordinator to obtain guidance on action to be taken.

D. Opportunity to Justify a Positive Test Result

When a confirmed positive result has been returned by the laboratory, the Medical Review Officer shall perform the duties set forth in the Mandatory Guidelines. For example, the Medical Review Officer may choose to conduct employee medical interviews, review employee medical history, or review any other relevant biomedical factors. The Medical Review Officer must review all medical records made available by the tested employee when a confirmed positive test could have resulted from legally prescribed medication. Evidence to justify a positive result may include, but is not limited to:

1. A valid prescription; or

2. A verification from the individual's physician verifying a valid prescription.

Individuals are not entitled, however, to present evidence to the Medical Review Officer in a trial-type administrative proceeding, although the Medical Review Officer has the discretion to accept evidence in any manner the Medical Review Officer deems most efficient or necessary. If the Medical Review Officer determines there is no justification for the positive result, such result will then be considered a verified positive test result. The Medical Review Officer shall immediately contact the EAP Administrator and appropriate management official* upon obtaining a verified positive test result.

* The Mandatory Guidelines for Federal Drug-Free Workplace Programs provide at 2.7(c), "Following verification of a positive test result, the Medical Review Officer shall refer the case to the agency Employee Assistance Program and to the management official empowered to recommend or take administrative action."

E. Employee Counseling and Assistance

While participating in a counseling or rehabilitation program, and at the request of the program, the employee may be exempted from the random testing designated positions pool for a period not to exceed sixty days, or for a time period specified in an abeyance contract or rehabilitation plan approved by the Agency head. Upon completion of the program, the employee immediately shall be subject to follow-up testing pursuant to Section XII(C).

F. Savings Clause

To the extent that any of the procedures specified in this section are inconsistent with any of those specified in the Mandatory Guidelines for Federal Workplace Drug Testing Programs promulgated by the Department of Health and Human Services, or any subsequent amendment thereto, such Mandatory Guidelines or amendment shall supersede the procedures specified in this section, but only to the extent of the inconsistency.

XIV. RECORDS AND REPORTS

A. Confidentiality of Test Results

The laboratory may disclose laboratory test results only to the Medical Review Officer or the staff of the Medical Review Officer. Any positive result which the Medical Review Officer justifies by acceptable and appropriate medical or scientific documentation to account for the result as other than the intentional ingestion of an illegal drug will be treated as a negative test result and may not be released for purposes of identifying illegal drug use. Test results will be protected under the provisions of the Privacy Act, 5 U.S.C. §552a, et seq., and Section 503(e) of the Act, and may not be released in violation of either Act. The Medical Review Officer may maintain only those records necessary for compliance with this order. Any records of the Medical Review Officer, including drug test results, may be released to any management official for purposes of auditing the activities of the Medical Review Officer, except that the disclosure of the results of any audit may not include personal identifying information on any employee.

In order to comply with Section 503(e) of the Act, the results of a drug test of a [Agency] employee may not be disclosed without the prior written consent of such employee, unless the disclosure would be--

1. To the Medical Review Officer;

2. To the EAP Administrator in which the employee is receiving counseling or treatment or is otherwise participating;

3. To any supervisory or management official within the [Agency] having authority to take adverse personnel action against such employee; or

4. Pursuant to the order of a court of competent jurisdiction or where required by the United States Government to defend against any challenge against any adverse personnel action.

For purposes of this Section, "management official" includes any management, government, security or personnel official whose duties necessitate review of the test results in order to process adverse personnel action against the employee. In addition, test results with all identifying information removed shall also be made available to [Agency] personnel, including the Drug Program Coordinator, for data collection and other activities necessary to comply with Section 503(f) of the Act.

B. Employee Access to Records

Any employee who is the subject of a drug test shall, upon written request, have access to any records relating to--

1. Such employee's drug test; and

2. The results of any relevant certification, review, or revocation-of-certification proceedings, as referred to in Section 503(a)(1)(A)(ii)(III) of the Act.

Except as authorized by law, an applicant who is the subject of a drug test, however, shall not be entitled to this information.

C. Confidentiality of Records in General

All drug testing information specifically relating to individuals is confidential and should be treated as such by anyone authorized to review or compile program records. In order to efficiently implement this order and to make information readily retrievable, the Drug Program Coordinator shall maintain all records relating to reasonable suspicion testing, suspicion of tampering with evidence, and any other authorized documentation necessary to implement this order.

All records and information of the personnel actions taken on employees with verified positive test results should be forwarded to the [Servicing Personnel Office.] Such shall remain confidential, locked in a combination safe, with only authorized individuals who have a "need-to-know" having access to them.

D. Employee Assistance Program Records

The EAP Administrator shall maintain only those records necessary to comply with this order. After [an operating unit head] refers an employee to an EAP, the EAP will maintain all records necessary to carry out its duties. All medical and or rehabilitation records concerning the employee's drug abuse, including EAP records of the identity, diagnosis, prognosis, or treatment are confidential and may be disclosed only as authorized by 42 CFR Part 2, including the provision of written consent by the employee. With written consent, the patient may authorize the disclosure of those records to the patient's employer for verification of treatment or for a general evaluation of treatment progress. (42 CFR. §2.1 et seq. (1986), revised regulations promulgated at 52 FR 21796, June 9, 1987).

E. Maintenance of Records

The [Agency] shall establish or amend a recordkeeping system to maintain the records of the [Agency's] Drug-Free Workplace Program consistent with the [Agency's] Privacy Act System of Records and with all applicable Federal laws, rules and regulations regarding confidentiality of records including the Privacy Act (5 U.S.C. §552a). If necessary, records may be maintained as required by subsequent administrative or judicial proceedings, or at the discretion of the [Agency head]. The recordkeeping system should capture sufficient documents to meet the operational and statistical needs of this order, and include:

1. Notices of verified positive test results referred by the Medical Review Officer;

2. Written materials justifying reasonable suspicion testing or evidence that an individual may have altered or tampered with a specimen;

3. Anonymous statistical reports; and

4. Other documents the Drug Program Coordinator, Medical Review Officer, or EAP Administrator deems necessary for efficient compliance with this order.

F. Records Maintained By Government Contractors

Any contractor hired to satisfy any part of this order shall comply with the confidentiality requirements of this order, and all applicable Federal laws, rules, regulations and guidelines.

G. Statistical Information

The Drug Program Coordinator shall collect and compile anonymous statistical data for reporting the number of--

1. Random tests, reasonable suspicion tests, accident or unsafe practice tests, follow-up tests, or applicant tests administered;

2. Verified positive test results;

3. Voluntary drug counseling referrals;

4. Involuntary drug counseling referrals;

5. Terminations or denial of employment offers resulting from refusal to submit to testing;

6. Terminations or denial of employment offers resulting from alteration of specimens;

7. Terminations or denial of employment offers resulting from failure to complete a drug abuse counseling program; and

8. Employees who successfully complete EAP.

This data, along with other pertinent information, shall be compiled for inclusion in the [Agency's] annual report to Congress required by Section 503(f) of the Act. This data shall also be provided to the Department of Health and Human Services semi-annually to assist in overall program evaluation and to determine whether changes to the Mandatory Guidelines may be required.

XV. POSITION TITLES DESIGNATED FOR RANDOM TESTING

[List position titles designated for random drug testing, the criteria and procedures applied in designating the position titles, and justification for the criteria and procedures. State the number of employees occupying testing designated positions and the frequency with which random tests will be administered. Also include a "drug impact statement" describing the duties of each testing designated position and the risks of harm arising from illegal drug use by an employee occupying that position.]

APPENDIX A

Federal Register
Vol. 51, No. 180
Wednesday, September 17, 1986

Presidential Documents

Title 3—

The President

Executive Order 12564 of September 15, 1986

Drug-Free Federal Workplace

I, RONALD REAGAN, President of the United States of America, find that:

Drug use is having serious adverse effects upon a significant proportion of the national work force and results in billions of dollars of lost productivity each year;

The Federal government, as an employer, is concerned with the well-being of its employees, the successful accomplishment of agency missions, and the need to maintain employee productivity;

The Federal government, as the largest employer in the Nation, can and should show the way towards achieving drug-free workplaces through a program designed to offer drug users a helping hand and, at the same time, demonstrating to drug users and potential drug users that drugs will not be tolerated in the Federal workplace;

The profits from illegal drugs provide the single greatest source of income for organized crime, fuel violent street crime, and otherwise contribute to the breakdown of our society;

The use of illegal drugs, on or off duty, by Federal employees is inconsistent not only with the law-abiding behavior expected of all citizens, but also with the special trust placed in such employees as servants of the public;

Federal employees who use illegal drugs, on or off duty, tend to be less productive, less reliable, and prone to greater absenteeism than their fellow employees who do not use illegal drugs;

The use of illegal drugs, on or off duty, by Federal employees impairs the efficiency of Federal departments and agencies, undermines public confidence in them, and makes it more difficult for other employees who do not use illegal drugs to perform their jobs effectively. The use of illegal drugs, on or off duty, by Federal employees also can pose a serious health and safety threat to members of the public and to other Federal employees;

The use of illegal drugs, on or off duty, by Federal employees in certain positions evidences less than the complete reliability, stability, and good judgment that is consistent with access to sensitive information and creates the possibility of coercion, influence, and irresponsible action under pressure that may pose a serious risk to national security, the public safety, and the effective enforcement of the law; and

Federal employees who use illegal drugs must themselves be primarily responsible for changing their behavior and, if necessary, begin the process of rehabilitating themselves.

By the authority vested in me as President by the Constitution and laws of the United States of America, including section 3301(2) of Title 5 of the United States Code, section 7301 of Title 5 of the United States Code, section 290ee–1 of Title 42 of the United States Code, deeming such action in the best interests of national security, public health and safety, law enforcement and the efficiency of the Federal service, and in order to establish standards and procedures to ensure fairness in achieving a drug-free Federal workplace and to protect the privacy of Federal employees, it is hereby ordered as follows:

Section 1. *Drug-Free Workplace.*

(a) Federal employees are required to refrain from the use of illegal drugs.

(b) The use of illegal drugs by Federal employees, whether on duty or off duty, is contrary to the efficiency of the service.

(c) Persons who use illegal drugs are not suitable for Federal employment.

Sec. 2. *Agency Responsibilities.*

(a) The head of each Executive agency shall develop a plan for achieving the objective of a drug-free workplace with due consideration of the rights of the government, the employee, and the general public.

(b) Each agency plan shall include:

(1) A statement of policy setting forth the agency's expectations regarding drug use and the action to be anticipated in response to identified drug use;

(2) Employee Assistance Programs emphasizing high level direction, education, counseling, referral to rehabilitation, and coordination with available community resources;

(3) Supervisory training to assist in identifying and addressing illegal drug use by agency employees;

(4) Provision for self-referrals as well as supervisory referrals to treatment with maximum respect for individual confidentiality consistent with safety and security issues; and

(5) Provision for identifying illegal drug users, including testing on a controlled and carefully monitored basis in accordance with this Order.

Sec. 3. *Drug Testing Programs.*

(a) The head of each Executive agency shall establish a program to test for the use of illegal drugs by employees in sensitive positions. The extent to which such employees are tested and the criteria for such testing shall be determined by the head of each agency, based upon the nature of the agency's mission and its employees' duties, the efficient use of agency resources, and the danger to the public health and safety or national security that could result from the failure of an employee adequately to discharge his or her position.

(b) The head of each Executive agency shall establish a program for voluntary employee drug testing.

(c) In addition to the testing authorized in subsections (a) and (b) of this section, the head of each Executive agency is authorized to test an employee for illegal drug use under the following circumstances:

(1) When there is a reasonable suspicion that any employee uses illegal drugs;

(2) In an examination authorized by the agency regarding an accident or unsafe practice; or

(3) As part of or as a follow-up to counseling or rehabilitation for illegal drug use through an Employee Assistance Program.

(d) The head of each Executive agency is authorized to test any applicant for illegal drug use.

Sec. 4. *Drug Testing Procedures.*

(a) Sixty days prior to the implementation of a drug testing program pursuant to this Order, agencies shall notify employees that testing for use of illegal drugs is to be conducted and that they may seek counseling and rehabilitation and inform them of the procedures for obtaining such assistance through the agency's Employee Assistance Program. Agency drug testing programs already ongoing are exempted from the 60-day notice requirement. Agencies may take action under section 3(c) of this Order without reference to the 60-day notice period.

(b) Before conducting a drug test, the agency shall inform the employee to be tested of the opportunity to submit medical documentation that may support a legitimate use for a specific drug.

(c) Drug testing programs shall contain procedures for timely submission of requests for retention of records and specimens; procedures for retesting; and procedures, consistent with applicable law, to protect the confidentiality of test results and related medical and rehabilitation records. 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.

(d) The Secretary of Health and Human Services is authorized to promulgate scientific and technical guidelines for drug testing programs, and agencies shall conduct their drug testing programs in accordance with these guidelines once promulgated.

Sec. 5. *Personnel Actions.*

(a) Agencies shall, in addition to any appropriate personnel actions, refer any employee who is found to use illegal drugs to an Employee Assistance Program for assessment, counseling, and referral for treatment or rehabilitation as appropriate.

(b) Agencies shall initiate action to discipline any employee who is found to use illegal drugs, *provided that* such action is not required for an employee who:

(1) Voluntarily identifies himself as a user of illegal drugs or who volunteers for drug testing pursuant to section 3(b) of this Order, prior to being identified through other means;

(2) Obtains counseling or rehabilitation through an Employee Assistance Program; and

(3) Thereafter refrains from using illegal drugs.

(c) Agencies shall not allow any employee to remain on duty in a sensitive position who is found to use illegal drugs, prior to successful completion of rehabilitation through an Employee Assistance Program. However, as part of a rehabilitation or counseling program, the head of an Executive agency may, in his or her discretion, allow an employee to return to duty in a sensitive position if it is determined that this action would not pose a danger to public health or safety or the national security.

(d) Agencies shall initiate action to remove from the service any employee who is found to use illegal drugs and:

(1) Refuses to obtain counseling or rehabilitation through an Employee Assistance Program; or

(2) Does not thereafter refrain from using illegal drugs.

(e) The results of a drug test and information developed by the agency in the course of the drug testing of the employee may be considered in processing any adverse action against the employee or for other administrative purposes. Preliminary test results may not be used in an administrative proceeding unless they are confirmed by a second analysis of the same sample or unless the employee confirms the accuracy of the initial test by admitting the use of illegal drugs.

(f) The determination of an agency that an employee uses illegal drugs can be made on the basis of any appropriate evidence, including direct observation, a criminal conviction, administrative inquiry, or the results of an authorized testing program. Positive drug test results may be rebutted by other evidence that an employee has not used illegal drugs.

(g) Any action to discipline an employee who is using illegal drugs (including removal from the service, if appropriate) shall be taken in compliance with otherwise applicable procedures, including the Civil Service Reform Act.

(h) Drug testing shall not be conducted pursuant to this Order for the purpose of gathering evidence for use in criminal proceedings. Agencies are not required to report to the Attorney General for investigation or prosecution any information, allegation, or evidence relating to violations of Title 21 of the United States Code received as a result of the operation of drug testing programs established pursuant to this Order.

Sec. 6. *Coordination of Agency Programs.*

(a) The Director of the Office of Personnel Management shall:

(1) Issue government-wide guidance to agencies on the implementation of the terms of this Order;

(2) Ensure that appropriate coverage for drug abuse is maintained for employees and their families under the Federal Employees Health Benefits Program;

(3) Develop a model Employee Assistance Program for Federal agencies and assist the agencies in putting programs in place;

(4) In consultation with the Secretary of Health and Human Services, develop and improve training programs for Federal supervisors and managers on illegal drug use; and

(5) In cooperation with the Secretary of Health and Human Services and heads of Executive agencies, mount an intensive drug awareness campaign throughout the Federal work force.

(b) The Attorney General shall render legal advice regarding the implementation of this Order and shall be consulted with regard to all guidelines, regulations, and policies proposed to be adopted pursuant to this Order.

(c) Nothing in this Order shall be deemed to limit the authorities of the Director of Central Intelligence under the National Security Act of 1947, as amended, or the statutory authorities of the National Security Agency or the Defense Intelligence Agency. Implementation of this Order within the Intelligence Community, as defined in Executive Order No. 12333, shall be subject to the approval of the head of the affected agency.

Sec. 7. *Definitions.*

(a) This Order applies to all agencies of the Executive Branch.

(b) For purposes of this Order, the term "agency" means an Executive agency, as defined in 5 U.S.C. 105; the Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the armed forces as defined by 5 U.S.C. 2101(2)); or 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.

(c) For purposes of this Order, the term "illegal drugs" means a controlled substance included in Schedule I or II, as defined by section 802(6) of Title 21 of the United States Code, the possession of which is unlawful under chapter 13 of that Title. The term "illegal drugs" does not mean the use of a controlled substance pursuant to a valid prescription or other uses authorized by law.

(d) For purposes of this Order, the term "employee in a sensitive position" refers to:

(1) An employee in a position that an agency head designates Special Sensitive, Critical-Sensitive, or Noncritical-Sensitive under Chapter 731 of the Federal Personnel Manual or an employee in a position that an agency head designates as sensitive in accordance with Executive Order No. 10450, as amended;

(2) An employee who has been granted access to classified information or may be granted access to classified information pursuant to a determination of trustworthiness by an agency head under Section 4 of Executive Order No. 12356;

(3) Individuals serving under Presidential appointments;

(4) Law enforcement officers as defined in 5 U.S.C. 8331(20); and

(5) Other positions that the agency head determines involve law enforcement, national security, the protection of life and property, public health or safety, or other functions requiring a high degree of trust and confidence.

(e) For purposes of this Order, the term "employee" means all persons appointed in the Civil Service as described in 5 U.S.C. 2105 (but excluding persons appointed in the armed services as defined in 5 U.S.C. 2102(2)).

(f) For purposes of this Order, the term "Employee Assistance Program" means agency-based counseling programs that offer assessment, short-term counseling, and referral services to employees for a wide range of drug, alcohol, and mental health programs that affect employee job performance. Employee Assistance Programs are responsible for referring drug-using employees for rehabilitation and for monitoring employees' progress while in treatment.

Sec. 8. *Effective Date.* This Order is effective immediately.

Ronald Reagan

THE WHITE HOUSE,
September 15, 1986.

[FR Doc. 86-21166
Filed 9-15-86; 3:47 pm]
Billing code 3195-01-M

Editorial note: For the President's remarks of September 15 on signing EO 12564, see the *Weekly Compilation of Presidential Documents* (vol. 22, no. 38).

TITLE V

GENERAL PROVISIONS

SEC. 501. No part of any appropriation contained in this Act shall remain available for obligation beyond the current fiscal year unless expressly so provided herein.

SEC. 502. Except where specifically increased or decreased elsewhere in this Act, the restrictions contained within appropriations, or provisions affecting appropriations or other funds, available during fiscal year 1987, limiting the amount which may be expended for personal services, or for purposes involving personal services, or amounts which may be transferred between appropriations or authorizations available for or involving such services, are hereby increased to the extent necessary to meet increased pay costs authorized by or pursuant to law.

Drugs and drug abuse. Government organization and employees. 5 USC 7301 note. 3 CFR, 1986 Comp., p. 224.

SEC. 503. (a)(1) Except as provided in subsection (b) or (c), none of the funds appropriated or made available by this Act, or any other Act, with respect to any fiscal year, shall be available to administer or implement any drug testing pursuant to Executive Order Numbered 12564 (dated September 15, 1986), or any subsequent order, unless and until—

(A) the Secretary of Health and Human Services certifies in writing to the Committees on Appropriations of the House of Representatives and the Senate, and other appropriate committees of the Congress, that—

(i) each agency has developed a plan for achieving a drug-free workplace in accordance with Executive Order Num-

bered 12564 and applicable provisions of law (including applicable provisions of this section); 3 CFR, 1986 Comp., p. 224.

(ii) the Department of Health and Human Services, in addition to the scientific and technical guidelines dated February 13, 1987, and any subsequent amendments thereto, has, in accordance with paragraph (3), published mandatory guidelines which—

(I) establish comprehensive standards for all aspects of laboratory drug testing and laboratory procedures to be applied in carrying out Executive Order Numbered 12564, including standards which require the use of the best available technology for ensuring the full reliability and accuracy of drug tests and strict procedures governing the chain of custody of specimens collected for drug testing;

(II) specify the drugs for which Federal employees may be tested; and

(III) establish appropriate standards and procedures for periodic review of laboratories and criteria for certification and revocation of certification of laboratories to perform drug testing in carrying out Executive Order Numbered 12564; and

(iii) all agency drug-testing programs and plans established pursuant to Executive Order Numbered 12564 comply with applicable provisions of law, including applicable provisions of the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.), title 5 of the United States Code, and the mandatory guidelines under clause (ii);

(B) the Secretary of Health and Human Services has submitted to the Congress, in writing, a detailed, agency-by-agency analysis relating to—

(i) the criteria and procedures to be applied in designating employees or positions for drug testing, including the justification for such criteria and procedures;

(ii) the position titles designated for random drug testing; and

(iii) the nature, frequency, and type of drug testing proposed to be instituted; and

(C) the Director of the Office of Management and Budget has submitted in writing to the Committees on Appropriations of the House of Representatives and the Senate a detailed, agency-by-agency analysis (as of the time of certification under subparagraph (A)) of the anticipated annual costs associated with carrying out Executive Order Numbered 12564 and all other requirements under this section during the 5-year period beginning on the date of the enactment of this Act.

(2) Notwithstanding subsection (g), for purposes of this subsection, the term "agency" means—

(A) the Executive Office of the President;

(B) an Executive department under section 101 of title 5, United States Code;

(C) the Environmental Protection Agency;

(D) the General Services Administration;

(E) the National Aeronautics and Space Administration;

(F) the Office of Personnel Management;

(G) the Small Business Administration;

(H) the United States Information Agency; and

(I) the Veterans' Administration;

except that such term does not include the Department of Transportation or any other entity (or component thereof) covered by subsection (b).

Federal Register, publication. 5 USC 500 *et seq.*

(3) Notwithstanding any provision of chapter 5 of title 5, United States Code, the mandatory guidelines to be published pursuant to subsection (a)(1)(A)(ii) shall be published and made effective exclusively according to the provisions of this paragraph. Notice of the mandatory guidelines proposed by the Secretary of Health and Human Services shall be published in the Federal Register, and interested persons shall be given not less than 60 days to submit written comments on the proposed mandatory guidelines. Following review and consideration of written comments, final mandatory guidelines shall be published in the Federal Register and shall become effective upon publication.

(b)(1) Nothing in subsection (a) shall limit or otherwise affect the availability of funds for drug testing by—

(A) the Department of Transportation;

(B) Department of Energy, for employees specifically involved in the handling of nuclear weapons or nuclear materials;

(C) any agency with an agency-wide drug-testing program in existence as of September 15, 1986; or

(D) any component of an agency if such component had a drug-testing program in existence as of September 15, 1986.

(2) The Departments of Transportation and Energy and any agency or component thereof with a drug-testing program in existence as of September 15, 1986—

8 CFR, 1986 Comp., p. 224.

(A) shall be brought into full compliance with Executive Order Numbered 12564 no later than the end of the 6-month period beginning on the date of the enactment of this Act; and

(B) shall take such actions as may be necessary to ensure that their respective drug-testing programs or plans are brought into full compliance with the mandatory guidelines published under subsection (a)(1)(A)(ii) no later than 90 days after such mandatory guidelines take effect, except that any judicial challenge that affects such guidelines should not affect drug-testing programs or plans subject to this paragraph.

(c) In the case of an agency (or component thereof) other than an agency as defined by subsection (a)(2) or an agency (or component thereof) covered by subsection (b), none of the funds appropriated or made available by this Act, or any other Act, with respect to any fiscal year, shall be available to administer or implement any drug testing pursuant to Executive Order Numbered 12564, or any subsequent order, unless and until—

(1) the Secretary of Health and Human Services provides written certification with respect to that agency (or component) in accordance with clauses (i) and (iii) of subsection (a)(1)(A);

(2) the Secretary of Health and Human Services has submitted a written, detailed analysis with respect to that agency (or component) in accordance with subsection (a)(1)(B); and

(3) the Director of the Office of Management and Budget has submitted a written, detailed analysis with respect to that agency (or component) in accordance with subsection (a)(1)(C).

(d) Any Federal employee who is the subject of a drug test under any program or plan shall, upon written request, have access to—

(1) any records relating to such employee's drug test; and

(2) any records relating to the results of any relevant certification, review, or revocation-of-certification proceedings, as referred to in subsection (a)(1)(A)(ii)(III).

(e) The results of a drug test of a Federal employee may not be disclosed without the prior written consent of such employee, unless the disclosure would be— Classified information.

(1) to the employee's medical review official (as defined in the scientific and technical guidelines referred to in subsection (a)(1)(A)(ii));

(2) to the administrator of any Employee Assistance Program in which the employee is receiving counseling or treatment or is otherwise participating;

(3) to any supervisory or management official within the employee's agency having authority to take the adverse personnel action against such employee; or

(4) pursuant to the order of a court of competent jurisdiction where required by the United States Government to defend against any challenge against any adverse personnel action.

(f) Each agency covered by Executive Order Numbered 12564 shall submit to the Committees on Appropriations of the House of Representatives and the Senate, and other appropriate committees of the Congress, an annual report relating to drug-testing activities conducted by such agency pursuant to such executive order. Each such annual report shall be submitted at the time of the President's budget submission to the Congress under section 1105(a) of title 31, United States Code. Reports. 3 CFR, 1986 Comp., p. 224.

(g) For purposes of this section, the terms "agency" and "Employee Assistance Program" each has the meaning given such term under section 7(b) of Executive Order Numbered 12564, as in effect on September 15, 1986.

SEC. 504. None of the funds appropriated by this Act may be obligated for the centralization, consolidation, or redeployment of the Customs Service Air Operations unless the Secretary of the Treasury submits a report to the Committees on Appropriations which sets forth specific details for the use of such funds thirty days in advance of such implementation.

SEC. 505. None of the funds appropriated or made available by this or any other Act or otherwise appropriated or made available to the Secretary of Transportation or the Maritime Administrator for purposes of administering the Merchant Marine Act, 1936, as amended (46 U.S.C. 1101 et seq.), shall be used by the United States Department of Transportation or the United States Maritime Administration to propose, promulgate, or implement any rule or regulation, or, with regard to vessels which repaid subsidy pursuant to the rule promulgated by the Secretary May 3, 1985 and vacated by Order of the U.S. Court of Appeals for the D.C. Circuit January 16, 1987, conduct any adjudicatory or other regulatory proceeding, execute or perform any contract, or participate in any judicial action with respect to the repayment of construction differential subsidy for the permanent release of vessels from the restrictions in section 506 of the Merchant Marine Act, 1936, as amended: *Provided*, That such funds may be used to the extent such expenditure relates to a rule which conforms to statutory standards hereafter enacted by Congress. Vessels. 46 USC 1156.

SEC. 506. Notwithstanding any other provision of this Act, appropriations made by title I of this Act for the following account shall be as follows:

federal register

Monday
April 11, 1988

Part IV

Department of Health and Human Services

Alcohol, Drug Abuse, and Mental Health Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs; Final Guidelines; Notice

MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS

Authority: E.O. 12564 and sec. 503 of Pub. L. 100-71.

Subpart A—General

1.1 Applicability.

(a) These mandatory guidelines apply to:

(1) Executive Agencies as defined in 5 U.S.C. 105;

(2) 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));

(3) And 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.

(b) Any agency or component of an agency with a drug testing program in existence as of September 15, 1986, and the Departments of Transportation and Energy shall take such action as may be necessary to ensure that the agency is brought into compliance with these Guidelines no later than 90 days after they take effect, except that any judicial challenge that affects these Guidelines shall not affect drug testing programs subject to this paragraph.

(c) Except as provided in 2.6, Subpart C of these Guidelines (which establishes laboratory certification standards) applies to any laboratory which has or seeks certification to perform urine drug testing for Federal agencies under a drug testing program conducted under E.O. 12564. Only laboratories certified under these standards are authorized to perform urine drug testing for Federal agencies.

(d) The Intelligence Community, as defined by Executive Order No. 12333, shall be subject to these Guidelines only to the extent agreed to by the head of the affected agency.

(e) These Guidelines do not apply to drug testing conducted under legal authority other than E.O. 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.

(f) Agencies may not deviate from the provisions of these Guidelines without the written approval of the Secretary. In requesting approval for a deviation, an agency must petition the Secretary in writing and describe the specific provision or provisions for which a deviation is sought and the rationale therefor. The Secretary may approve the request upon a finding of good cause as determined by the Secretary.

1.2 Definitions.

For purposes of these Guidelines the following definitions are adopted:

Aliquot A portion of a specimen used for testing.

Chain of Custody Procedures to account for the integrity of each urine specimen by tracking its handling and storage from point of specimen collection to final disposition of the specimen. These procedures shall require that an approved agency chain of custody form be used from time of collection to receipt by the laboratory and that upon receipt of the laboratory an appropriate laboratory chain of custody form(s) account for the sample or sample aliquots within the laboratory. Chain of custody forms shall, at a minimum, include an entry documenting date and purpose each time a specimen or aliquot is handled or transferred and identifying every individual in the chain of custody.

Collection Site A place designated by the agency where individuals present themselves for the purpose of providing a specimen of their urine to be analyzed for the presence of drugs.

Collection Site Person A person who instructs and assists individuals at a collection site and who receives and makes an initial examination of the urine specimen provided by those individuals. A collection site person shall have successfully completed training to carry out this function.

Confirmatory Test A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability

and accuracy. (At this time gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.)

Initial Test (also known as Screening Test) An immunoassay screen to eliminate "negative" urine specimens from further consideration.

Medical Review Officer A licensed physician responsible for receiving laboratory results generated by an agency's drug testing program who has knowledge of substance abuse disorders and has appropriate medical training to interpret and evaluate an individual's positive test result together with his or her medical history and any other relevant biomedical information.

Permanent Record Book A permanently bound book in which identifying data on each specimen collected at a collection site are permanently recorded in the sequence of collection.

Reason to Believe Reason to believe that a particular individual may alter or substitute the urine specimen as provided in section 4(c) of E.O. 12564.

Secretary The Secretary of Health and Human Services or the Secretary's designee. The Secretary's designee may be contractor or other recognized organization which acts on behalf of the Secretary in implementing these Guidelines.

1.3 Future Revisions.

In order to ensure the full reliability and accuracy of drug assays, the accurate reporting of test results, and the integrity and efficacy of Federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology. These changes will be published in final as a notice in the Federal Register.

Subpart B—Scientific and Technical Requirements

2.1 The Drugs.

(a) The President's 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. Hundreds of drugs are covered under Schedule I and II and while it is not feasible to test routinely for all of them, Federal drug testing programs shall test for drugs as follows:

(1) Federal agency applicant and random drug testing programs shall at a minimum test for marijuana and cocaine;

(2) Federal agency applicant and random drug testing programs are also authorized to test for opiates, amphetamines, and phencyclidine; and

(3) When conducting reasonable suspicion, accident, or unsafe practice testing, a Federal agency may test for any drug listed in Schedule I or II of the CSA.

(b) Any agency covered by these guidelines shall petition the Secretary in writing for approval to include in its testing protocols any drugs (or classes of drugs) not listed for Federal agency testing in paragraph (a) of this section. 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 drugs covered under Schedule I or II of the CSA.

(c) Urine specimens collected pursuant to Executive Order 12564, Pub. L. 100-71, and these Guidelines shall be used only to test for those drugs included in agency drug-free workplace plans and may not be used to conduct any other analysis or test unless otherwise authorized by law.

(d) These Guidelines are not intended to limit any agency which is specifically authorized by law to include additional categories of drugs in the drug testing of its own employees or employees in its regulated industries.

2.2 Specimen Collection Procedures.

(a) Designation of Collection Site. Each agency drug testing program shall have one or more designated collection sites which have all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a certified drug testing laboratory.

(b) Security Procedures shall provide for the designated collection site to be secure. If a collection site facility is dedicated solely to urine collection, it shall be secure at all times. If a facility cannot be dedicated solely to drug testing, the portion of the facility used for testing shall be secured during drug testing.

(c) Chain of Custody. Chain of custody standardized forms shall be properly executed by authorized collection site personnel upon receipt of specimens. Handling and transportation of urine specimens from one authorized individual or place to another shall always be accomplished through chain of custody procedures. Every effort shall be made to minimize the number of persons handling specimens.

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

(e) Privacy. Procedures for collecting urine specimens shall allow individual privacy unless there is reason to believe that a particular individual may alter or substitute the specimen to be provided.

(f) Integrity and Identity of Specimen. Agencies shall take precautions to ensure that a urine specimen not be adulterated or diluted during the collection procedure and that information on the urine bottle and in the record book can identify the individual from whom the specimen was collected. The following minimum precautions shall be taken to ensure that unadulterated specimens are obtained and correctly identified:

(1) To deter the dilution of specimens at the collection site, toilet bluing agents shall be placed in toilet tanks wherever possible, so the reservoir of water in the toilet bowl always remains blue. There shall be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs.

(2) When an individual arrives at the collection site, the collection site person shall request the individual to present photo identification. If the individual does not have proper photo identification, the collection site person shall contact the supervisor of the individual, the coordinator of the drug testing program, or any other agency official who can positively identify the individual. If the individual's identity cannot be established, the collection site person shall not proceed with the collection.

(3) If the individual fails to arrive at the assigned time, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collection site person shall ask the individual to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to tamper with or adulterate the individual's urine specimen. The collection site person shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The individual may retain his or her wallet.

(5) The individual shall be instructed to wash and dry his or her hands prior to urination.

(6) After washing hands, the individual shall remain in the presence of the collection site person and shall not have access to any water fountain, faucet, soap dispenser, cleaning agent or

any other materials which could be used to adulterate the specimen.

(7) The individual may provide his/her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy.

(8) The collection site person shall note any unusual behavior or appearance in the permanent record book.

(9) In the exceptional event that an agency-designated collection site is not accessible and there is an immediate requirement for specimen collection (e.g., an accident investigation), a public rest room may be used according to the following procedures: A collection site person of the same gender as the individual shall accompany the individual into the public rest room which shall be made secure during the collection procedure. If possible, a toilet bluing agent shall be placed in the bowl and any accessible toilet tank. The collection site person shall remain in the rest room, but outside the stall, until the specimen is collected. If no bluing agent is available to deter specimen dilution, the collection site person shall instruct the individual not to flush the toilet until the specimen is delivered to the collection site person. After the collection site person has possession of the specimen, the individual will be instructed to flush the toilet and to participate with the collection site person in completing the chain of custody procedures.

(10) Upon receiving the specimen from the individual, the collection site person shall determine that it contains at least 60 milliliters of urine. If there is less than 60 milliliters of urine in the container, additional urine shall be collected in a separate container to reach a total of 60 milliliters. (The temperature of the partial specimen in each separate container shall be measured in accordance with paragraph (f)(12) of this section, and the partial specimens shall be combined in one container.) The individual may be given a reasonable amount of liquid to drink for this purpose (e.g., a glass of water). If the individual fails for any reason to provide 60 milliliters of urine, the collection site person shall contact the appropriate authority to obtain guidance on the action to be taken.

(11) After the specimen has been provided and submitted to the collection site person, the individual shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collection site person shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement is critical and in no case shall exceed 4 minutes.

(13) If the temperature of a specimen is outside the range of 32.5°–37.7°C/90.5°–99.8°F, that is a reason to believe that the individual may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a same gender collection site person and both specimens shall be forwarded to the laboratory for testing. An individual may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the individual may have altered or substituted the specimen caused by the specimen's temperature falling outside the prescribed range.

(14) Immediately after the specimen is collected, the collection site person shall also inspect the specimen to determine its color and look for any signs of contaminants. Any unusual findings shall be noted in the permanent record book.

(15) All specimens suspected of being adulterated shall be forwarded to the laboratory for testing.

(16) Whenever there is reason to believe that a particular individual may alter or substitute the specimen to be provided, a second specimen shall be obtained as soon as possible under the direct observation of a same gender collection site person.

(17) Both the individual being tested and the collection site person shall keep the specimen in view at all times prior to its being sealed and labeled. If the specimen is transferred to a second bottle, 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.

(18) The collection site person and the individual shall be present at the same time during procedures outlined in paragraphs (f)((19)–(f)(22) of this section.

(19) The collection site person shall place securely on the bottle an identification label which contains the date, the individual's specimen number, and any other identifying information provided or required by the agency.

(20) The individual shall initial the identification label on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her.

(21) The collection site person shall enter in the permanent record book all information identifying the specimen. The collection site person shall sign the permanent record book next to the identifying information.

(22) The individual shall be asked to read and sign a statement in the permanent record book certifying that the specimen identified as having been collected from him or her is in fact that specimen he or she provided.

(23) A higher level supervisor shall review and concur in advance with any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person based on a reason to believe that the individual may alter or substitute the specimen to be provided.

(24) The collection site person shall complete the chain of custody form.

(25) The urine specimen and chain of custody form are now ready for shipment. If the specimen is not immediately prepared for shipment, it shall be appropriately safeguarded during temporary storage.

(26) While any part of the above chain of custody procedures is being performed, 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 leaves his or her work station momentarily, the specimen and custody form shall be taken with him or her or shall be secured. After the collection site person returns to the work station, the custody process will continue. If the collection site person is leaving for an extended period of time, the specimen shall be packaged for mailing before he or she leaves the site.

(g) Collection Control. To the maximum extent possible, collection site personnel shall keep the individual's specimen bottle within sight both before and after the individual has urinated. After the specimen is collected, it shall be properly sealed and labeled. An approved chain of custody form shall be used for maintaining control and accountability of each specimen from the point of collection to final disposition of the specimen. The date and purpose shall be documented on an approved chain of custody form each time a specimen is handled or transferred and every individual in the chain shall be identified. Every effort shall be made to minimize the number of persons handling specimens.

(h) Transportation to Laboratory. Collection site personnel shall arrange to ship the collected specimens to the drug testing laboratory. The specimens shall be placed in containers designed to minimize the possibility of damage during shipment, for example, specimen boxes or padded mailers; and those containers shall be securely sealed to eliminate the possibility of undetected tampering. On the tape sealing the

container, the collection site supervisor shall sign and enter the date specimens were sealed in the containers for shipment. The collection site personnel shall ensure that the chain of custody documentation is attached to each container sealed for shipment to the drug testing laboratory.

2.3 Laboratory Personnel.

(a) Day-to-Day Management.

(1) The laboratory shall have a qualified individual to assume professional, organizational, educational, and administrative responsibility for the laboratory's urine drug testing facility.

(2) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are:

(i) Certification as a laboratory director by the State in forensic or clinical laboratory toxicology; or

(ii) A Ph.D. in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology, or

(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and

(iv) In addition to the requirements in (i), (ii), and (iii) above, minimum qualifications also require:

(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse, and

(B) 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.

(3) This individual shall be engaged in and responsible for the day-to-day management of the drug testing laboratory even where another individual has overall responsibility for an entire multispecialty laboratory.

(4) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall assure the continued competency of laboratory personnel by documenting their inservice training, reviewing their work performance, and verifying their skills.

(5) This individual shall be responsible for the laboratory's having a procedure manual which is complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible individual whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory. Copies of all procedures and dates on which they are in effect shall be maintained. (Specific contents of the procedure manual are described in 2.4(n)(1).)

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

(7) This individual shall be responsible for taking 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 shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the tests results provided are accurate and reliable.

(b) Test Validation. The laboratory's urine drug testing facility shall have a qualified individual(s) who reviews all pertinent data and quality control results in order to attest to the validity of the laboratory's test reports. A laboratory may designate more than one person to perform this function. This individual(s) may be any employee who is qualified to be responsible for day-to-day management or operation of the drug testing laboratory.

(c) Day-to-Day Operations and Supervision of Analysts. The laboratory's urine drug testing facility shall have an individual to be responsible for day-to-day operations and to supervise the technical analysts. This individual(s) shall have at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent. He or she shall have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial actions to be taken in response to test systems being out of control limits or detecting aberrant test or quality control results.

(d) Other Personnel. Other technicians or nontechnical staff shall have the necessary training and skills for the tasks assigned.

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

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

2.4 Laboratory Analysis Procedures.

(a) Security and Chain of Custody. (1) Drug testing laboratories shall be secure at all times. They shall have in place sufficient security measures to control access to the premises and to ensure that no unauthorized personnel handle specimens or gain access to the laboratory processes or to areas where records are stored. Access to these secured areas shall be limited to specifically authorized individuals whose authorization is documented. With the exception of personnel authorized to conduct inspections on behalf of Federal agencies for which the laboratory is engaged in urine testing or on behalf of the Secretary, all authorized visitors and maintenance and service personnel shall be escorted at all times. Documentation of individuals accessing these areas, dates, and time of entry and purpose of entry must be maintained.

(2) Laboratories shall use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of specimens. The date and purpose shall be documented on an appropriate chain of custody form each time a specimen is handled or transferred, and every individual in the chain shall be identified. Accordingly, authorized technicians shall be responsible for each urine specimen or aliquot in their possession and shall sign and complete chain of custody forms for those specimens or aliquots as they are received.

(b) Receiving. (1) When a shipment of specimens is received, laboratory personnel shall inspect each package for evidence of possible tampering and compare information on specimen bottles within each package to the information on the accompanying chain of custody forms. Any direct evidence of tampering or discrepancies in the information on specimen bottles and the agency's chain of custody forms attached to the shipment shall be immediately reported to the agency and shall be noted on the laboratory's chain of custody form which shall accompany the specimens while they are in the laboratory's possession.

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

(c) Short-Term Refrigerated Storage. Specimens that do not receive an initial test within 7 days of arrival at the laboratory shall be placed in secure refrigeration units. Temperatures shall not exceed 6°C. Emergency power equipment shall be available in case of prolonged power failure.

(d) Specimen Processing. Laboratory facilities for urine drug testing 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 tests, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts.

(e) Initial Test. (1) The initial test 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 they are negative for these five drugs or classes of drugs:

	Initial test level (ng/ml)
Marijuana metabolites	100
Cocaine metabolites	300
Opiate metabolites	[1] 300
Phencyclidine	25
Amphetamines	1,000

[1] 25ng/ml if immunoassay specific for free morphine.

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. Initial test methods and testing levels for other drugs shall be submitted in writing by the agency for the written approval of the Secretary.

(f) Confirmatory Test. (1) All specimens identified as positive on the initial test shall be confirmed using gas chromatography/mass spectrometry (GC/MS) techniques at the cutoff values listed in this paragraph for each drug. All confirmations shall be by quantitative analysis. Concentrations which exceed the linear region of the standard curve shall be documented in the laboratory record as "greater than highest standard curve value."

	Confirmatory test level (ng/ml)
Marijuana metabolite [1]	15
Cocaine metabolite [2]	150
Opiates:	
Morphine	* 300
Codeine	* 300
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine	500

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

(2) These test levels are subject to change by the Department of Health and Human Services as advances in technology or other considerations warrant identification of these substances at other concentrations. Confirmatory test methods and testing levels for other drugs shall be submitted in writing by the agency for the written approval of the Secretary.

(g) Reporting Results. (1) The laboratory shall report test results to the agency's Medical Review Officer within an average of 5 working days after receipt of the specimen by the laboratory. Before any test result is reported (the results of initial tests, confirmatory tests, or quality control data), it shall be reviewed and the test certified as an accurate report by the responsible individual. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the cutoff for each, the specimen number assigned by the agency, and the drug testing laboratory specimen identification number. The results (positive and negative) for all specimens submitted at the same time to the laboratory shall be reported back to the Medical Review Officer at the same time.

(2) The laboratory *shall report as negative* all specimens which are negative on the initial test or negative on the confirmatory test. Only specimens confirmed positive shall be reported positive for a specific drug.

(3) The Medical Review Officer may request from the laboratory and the laboratory shall provide quantitation of test results. The Medical Review Officer may not disclose quantitation of test results to the agency but shall report only whether the test was positive or negative.

(4) The laboratory may transmit results to the Medical Review Officer by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. Results may not be provided verbally by telephone. The laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(5) The laboratory shall send only to the Medical Review Officer a certified copy of the original chain of custody form signed by the individual responsible for day-to-day management of the drug testing laboratory or the individual responsible for attesting to the validity of the test reports.

(6) The laboratory shall provide to the agency official responsible for coordination of the drug-free workplace program a monthly statistical summary of urinalysis testing of Federal employees and shall not include in the summary any personal identifying information. Initial and confirmation data shall be included from test results reported within that month. Normally this summary shall be forwarded by registered or certified mail not more than 14 calendar days after the end of the month covered by the summary. The summary shall contain the following information:

(i) Initial Testing:

(A) Number of specimens received;

(B) Number of specimens reported out; and

(C) Number of specimens screened positive for:

Marijuana metabolites
Cocaine metabolites
Opiate metabolites
Phencyclidine
Amphetamines

(ii) Confirmatory Testing:

(A) Number of specimens received for confirmation;

(B) Number of specimens confirmed positive for:

Marijuana metabolite

Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine

(7) The laboratory shall make available copies of all analytical results for Federal drug testing programs when requested by DHHS or any Federal agency for which the laboratory is performing drug testing services.

(8) Unless otherwise instructed by the agency in writing, all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years.

(h) Long-Term Storage. Long-term frozen storage (−20 °C or less) ensures that positive urine specimens will be available for any necessary retest during administrative or disciplinary proceedings. Unless otherwise authorized in writing by the agency, drug testing laboratories shall retain and place in properly secured long-term frozen storage for a minimum of 1 year all specimens confirmed positive. Within this 1-year period an agency may request the laboratory to retain the specimen for an additional period of time, but if no such request is received the laboratory may discard the specimen after the end of 1 year, except that the laboratory shall be required to maintain any specimens under legal challenge for an indefinite period.

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

(j) Subcontracting. Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the agency. The laboratory must be capable of performing testing for the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) using the initial immunoassay and confirmatory GC/MS methods specified in these Guidelines.

(k) Laboratory Facilities. (1) Laboratory facilities shall comply with applicable provisions of any State licensure requirements.

(2) Laboratories certified in accordance with Subpart C of these Guidelines shall have the capability, at the same laboratory premises, of performing initial and confirmatory tests for each drug or metabolite for which service is offered.

(l) Inspections. The Secretary, any Federal agency utilizing the laboratory, or any organization performing laboratory certification on behalf of the Secretary shall reserve the right to inspect the laboratory at any time. Agency contracts with laboratories for drug testing, as well as contracts for collection site services, shall permit the agency to conduct unannounced inspections. In addition, prior to the award of a contract the agency shall carry out preaward inspections and evaluation of the procedural aspects of the laboratory's drug testing operation.

(m) Documentation. The drug testing laboratories shall maintain and make available for at least 2 years documentation of all aspects of the testing process. This 2-year period may be extended upon written notification by DHHS or by any Federal agency for which laboratory services are being provided. The required documentation shall include personnel files on all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; procedure manuals; all test data (including calibration curves and any calculations used in determining test results); reports; performance records on performance testing; performance on certification inspections; and hard copies of computer-generated data. The laboratory shall be required to maintain documents for any specimen under legal challenge for an indefinite period.

(n) Additional Requirements for Certified Laboratories.—(1) Procedure Manual. Each laboratory shall have a procedure manual which includes the principles of each test, preparation of reagents, standards and controls, calibration procedures, derivation of results, linearity of methods, sensitivity of the methods, cutoff values, mechanisms for reporting results, controls, criteria for unacceptable specimens and results, remedial actions to be taken when the test systems are outside of acceptable limits, reagents and expiration dates, and references. Copies of all procedures and dates on which they are in effect shall be maintained as part of the manual.

(2) Standards and Controls. Laboratory standards shall be prepared with pure drug standards which are properly labeled as to content and concentration. The standards shall be labeled with the following dates: when received; when prepared or opened; when placed in services; and expiration date.

(3) Instruments and Equipment. (i) Volumetric pipettes and measuring devices shall be certified for accuracy or be checked by gravimetric, colorimetric, or other verification procedure. Automatic pipettes and dilutors shall be checked for accuracy and reproducibility before being placed in service and checked periodically thereafter.

(ii) There shall be written procedures for instrument set-up and normal operation, a schedule for checking critical operating characteristics for all instruments, tolerance limits for acceptable function checks and instructions for major trouble shooting and repair. Records shall be available on preventive maintenance.

(4) Remedial Actions. There shall be written procedures for the actions to be taken when systems are out of accceptable limits or errors are detected. There shall be documentation that these procedures are followed and that all necessary corrective actions are taken. There shall also be in place systems to verify all stages of testing and reporting and documentation that these procedures are followed.

(5) Personnel Available To Testify at Proceedings. A laboratory shall have qualified personnel available to testify in an administrative or disciplinary proceeding against a Federal employee when that proceeding is based on positive urinalysis results reported by the laboratory.

2.5 Quality Assurance and Quality Control.

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

(b) Laboratory Quality Control Requirements for Initial Tests. Each analytical run of specimens to be screened shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

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

In addition, with each batch of samples a sufficient number of standards shall be included to ensure and document the linearity of the assay method over time in the concentration area of the cutoff. After acceptable values are obtained for the known standards, those values will be used to calculate sample data. Implementation of procedures to ensure that carryover does not contaminate the

testing of an individual's specimen shall be documented. A minimum of 10 percent of all test samples shall be quality control specimens. Laboratory quality control samples, prepared from spiked urine samples of determined concentration shall be included in the run and should appear as normal samples to laboratory analysts. One percent of each run, with a minimum of at least one sample, shall be the laboratory's own quality control samples.

(c) Laboratory Quality Control Requirements for Confirmation Tests. Each analytical run of specimens to be confirmed shall include:

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

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

The linearity and precision of the method shall be periodically documented. Implementation of procedures to ensure that carryover does not contaminate the testing of an individual's specimen shall also be documented.

(d) Agency Blind Performance Test Procedures. (1) Agencies shall purchase drug testing services only from laboratories certified by DHHS or a DHHS-Recognized certification program in accordance with these Guidelines. Laboratory participation is encouraged in other performance testing surveys by which the laboratory's performance is compared with peers and reference laboratories.

(2) During the initial 90-day period of any new drug testing program, each agency shall submit blind performance test specimens to each laboratory it contracts with in the amount of at least 50 percent of the total number of samples submitted (up to a maximum of 500 samples) and thereafter a minimum of 10 percent of all samples (to a maximum of 250) submitted per quarter.

(3) Approximately 80 percent of the blind performance test samples shall be blank (i.e., certified to contain no drug) and the remaining samples shall be positive for one or more drugs per sample in a distribution such that all the drugs to be tested are included in approximately equal frequencies of challenge. The positive samples shall be spiked only with those drugs for which the agency is testing.

(4) The Secretary shall investigate any unsatisfactory performance testing result and, based on this investigation, the laboratory shall take action to correct the cause of the unsatisfactory performance test result. A record shall be make of the Secretary's investigative findings and the corrective action taken by the laboratory, and that record shall be dated and signed by the individuals responsible for the day-to-day management and operation of the drug testing laboratory. Then the Secretary shall send the document to the agency contracting officer as a report of the unsatisfactory performance testing incident. The Secretary shall ensure notification of the finding to all other Federal agencies for which the laboratory is engaged in urine drug testing and coordinate any necessary action.

(5) Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the Secretary shall require the laboratory to take corrective action to minimize the occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the Secretary may also require review and reanalysis of previously run specimens.

(6) Should a false positive error occur on a blind performance test specimen and the error is determined to be a technical or methodological error, the laboratory shall submit all quality control data from the batch of specimens which included the false positive specimen. In addition, the laboratory shall retest all specimens analyzed positive for that drug or metabolite from the time of final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for day-to-day management of the laboratory's urine drug testing. The Secretary may require an on-site review of the laboratory which may be conducted unannounced during any hours of operations of the laboratory. The Secretary has the option of revoking (3.13) or suspending (3.14) the laboratory's certification or recommending that no further action be taken if the case is one of less serious error in which corrective action has already been taken, thus reasonably assuring that the error will not occur again.

2.6 Interim Certification Procedures.

During the interim certification period as determined under paragraph (c), agencies shall ensure laboratory competence by one of the following methods:

(a) Agencies may use agency or contract laboratories that have been certified for urinalysis testing by the Department of Defense; or

(b) Agencies may develop interim self-certification procedures by establishing preaward inspections and performance testing plans approved by DHHS.

(c) The period during which these interim certification procedures will apply shall be determined by the Secretary. Upon noticed by the Secretary that these interim certification procedures are no longer available, all Federal agencies subject to these Guidelines shall only use laboratories that have been certified in accordance with Subpart C of these Guidelines and all laboratories approved for interim certification under paragraphs (a) and (b) of this section shall become certified in accordance with Subpart C within 120 days of the date of this notice.

2.7 Reporting and Review of Results.

(a) Medical Review Officer Shall Review 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 is essential to the review of results. This review shall be performed by the Medical Review Officer prior to the transmission of results to agency administrative officials.

(b) Medical Review Officer—Qualifications and Responsibilities. The Medical Review Officer shall be a licensed physician with knowledge of substance abuse disorders and may be an agency or contract employee. The role of the Medical Review Officer is to review and interpret positive test results obtained through the agency's testing program. In carrying out this responsibility, the Medical Review Officer shall examine alternate medical explanations for any positive test result. This action could include conducting a medical interview with the individual, review of the individual's medical history, or review of any other relevant biomedical factors. The Medical Review Officer shall review all medical records made available by the tested individual when a confirmed positive test could have resulted from legally prescribed medication. The Medical Review Officer shall not, however, consider the results of urine samples that are not obtained or processed in accordance with these Guidelines.

(c) Positive Test Result. Prior to making a final decision to verify a positive test result, the Medical Review Officer shall give the individual an opportunity to discuss the test result

with him or her. Following verification of a positive test result, the Medical Review Officer shall refer the case to the agency Employee Assistance Program and to the management official empowered to recommend or take administrative action.

(d) Verification for opiates; review for prescription mediation. Before the Medical Review Officer verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test—of illegal use of any opium, opiate, or opium derivative (e.g., morphine/codeine) listed in Schedule I or II of the Controlled Substances Act. (This requirement does not apply if the agency's GC/MS confirmation testing for opiates confirms the presence of 6-monoacetylmorphine.)

(e) Reanalysis Authorized. Should any question arise as to the accuracy or validity of a positive test result, only the Medical Review Officer is authorized to order a reanalysis of the original sample and such retests are authorized only at laboratories certified under these Guidelines.

(f) Result Consistent with Legal Drug Use. If the Medical Review Officer determines there is a legitimate medical explanation for the positive test result, he or she shall determine that the result is consistent with legal drug use and take no further action.

(g) Result Scientifically Insufficient. Additionally, the Medical Review Officer, based on review of inspection reports, quality control data, multiple samples, and other pertinent results, may determine that the result is scientifically insufficient for further action and declare the test specimen negative. In this situation the Medical Review Officer may request reanalysis of the original sample before making this decision. (The Medical Review Officer may request that reanalysis be performed by the same laboratory or, as provided in 2.7(e), that an aliquot of the original specimen be sent for reanalysis to an alternate laboratory which is certified in accordance with these Guidelines.) The laboratory shall assist in this review process as requested by the Medical Review Officer by making available the individual responsible for day-to-day management of the urine drug testing laboratory or other employee who is a forensic toxicologist or who has equivalent forensic experience in urine drug testing, to provide specific consultation as required by the agency. The Medical Review Officer shall report to the Secretary all negative findings based on scientific insufficiency but shall not include any personal identifying information in such reports.

2.8 Protection of Employee Records.

Consistent with 5 U.S.C. 522a(m) and 48 CFR 24.101–24.104, all laboratory contracts shall require that the contractor comply with the Privacy Act, 5 U.S.C. 552a. In addition, laboratory contracts shall require compliance with the patient access and confidentiality provisions of section 503 of Pub. L. 100–71. The agency shall establish a Privacy Act System of Records or modify an existing system, or use any applicable Government-wide system of records to cover both the agency's and the laboratory's records of employee urinalysis results. The contract and the Privacy Act System shall specifically require that employee records be maintained and used with the highest regard for employee privacy.

2.9 Individual Access to Test and Laboratory Certification Results.

In accordance with section 503 of Pub. L. 100–71, any Federal employee who is the subject of a drug test shall, upon written request, have access to any records relating to his or her drug test and any records relating to the results of any relevant certification, review, or revocation-of-certification proceedings.

Subpart C—Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies

3.1 Introduction.

Urine drug testing is a critical component of efforts to combat drug abuse in our society. Many laboratories are familiar with good laboratory practices but may be unfamiliar with the special procedures required when drug test results are used in the employment context. Accordingly, the following are minimum standards to certify laboratories engaged in urine drug testing for Federal agencies. Certification, even at the highest level, does not guarantee accuracy of each result reported by a laboratory conducting urine drug testing for Federal agencies. Therefore, results from laboratories certified under these Guidelines must be interpreted with a complete understanding of the total collection, analysis, and reporting process before a final conclusion is made.

3.2 Goals and Objectives of Certification.

(a) Uses of Urine Drug Testing. Urine drug testing is an important tool to identify drug users in a variety of settings. In the proper context, urine drug testing can be used to deter drug abuse in general. To be a useful tool, the testing procedure must be capable of detecting drugs or their metabolites at concentrations indicated in 2.4 (e) and (f).

(b) Need to Set Standards; Inspections. Reliable discrimination between the presence, or absence, of specific drugs or their metabolites is critical, not only to achieve the goals of the testing program but to protect the rights of the Federal employees being tested. Thus, standards have been set which laboratories engaged in Federal employee urine drug testing must meet in order to achieve maximum accuracy of test results. These laboratories will be evaluated by the Secretary or the Secretary's designee as defined in 1.2 in accordance with these Guidelines. The qualifying evaluation will involve three rounds of performance testing plus on-site inspection. Maintenance of certification requires participation in an every-other-month performance testing program plus periodic, on-site inspections. One inspection following successful completion of a performance testing regimen is required for initial certification. This must be followed by a second inspection within 3 months, after which biannual inspections will be required to maintain certification.

(c) Urine Drug Testing Applies Analytical Forensic Toxicology. The possible impact of a positive test result on an individual's livelihood or rights, together with the possibility of a legal challenge of the result, sets this type of test apart from most clinical laboratory testing. In fact, urine drug testing should be considered a special application of analytical forensic toxicology. That is, in addition to the application of appropriate analytical methodology, the specimen must be treated as evidence, and all aspects of the testing procedure must be documented and available for possible court testimony. Laboratories engaged in urine drug testing for Federal agencies will require the services and advice of a qualified forensic toxicologist, or individual with equivalent qualifications (both training and experience) to address the specific needs of the Federal drug testing program, including the demands of chain of custody of specimens, security, property documentation of all records, storage of positive specimens for later or independent testing, presentation of evidence in court, and expert witness testimony.

3.3 General Certification Requirements.

A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for certification under these standards.

3.4 Capability to Test for Five Classes of Drugs.

To be certified, a laboratory must be capable of testing for at least the following five classes of drugs: Marijuana, cocaine, opiates, amphetamines, and phencyclidine, using the initial immunoassay and quantitative confirmatory GC/MS methods specified in these Guidelines. The certification program will be limited to the five classes of drugs (2.1(a) (1) and (2)) and the methods (2.4 (e) and (f)) specified in these Guidelines. The laboratory will be surveyed and performance tested only for these methods and drugs. Certification of a laboratory indicates that any test result reported by the laboratory for the Federal Government meets the standards in these Guidelines for the five classes of using the methods specified. Certified laboratories must clearly inform non-Federal clients when procedures followed for those clients conform to the standards specified in these Guidelines.

3.5 Initial and Confirmatory Capability at Same Site.

Certified laboratories shall have the capability, at the same laboratory site, of performing both initial immunoassays and confirmatory GC/MS tests (2.4 (e) and (f)) for marijuana, cocaine, opiates, amphetamines, and phencyclidine and for any other drug or metabolite for which agency drug testing is authorized (2.1(a) (1) and (2)). All positive initial test results shall be confirmed prior to reporting them.

3.6 Personnel.

Laboratory personnel shall meet the requirements specified in 2.3 of these Guidelines. These Guidelines establish the exclusive standards for qualifying or certifying those laboratory personnel involved in urinalysis testing whose functions are prescribed by these Guidelines. A certification of a laboratory under these Guidelines shall be a determination that these qualification requirements have been met.

3.7 Quality Assurance and Quality Control.

Drug testing laboratories shall have a quality assurance program which encompasses all aspects of the testing process, including but not limited to specimen acquisition, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. Quality control procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the process of testing for drugs as specified in 2.5 of these Guidelines.

3.8 Security and Chain of Custody.

Laboratories shall meet the security and chain of custody requirements provided in 2.4(a).

3.9 One-Year Storage for Confirmed Positives.

All confirmed positive specimens shall be retained in accordance with the provisions of 2.4(h) of these Guidelines.

3.10 Documentation.

The laboratory shall maintain and make available for at least 2 years documentation in accordance with the specifications in 2.4(m).

3.11 Reports.

The laboratory shall report test results in accordance with the specifications in 2.4(g).

3.12 Certification.

(a) General. The Secretary may certify any laboratory that meets the standards in these Guidelines to conduct urine drug testing. In addition, the Secretary may consider to be certified and laboratory that is certified by a DHHS-recognized certification program in accordance with these Guidelines.

(b) Criteria. In determining whether to certify a laboratory or to accept the certification of a DHHS-recognized certification program in accordance with these Guidelines, the Secretary shall consider the following criteria:

(1) The adequacy of the laboratory facilities;

(2) The expertise and experience of the laboratory personnel;

(3) The excellence of the laboratory's quality assurance/quality control program;

(4) The performance of the laboratory on any performance tests;

(5) The laboratory's compliance with standards as reflected in any laboratory inspections; and

(6) Any other factors affecting the reliability and accuracy of drug tests and reporting done by the laboratory.

3.13 Revocation.

(a) General. The Secretary shall revoke certification of any laboratory certified under these provisions or accept revocation by a DHHS-recognized certification program in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure the full reliability and accuracy of drug tests and the accurate reporting of test results.

(b) Factors to Consider. The Secretary shall consider the following factors in determining whether revocation is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests; for example, a false positive error in reporting the results of an employee's drug test;

(2) Unsatisfactory participation in performance evaluations or laboratory inspections;

(3) A material violation of a certification standard or a contract term or other condition imposed on the laboratory by a Federal agency using the laboratory's services;

(4) Conviction for any criminal offense committed as an incident to operation of the laboratory; or

(5) Any other cause which materially affects the ability of the laboratory to ensure the full reliability and accuracy of drug tests and the accurate reporting of results.

(c) Period and Terms. The period and terms of revocation shall be determined by the Secretary and shall depend upon the facts and circumstances of the revocation and the need to ensure accurate and reliable drug testing of Federal employees.

3.14 Suspension.

(a) Criteria. Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary in order to protect the interests of the United States and its employees, the Secretary may immediately suspend a laboratory's certification to conduct urine drug testing for Federal agencies. The Secretary may also accept suspension of certification by a DHHS-recognized certification program in accordance with these Guidelines.

(b) Period and Terms. The period and terms of suspension shall be determined by the Secretary and shall depend upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing of Federal employees.

3.15 Notice; Opportunity for Review.

(a) Written Notice. When a laboratory is suspended or the Secretary seeks to revoke certification, the Secretary shall immediately serve the laboratory with written notice of the suspension or proposed revocation by personal service or registered or certified mail, return

receipt requested. This notice shall state the following:

(1) The reasons for the suspension or proposed revocation;

(2) The terms of the suspension or proposed revocation; and

(3) The period of suspension or proposed revocation.

(b) Opportunity for Informal Review. The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date of mailing or service of the notice. The review shall be by a person or persons designated by the Secretary and shall be based on written submissions by the laboratory and the Department of Health and Human Services and, at the Secretary's discretion, may include an opportunity for an oral presentation. Formal rules of evidence and procedures applicable to proceedings in a court of law shall not apply. The decision of the reviewing official shall be final.

(c) Effective Date. A suspension shall be effective immediately. A proposed revocation shall be effective 30 days after written notice is given or, if review is requested, upon the reviewing official's decision to uphold the proposed revocation. If the reviewing official decides not to uphold the suspension or proposed revocation, the suspension shall terminate immediately and any proposed revocation shall not take effect.

(d) DHHS-Recognized Certification Program. The Secretary's responsibility under this section may be carried out by a DHHS-recognized certification program in accordance with these Guidelines.

3.16 Recertification.

Following the termination or expiration of any suspension or revocation, a laboratory may apply for recertification. Upon the submission of evidence satisfactory to the Secretary that the laboratory is in compliance with these Guidelines or any DHHS-recognized certification program in accordance with these Guidelines, and any other conditions imposed as part of the suspension or revocation, the Secretary may recertify the laboratory or accept the recertification of the laboratory by a DHHS-recognized certification program.

3.17 Performance Test Requirement for Certification.

(a) An Initial and Continuing Requirement. The performance testing program is a part of the initial evaluation of a laboratory seeking certification (both performance testing and laboratory inspection are required) and of the continuing assessment of laboratory performance necessary to maintain this certification.

(b) Three Initial Cycles Required. Successful participation in three cycles of testing shall be required before a laboratory is eligible to be considered for inspection and certification. These initial three cycles (and any required for recertification) can be compressed into a 3-month period (one per month).

(c) Six Challenges Per Year. After certification, laboratories shall be challenged every other month with one set of at least 10 specimens a total of six cycles per year.

(d) Laboratory Procedures Identical for Performance Test and Routine Employee Specimens. All procedures associated with the handling and testing of the performance test specimens by the laboratory shall to the greatest extent possible be carried out in a manner identical to that applied to routine laboratory specimens, unless otherwise specified.

(e) Blind Performance Test. Any certified laboratory shall be subject to blind performance testing (see 2.5(d)). Performance on blind test specimens shall be at the same level as for the open or non-blind performance testing.

(f) Reporting—Open Performance Test. The laboratory shall report results of open performance tests to the certifying organization in the same manner as specified in 2.4(g)(2) for routine laboratory specimens.

3.18 Performance Test Specimen Composition.

(a) Description of the Drugs. Performance test specimens shall contain those drugs and metabolites which each certified laboratory must be prepared to assay in concentration ranges that allow detection of the analyte by commonly used immunoassay screening techniques. These levels are generally in the range of concentrations which might be expected in the urine of recent drug users. For some drug analytes, the specimen composition will consist of the parent drug as well as major metabolites. In some cases, more than one drug class may be included in one specimen container, but generally no more than two drugs will be present in any one specimen in order to imitate the type of specimen which a laboratory normally encounters. For any particular performance testing cycle, the actual composition of kits going to different laboratories will vary but, within any annual period, all laboratories participating will have analyzed the same total set of specimens.

(b) Concentrations. Performance test specimens shall be spiked with the drug classes and their metabolites which are required for certifications: marijuana, cocaine, opiates, amphetamines, and phencyclidine, with concentration levels set at least 20 percent above the cutoff limit for either the initial assay or the confirmatory test, depending on which is to be evaluated. Some performance test specimens may be identified for GC/MS assay only. Blanks shall contain less than 2 ng/ml of any of the target drugs. These concentration and drug types may be changed periodically in response to factors such as changes in detection technology and patterns of drug use.

3.19 Evaluation of Peformance Testing.

(a) Initial Certification. (1) An applicant laboratory shall not report any false positive result during performance testing for initial certification. Any false positive will automatically disqualify a laboratory from further consideration.

(2) An applicant laboratory shall maintain an overall grade level of 90 percent for the three cycles of performance testing required for initial certification, i.e., it must correctly identify and confirm 90 percent of the total drug challenges for each shipment. Any laboratory which achieves a score on any one cycle of the initial certification such that it can no longer achieve a total grade of 90 percent over the three cycles will be immediately disqualified from further consideration.

(3) An applicant laboratory shall obtain quantitative values for at least 80 percent of the total drug challenges which are ±20 percent or ±2 standard deviations of the calculated reference group mean (whichever is larger). Failure to achieve 80 percent will result in disqualification.

(4) An applicant laboratory shall not obtain any quantitative values that differ by more than 50 percent from the calculated reference group mean. Any quantitative values that differ by more than 50 percent will result in disqualification.

(5) For any individual drug, an applicant laboratory shall successfully detect and quantitate in accordance with paragraphs (a)(2), (a)(3), and (a)(4) of this section at least 50 percent of the total drug challenges. Failure to successfully quantitate at least 50 percent of the challenges for any individual drug will result in disqualification.

(b) Ongoing Testing of Certified Laboratories.—(1) False Positives and Procedures for Dealing With Them. No

false drug identifications are acceptable for any drugs for which a laboratory offers service. Under some circumstances a false positive test may result in suspension or revocation of certification. The most serious false positives are by drug class, such as reporting THC in a blank specimen or reporting cocaine in a specimen known to contain only opiates. Misidentifications within a class (e.g., codeine for morphine) are also false positives which are unacceptable in an appropriately controlled laboratory, but they are clearly less serious errors than misidentification of a class. The following procedures shall be followed when dealing with a false positive:

(i) The agency detecting a false positive error shall immediately notify the laboratory and the Secretary of any such error.

(ii) The laboratory shall provide the Secretary with a written explanation of the reasons for the error within 5 working days. If required by paragraph (b)(1)(v) below, this explanation shall include the submission of all quality control data from the batch of specimens that included the false positive specimen.

(iii) The Secretary shall review the laboratory's explanation within 5 working days and decide what further action, if any, to take.

(iv) If the error is determined to be an administrative error (clerical, sample mixup, etc.), the Secretary may direct the laboratory to take corrective action to minimize the occurence of the particular error in the future and, if there is reason to believe the error could have been systematic, may require the laboratory to review and reanalyze previously run specimens.

(v) If the error is determined to be technical or methodological error, the laboratory shall submit to the Secretary all quality control data from the batch of specimens which included the false positive specimen. In addition, the laboratory shall retest all specimens analyzed positive by the laboratory from the time fo final resolution of the error back to the time of the last satisfactory performance test cycle. This retesting shall be documented by a statement signed by the individual responsible for the day-to-day management of the laboratory's urine drug testing. Depending on the type of error which caused the false positive, this retesting may be limited to one analyte or may include any drugs a laboratory certified under these Guidelines must be prepared to assay. The laboratory shall immediately notify the agency if any result on a retest sample must be corrected because the critieria for a positive are not satisfied. The Secretary may suspend or revoke the laboratory's certification for all drugs or for only the drug or drug class in which the error occurred. However, if the case is one of a less serious error for which effective corrections have already been made, thus reasonably assuring that the error will not occur again, the Secretary may decide to take no further action.

(vi) During the time required to resolve the error, the laboratory shall remain certified but shall have a designation indicating that a false positive result is pending resolution. If the Secretary determines that the laboratory's certification must be suspended or revoked, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or any recertification process is complete.

(2) Requirement to Identify and Confirm 90 Percent of Total Drug Challenges. In order to remain certified, laboratories must successfully complete six cycles of performance testing per year. Failure of a certified laboratory to maintain a grade of 90 percent on any required performance test cycle, i.e., to identify 90 percent of the total drug challenges and to correctly confirm 90 percent of the total drug challenges, may result in suspension or revocation of certification.

(3) Requirement to Quantitate 80 Percent of Total Drug Challenges at ±20 Percent or ±2 standard deviations. Quantitative values obtained by a certified laboratory for at least 80 percent of the total drug challenges must be ±20 percent or ±2 standard deviations of the calculated reference group mean (whichever is larger).

(4) Requirement to Quantitate within 50 Percent of Calculated Reference Group Mean. No quantitative values obtained by a certified laboratory may differ by more than 50 percent from the calculated reference group mean.

(5) Requirement to Successfully Detect and Quantitate 50 Percent of the Total Drug Challenges for Any Individual Drug. For any individual drug, a certified laboratory must successfully detect and quantitate in accordance with paragraphs (b)(2), (b)(3), and (b)(4) of this section at least 50 percent of the total drug challenges.

(6) Procedures When Requirements in Paragraphs (b)(2)–(b)(5) of this Section Are Not Met. If a certified laboratory fails to maintain a grade of 90 percent per test cycle after initial certification as required by paragraph (b)(2) of this section or if it fails to successfully quantitate results as required by paragraphs (b)(3), (b)(4), or (b)(5) of this section, the laboratory shall be immediately informed that its performance fell under the 90 percent level or that it failed to successfully quantitate test results and how it failed to successfully quantitate. The laboratory shall be allowed 5 working days in which to provide any explanation for its unsuccessful performance, including administrative error or methodological error, and evidence that the source of the poor performance has been corrected. The Secretary may revoke or suspend the laboratory's certification or take no further action, depending on the seriousness of the errors and whether there is evidence that the source of the poor performance has been corrected and that current performance meets the requirements for a certified laboratory under these Guidelines. The Secretary may require that additional performance tests be carried out to determine whether the source of the poor performance has been removed. If the Secretary determines to suspend or revoke the laboratory's certification, the laboratory's official status will become "Suspended" or "Revoked" until the suspension or revocation is lifted or until any recertification process is complete.

(c) 80 Percent of Participating Laboratories Must Detect Drug. A laboratory's performance shall be evaluated for all samples for which drugs were spiked at concentrations above the specified performance test level unless the overall response from participating laboratories indicates that less than 80 percent of them were able to detect a drug.

(d) Participation Required. Failure to participate in a performance test or to participate satisfactorily may result in suspension or revocation of certification.

3.20 Inspections.

Prior to laboratory certification under these Guidelines and at least twice a year after certification, a team of three qualified inspectors, at least two of whom have been trained as laboratory inspectors, shall conduct an on-site inspection of laboratory premises. Inspections shall document the overall quality of the laboratory setting for the purposes of certification to conduct urine drug testing. Inspection reports may also contain recommendations to the laboratory to correct deficiencies noted during the inspection.

3.21 Results of Inadequate Performance.

Failure of a laboratory to comply with any aspect of these Guidelines may lead to revocation or suspension of certification as provided in 3.13 and 3.14 of these Guidelines.

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