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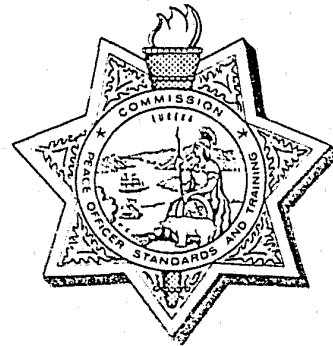


PRE-EMPLOYMENT DRUG SCREENING GUIDELINES

NCJRS

JUL 20 1992

ACQUISITIONS



THE COMMISSION
ON PEACE OFFICER STANDARDS AND TRAINING

STATE OF CALIFORNIA

PRE-EMPLOYMENT

DRUG SCREENING GUIDELINES

1992

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**U.S. Department of Justice
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PREFACE

This manual has been developed in response to the wishes expressed by California law enforcement in a recently completed POST survey concerning pre-employment drug screening policies and practices.

An attempt is made in the manual to cover the full range of legal, technical, and procedural issues that should be considered when instituting a pre-employment drug screening program.

While the intent of the manual is to provide general guidance to those agencies that are preparing to implement such a program, the information provided should also prove useful for purposes of evaluating ongoing programs.

We welcome your comments and suggestions.



NORMAN C. BOEHM
Executive Director

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INTRODUCTION

Statement of Purpose

A recent POST survey of California law enforcement agencies (see Appendix 1) indicated that there is much interest in pre-employment drug screening. Slightly over one-third of the responding law enforcement agencies reported having a drug screening program, and more than half indicated that POST should provide general information or guidelines to those agencies that wish to establish their own programs.

These guidelines have been developed in response to the widespread interest expressed for guidance from POST in establishing pre-employment drug screening programs. They have been developed solely for **pre-employment** screening and do **not** address employee testing whether random, for reasonable suspicion, or post-accident.

The purpose of these guidelines is to assist local law enforcement agencies in establishing pre-employment drug screening programs that are as cost efficient and legally defensible as possible. The merits of such a program will no doubt vary as a function of the characteristics of the local applicant pool, the financial and other resources of the agency, the presence or absence of pre-employment polygraph testing, etc. In addition, local regulations or collective bargaining agreements may place limits on instituting such a program. The purpose of this document is not to influence the decision to institute pre-employment drug screening, but rather to assist an agency once the decision has been made to conduct pre-employment drug screening.

Concerned exclusively with pre-employment drug screening, these guidelines may be used to develop part of an agency's comprehensive substance abuse program. The U.S. Department of Labor recommends that a comprehensive program include: (1) a written substance abuse policy, (2) a supervisory training program, (3) an employee education and awareness program, (4) access to an employee assistance program (EAP), and (5) a drug testing program, where appropriate. More information on each of these areas can be found in the POST publication Substance Abuse Resource Manual (1988).

National Institute on Drug Abuse

Great deference is given throughout these guidelines to the National Institute on Drug Abuse (NIDA). NIDA is the federal agency under the Department of Health and Human Services responsible for developing scientific and technical guidelines for drug testing programs for federal agencies. The issuance of the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" on April 11, 1988 (see Appendix 2) established an industry standard that is widely and highly respected. Often cited for their defensibility, NIDA standards are referred to often throughout these guidelines.

Organization of the Guidelines

These guidelines have been grouped in what is hoped will be a useful organization for the user agency. Following the "Introduction," is a brief discussion of legal issues, including court decisions and federal guidelines, concerning pre-employment drug screening. After the "Legal Considerations" section is the "Technical Issues" section which discusses some of the decisions that must be made concerning specimen collection, analytical methodologies, substances to be tested, choosing laboratories, etc. The next major section is titled "Procedural Issues" and addresses the logistics of moving applicants through drug screening in a secure, efficient manner. Following that section is the "Summary," then a "Glossary of Terms" with definitions of some of the applicable vocabulary, followed by the "Bibliography." Finally, supporting documents are assembled in the "Appendices" section.

LEGAL CONSIDERATIONS

In the public sector, the principal grounds for challenging drug testing has been the Fourth Amendment which provides:

The right of the people to be secure in their persons, houses, papers and effects, against unreasonable searches and seizures, shall not be violated, and no warrants shall issue, but upon probable cause, supported by oath or affirmation, and particularly describing the place to be searched, and the person or things to be seized.

The U.S. Supreme Court issued two decisions in 1989 which considered the applicability of the Fourth Amendment to the testing of government employees for drug usage. In one case, Skinner v. Railway Labor Executives' Association (1989) 109 S. Ct. 1402, the court held that drug and alcohol testing of employees was reasonable under the Fourth Amendment even though there was no requirement of a warrant or a reasonable suspicion that any particular employee might be impaired. The Court concluded that the government's compelling interest in safety outweighed the employee's privacy concerns. In the second case, National Treasury Employees Union v. Von Raab (1989) 109 S. Ct. 1384, the Supreme Court held that the U.S. Customs Service's drug testing program for its employees who transferred or promoted to a position involving (1) the carrying of firearms or (2) the interdiction of drug smugglers was reasonable under the Fourth Amendment. The program was reasonable despite the absence of a requirement for a warrant or individualized suspicion and was permissible because the government's compelling interests in public safety and in the integrity of U.S. borders outweighed the privacy interests of the workers subject to the testing. (The two cases discussed above are concerned with employees as opposed to applicants. However, Von Raab was concerned with employees who were required to undergo testing as part of an application process.)

Since the seminal decisions in Von Raab and Skinner, lower federal courts have upheld government-compelled pre-employment drug testing of employee applicants [International Brotherhood of Teamsters v. Dept. of Transportation, 932 F.2d 1292, 1307 (9th Cir.1991) and Willner v. Thornburg, 928 F.2d 1185, 1193-1194 (D.C.Cir.1991)]. Thus, most likely the Fourth Amendment will not bar pre-employment drug testing of peace officer applicants.

The recently enacted Americans with Disabilities Act (ADA) makes it unlawful to discriminate in employment against a qualified individual with a disability and affects all employers, including state and local government employers. The ADA, whose regulations are effective on July 26, 1992, protects prior drug users, but specifically

exempts current drug users from its protection and permits drug testing to determine current use.

Section 1630.3 of the ADA regulations states that "[t]he terms 'disability' and 'qualified individual with a disability' do not include individuals currently engaging in the illegal use of drugs . . ."

Section 1630.3(b) of the ADA does not, however, exclude from the terms "disability" and "qualified individual with a disability," an individual who (1) has successfully completed a supervised drug rehabilitation program and is no longer engaging in the illegal use of drugs, or has otherwise been rehabilitated successfully and is no longer engaging in the illegal use of drugs; or (2) is participating in a supervised rehabilitation program and is no longer engaging in such use; or (3) is erroneously regarded as engaging in such use, but is not engaging in such use.

With specific regard to drug testing, the ADA in Section 1630.16(c) reflects a general neutrality:

(1) General policy. For purposes of this part, a test to determine the illegal use of drugs is not considered a medical examination. Thus, the administration of such drug tests by a covered entity to its job applicants or employees is not a violation of Section 1630.13 of this part. However, this part does not encourage, prohibit, or authorize a covered entity to conduct drug tests of job applicants or employees to determine the illegal use of drugs or to make employment decisions based on such test results.

Further elaboration of the ADA regulations is provided in the "Appendix to Part 1630-- Interpretive Guidance on Title I of the Americans with Disabilities Act." In reference to Section 1630.3, the appendix states (in part),

Part 1630 provides that an individual currently engaging in the illegal use of drugs is not an individual with a disability for purposes of this part when the employer or other covered entity acts on the basis of such use. Illegal use of drugs refers both to the use of unlawful drugs, such as cocaine, and to the unlawful use of prescription drugs.

Employers, for example, may discharge or deny employment to persons who illegally use drugs, on the basis of such use, without fear of being held liable for discrimination. The term "currently engaging" is not intended to be limited to the use of drugs on the day of, or within a matter of days or weeks before, the employment action in question. Rather, the provision is intended to apply to the illegal use of drugs that has occurred recently enough to indicate that the individual is actively engaged in such conduct."

With regard to drug testing and history of illegal drug use, the Appendix states:

Employers are entitled to seek reasonable assurances that no illegal use of drugs is occurring or has occurred recently enough so that continuing use is a real and ongoing problem. The reasonable assurances that employers may ask applicants or employees to provide include evidence that the individual is participating in a drug treatment program and/or evidence, such as drug test results, to show that the individual is not currently engaging in the illegal use of drugs. An employer, such as a law enforcement agency, may also be able to impose a qualification standard that excludes individuals with a history of illegal use of drugs if it can show that the standard is job-related and consistent with business necessity.

At the state level, the principal potential limitation upon drug testing of public employees is the constitutional right of privacy, Article 1, Section 1 of the California Constitution. To date, there has been relatively little case law on whether or not public employee drug testing violates that right of privacy, and no definitive rulings from the California Supreme Court. Given this current situation, the legality of peace officer applicant drug testing under the state right of privacy is uncertain.

Once decided, two cases currently pending before the state Supreme Court most likely will have great impact on the law in this area: Hill v. NCAA (involving athlete drug testing) and Soroka v. Dayton-Hudson Corp. (involving pre-employment psychological screening). Among the issues raised in the pending cases are: (1) whether the state right of privacy requires that a procedure (such as drug testing) meet a compelling interest test or a mere reasonableness standard, and (2) whether employee applicants enjoy the same standard of protection under the right of privacy as employees. Pending resolution of these issues by the state Supreme Court, it remains an open question whether pre-employment drug testing meets state constitutional standards.

TECHNICAL ISSUES

Specimens, Analytical Methodologies, and Substances to be Tested

Once an agency has made the decision to proceed with pre-employment drug screening, it must begin to grapple with a host of technical and procedural issues including which substances are to be tested? using what analytical methods? on what types of specimens collected? under what conditions? As mentioned previously, great deference is given throughout these guidelines to the National Institute on Drug Abuse (NIDA) on these matters. NIDA, under the Department of Health and Human Services is responsible for developing scientific and technical guidelines for drug testing programs for federal agencies. The issuance of the "Mandatory Guidelines for Federal Workplace Drug Testing Programs" on April 11, 1988 established an industry standard that is widely and highly respected. In fact, recent years have seen federal legislation proposed in both houses which would impose federal standards for drug testing in the private sector. Further, there is apparent widespread support among business and labor for a single federal standard that would apply to all employee drug testing and would be preemptive of any state laws.

Given this encompassing trend, and given the realization that the NIDA guidelines should not be considered "immutable," much less perfect, NIDA itself recently (1990) sponsored a Consensus Conference to assess its guidelines and to develop recommendations for change. Participants in the Consensus Conference included politicians and government officials, representatives of business, industry and labor, as well as laboratory scientists and physicians. Their recommendations will also be cited throughout these guidelines.

Specimens

For a number of reasons, NIDA states that urine continues to be the best specimen for analysis in the context of detecting drug use related to employment.

While analyses of blood for drugs may potentially provide more specific indication of drug impairment, blood analysis generally requires more sophisticated techniques of analysis, is more invasive to obtain, and requires more trained personnel to obtain. For these reasons, it is less suitable for use in mass screening such as would be required for pre-employment purposes. However, of those agencies with drug screening programs in place that responded to the POST survey, almost 23% reported collection of blood specimens, presumably with satisfactory results. If an agency should choose to collect blood samples rather than urine, the same testing methodologies can generally be used

(though blood samples must be first prepared for testing by the laboratory) and the same security precautions would apply; however, the cost for processing blood samples is higher than for urine.

Saliva and hair are among the easiest to obtain samples. However, though drugs can be detected through both samples, because of incomplete knowledge and lack of scientific data, neither are recommended by NIDA for mass screening. The following statement is from the 1990 NIDA Consensus Report resulting from its Consensus Conference:

Saliva, a biological fluid generally collected from the parotid gland in the mouth has perhaps even more difficulties and variables than a urine specimen, and, therefore, may not provide any advantage other than convenience of collection. The biodisposition and kinetics of abused drugs in saliva are not well understood and therefore interpretation of analytical data cannot be made reliably. Recent research reports on the analysis of hair have clearly indicated that there is a great deal yet to be learned about the pharmacokinetics of drugs in hair and the adequacy of hair as a specimen for drug and metabolite analysis. Drugs of abuse and their metabolites can be detected in hair but studies have raised many questions about the nature and specification of the hair sample, the dispositional kinetics and reproducibility of results from hair analysis. It is, therefore, too soon to adopt these alternative specimens because there is clearly insufficient, established data available, at present, for their use in mass screening.

The NIDA Consensus Conference also addressed the acceptable volume of urine needed for testing. Current NIDA Guidelines require "at least 60 milliliters." This requirement, however, has resulted in some difficulties in the real world setting. Given this situation, the following recommendation was made: "A urine volume of 30ml should be an acceptable specimen volume, provided that it does not create any technical problems for the laboratory."

Analytical Methodologies

The NIDA Guidelines require an initial test and a confirmatory test for screening specimens. The initial screening and confirmatory methods must be based on different chemical principles or different chromatographic separations.

Initial Test. The goal of the initial test (also known as a screening test) is to eliminate negative urine specimens from further consideration in a expeditious and inexpensive manner. For this purpose, NIDA recommends an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution (FDA approved). Specimens that do not test negative are considered **presumptively positive**.

Immunoassay tests work on the principle of competition between labeled (known) and unlabeled antigens (drugs) for binding sites on a specific antibody (a protein substance to which specific drugs or drug metabolites will bind). Two types of immunoassay are commonly used with urinalysis. They are radioimmunoassay (RIA) and enzyme immunoassay (EIA). Two commonly used forms each of these types of immunoassay tests are Abuscreen (a radioimmunoassay test) manufactured by Roche Diagnostics and Enzyme Multiplied Immunoassay Technique (EMIT), manufactured by Syva Company, and the most widely used enzyme immunoassay. A third type of immunoassay test is fluorescein polarization immunoassay (FPIA) which is the basis for Abbott Laboratories' TDxToxicology/ Abused Drug Assays.

Immunoassays can produce false-positive results because antibodies used in immunoassays can cross-react with related drugs and sometimes even with unrelated compounds. This makes confirmation of **presumptively** positive immunoassay results with an independent procedure **imperative**. For the confirmatory test, NIDA recommends using gas chromatography/mass spectrometry (GC/MS).

Confirmatory Test. The gas chromatography/mass spectrometry (GC/MS) confirmatory test recommended by NIDA is often referred to as the "gold standard" in drug testing.

Gas chromatography separates a substance into its component parts by using an inert gas, such as nitrogen or helium, as the moving phase to transport a vaporized sample of a drug through a glass column containing a coated packing. The column is stored within a tubing; when the components leave the tubing, they enter into a detector that registers the presence of the component and its quantity.

Mass spectrometry is based on the fact that molecules of known substances will exhibit characteristic spectra patterns when fragmented and that one fragmentation pattern is peculiar to one compound. Mass spectrometry can detect the presence of a substance and its concentration with great accuracy; however, the substance must be in pure form. Therefore, chromatography testing is needed as a preparatory step.

When the efficient separating power of gas chromatography is combined with the high sensitivity and specificity of mass spectrometry, accuracy can approach 99 percent. POST survey results indicate that by far, GC/MS is the most widely used confirmatory test by California law enforcement agencies.

Substances to be Tested

Currently, NIDA Guidelines identify five drugs (or classes of drugs) for which specimens should be tested. Those drugs, along with recommended cutoff levels for both initial and confirmatory tests are indicated below. (See Appendix 3 for more information on drugs.)

	Initial test level (ng/ml)
Marijuana metabolites	100
Cocaine metabolites	300
Opiate metabolites	300*
Phencyclidine	25
Amphetamines	1,000
*25ng/ml if immunoassay specific for free morphine.	
	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 Benzoylcegonine.	

NIDA considered incidence and prevalence of abuse of these drugs in the general population and also within the workforces of the Departments of Defense and Transportation as criteria for selecting these five drugs for testing.

During the NIDA Consensus Conference, the addition of other drugs as well as revised cut-off levels for currently screened drugs were considered. Some of the Consensus Statements on these issues follow:

- Additional drugs should be considered for inclusion in urine testing protocols when they can be justified as special problems in particular workplace environments.
- Drugs that might be considered included the benzodiazepines, barbiturates, and other selected psychoactive agents.

With regard to revised cut-off values, the Consensus Conference issued the following recommendations:

- Cannabinoids (delta-9-THC-acid) - reduce the screening cut-off from 100 ng/ml to 50ng/ml; the confirmation cut-off level should remain unchanged at 15ng/ml. Cocaine (benzoylecgonine) - reduce the present screening cut-off level to 200 ng/ml and the confirmation level to 100 ng/ml. No changes are recommended for the opiates and phencyclidine.
- For the amphetamine(s) a study should be undertaken to critically evaluate present data for the purpose of recommending lower cut-off levels for both screening and confirmation . . .
- All of the present cut-off levels should be retained until a careful laboratory evaluation of the recommended changes has been completed.

Anabolic Steroids. The abuse of anabolic steroids, synthetic male hormones used to build muscle tissue, is becoming of increasing concern to many law enforcement agencies. Detection of abuse through pre-employment drug screening, however, may not be the most effective and efficient method available. Steroids occur naturally in the body, and the laboratory test for detection is less reliable than are tests for other substances. In addition, the test is very costly. For these reasons, a more effective means of detection may be through the background investigation process.

Laboratories

Selection of a reputable, highly accurate laboratory to analyze specimens is essential to the success of a drug testing program. To ensure the highest level of laboratory accuracy possible for federal drug testing programs, NIDA in July of 1988 instituted a National Laboratory Certification Program under criteria established by the Mandatory Guidelines for Federal Workplace Drug Testing Programs, Subpart C. Among its stringent requirements, this program provides for periodic on-site inspections; every-other-month performance testing; requirements for laboratory personnel, chain of custody, security, documentation, storage, etc.; and of course, the capability (at the same laboratory site) to perform both initial immunoassays and confirmatory GC/MS tests.

NIDA certified labs will also provide required chain of custody forms, specimen bottles and materials used to secure specimens, and may provide testing consent forms.

Monthly, NIDA publishes the most recent information on laboratories certified under their National Laboratory Certification Program (see Appendix 4). There are currently eight laboratories in California that are NIDA certified.

Another certification program is administered by the College of American Pathologists (CAP) 325 Waukegana Road, Northfield, Illinois 60093-2750. Currently there are five laboratories in California that are accredited under CAP's Forensic Urine Drug Testing Laboratories program. All five laboratories are also NIDA certified.

Once again, because the selection of a laboratory is an essential element to the success of the entire program, it is recommended that a NIDA or CAP certified laboratory be chosen.¹

¹This recommendation does not, however, preclude the existence of non-certified laboratories that may have the experience and technical ability to conduct proficient forensic testing.

PROCEDURAL ISSUES

In any successful drug screening program, procedures that ensure the integrity and security of the samples are critical. This section addresses such issues as collection site security, chain of custody, personal privacy, etc. Current practices in California law enforcement agencies are reported as well as recommendations from the model drug testing policy provided by the International Association of Chiefs of Police (see Appendix 5), and procedures recommended by NIDA.

NIDA Recommendations

The Specimen Collection Procedures from the NIDA Guidelines, though lengthy, are particularly comprehensive and are worthy of review:

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 obtain 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 of urine. (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.

Comments on NIDA Specimen Collection Procedures

Though the NIDA Guidelines may appear imposing in their detail, it is important to note that many successful challenges to drug testing results are based on breaches in security. The following is a statement from the NIDA Consensus Conference:

The specimen is considered to be the total volume of urine collected and supplied to the laboratory, and any aliquot or portion taken from it. The specimen particularly, and aliquots taken from it, constitute the physical evidence upon which analytical procedures are used to produce information to decide whether drug use has occurred. A decision that drug use has occurred can be challenged; it must be defensible in a legal setting and, therefore, specimen management is a critical issue. Inadequacies in the specimen which are a result of mismanagement, can negate or reverse any decision made from the testing procedure. **Management problems are the most common and most successfully challenged deficiencies in forensic urine drug testing. They include misidentification of the specimen, non-identification, contamination, substitution, adulteration, and loss . . .**
[emphasis added]

IACP Drug Testing - Model Policy

While the model IACP drug testing policy concerns itself similarly with maintaining the integrity of the drug testing process, it differs from the NIDA Guidelines in two procedural areas.

Specimen Collection - Direct Observation

The IACP model, which applies to all applicants, probationary, and sworn employees, recommends that, "Testing personnel of the same sex as the employee shall observe production of the urine sample." [emphasis added] The NIDA Guidelines, by comparison, require direct observation only in collection of a second specimen when there is reason to believe that the first specimen has been altered or substituted.

Specimen Collection - Split Sample

The split sample technique involves dividing a urine specimen into two parts, one for immediate testing, the other to be held in storage in case of the need for confirmation analysis or reanalysis. The IACP model program makes provision for requests for split samples; NIDA Guidelines do not.

When the NIDA Guidelines were first adopted, the split sample technique was not included because it was viewed as "cumbersome and expensive," carrying with it the potential increased "risk of administrative error by doubling the labeling, initialing, storage, and accountability requirements." The NIDA Consensus Conference, however, has subsequently stated that, "Split urine specimens should be permitted provided they are both part of the same specimen and are handled with identical safeguards." This recommendation was made after taking into account the fact that many employers in the private sector have binding labor agreements which require split samples. However, in the absence of such agreements, the inclusion of the split sample technique in a drug testing program may unnecessarily add additional handling and expense.

Current Practices in California Law Enforcement Agencies

In the POST survey a number of questions dealt with how those California agencies with pre-employment drug screening programs handle the procedural aspects of their programs.

By far, the majority of California agencies with drug testing programs collect specimens at the time and site of the medical examination. Most give no more than one week's advance notification to the applicants or no notification at all. (See Appendix 6 for approximate lengths of time drugs are detectable.) Medical personnel (examining physicians or physicians' designees) are responsible for specimen collection in the majority of cases, and presumably take responsibility for security precautions including applicant identification, specimen handling and chain of custody forms. Approximately one-third of the agencies with drug testing programs practice observed sample collection.

Other Issues

Applicant Consent Form

All applicants should be asked to sign a consent form which authorizes the test and authorizes communication of the test results to the employer. To ensure that an informed consent is given, the form should disclose who will have access to the test results, the consequences of a positive result, and the consequences of a refusal to sign the consent form.

The consent form should also include a section which gives the applicant an opportunity to list all medications, alcohol or controlled substances which may be detected in the drug testing. Such information would be reviewed by the Medical Review Officer (see below) in the event of a positive test result and could provide important information in regard to a positive finding. An example of such a form used by a California law enforcement agency is shown in Appendix 7.

Medical Review Officer

NIDA defines the Medical Review Officer (MRO) as "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."

It is the job of the Medical Review Officer to conduct the final review of test results. The Medical Review Officer looks for possible alternate medical explanations for positive test results by conducting medical interviews with applicants, reviewing applicants' medical histories or any other relevant biomedical factors, or reviewing medical records made available by the tested individual that may reveal use of legally prescribed medication.

The Medical Review Officer may be an employee of the hiring agency, a contract physician, or may be provided by the laboratory providing the testing services. Currently, there is no certification program for MROs; however, at the NIDA Consensus Conference, it was recommended that:

- Medical Review Officers should be licensed doctors of medicine or osteopathy.
- A comprehensive, continuing education program that addresses all aspects of MRO function (not just drug abuse recognition) should be developed.
- Professional associations, forensic toxicologists and others should be involved in developing guidelines for continuing education.
- Maintenance of adequate continuing education and training in MRO functions should be required for MROs.
- MROs should be required to develop standard operating procedures that clearly define how all MRO functions are addressed.

Four programs that now provide MRO training are the American College of Occupational Medicine, the American Society of Addiction Medicine, the Federal Aviation Administration, and Employee Health Programs.

Length of Specimen Storage and Testing Records

NIDA Guidelines require that positive urine specimens be retained and placed in properly secured long-term frozen storage (-20° C or less) for a minimum of 1 year. This practice assures that the specimens will be available for any necessary retest during administrative or disciplinary proceedings. NIDA also requires that "... all records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of 2 years."

California law enforcement agencies adhere to similar practices. According to the POST survey, typically only those specimens that test positive are retained. The most common period of retention of positive specimens is 12 months.

Confidentiality

The sensitive nature of records pertaining to drug testing make it apparent that they should be handled confidentially. The IACP model policy states, "All records pertaining to department required drug tests shall remain confidential, and shall not be provided to other employers or agencies without the written permission of the person whose records are sought." The IACP includes as confidential ". . . pre-test consent forms, interviews containing lists of prescribed drugs used, preliminary test results, and any other written documentation of the drug test."

Appeals

As indicated in the POST survey, about one half of those agencies with a drug testing program in place have an appeals procedure. However, very few (less than one percent) of disqualified applicants ever appeal the decision.

For many agencies, pre-existing appeals requirements and procedures may exist for local civil service pursuant to the city/county charter, city/county ordinances, or city/county regulations.

Resources

Two particularly useful services provided by NIDA are their toll-free helpline and their clearinghouse. The helpline is staffed until 8:00 p.m. (eastern time zone) to accommodate the west coast and provides information to employers who want to establish drug free workplace policies and programs. The NIDA Clearinghouse for Alcohol and Drug Information provides NIDA publications free of charge and produces a catalog of its most recent documents. To contact either of these resources, agencies may contact:

NIDA Drug Free Workplace Helpline
1-800-843-4971

NIDA Clearinghouse for Alcohol and Drug Information
1-800-729-6686

SUMMARY

A law enforcement agency's decision to institute a pre-employment drug screening program must be made locally on an agency-by-agency basis. It should take into account such factors as the prevalence of drug abuse in the geographical recruitment area, the types of drugs abused, the perceived cost effectiveness of drug screening, and the effectiveness of other procedures for detecting drug abusers, such as the polygraph, background investigation, or medical examination.

These guidelines were developed with the intention of providing a foundation upon which those agencies that choose to institute pre-employment drug testing can build a program. Extensive reference is made to the NIDA Guidelines and recommendations because they are by far the most widely recognized and thoroughly researched. However, unquestioned wholesale adoption of the NIDA Guidelines is neither necessary nor recommended.

For example, the NIDA Guidelines recommend that testing be conducted for five drugs only, based on a variety of factors, not the least of which is the incidence of abuse of different substances. However, NIDA acknowledges that there are many other drugs that are misused or abused and that such misuse or abuse can result in impaired behavior in the workplace. Once again, each agency considering a drug screening program must decide, based on local factors, the drugs for which it will screen.

Whether the decision is to test for the five NIDA recommended drugs or to tailor the testing to local conditions, POST strongly recommends that the **NIDA procedures for guarding the integrity of the process be followed** (see pp. 13-18). Following NIDA's carefully considered security procedures will help to ensure the success of any pre-employment drug testing program.

GLOSSARY OF TERMS

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, using a chain of custody form.

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.

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.

Cross Reactivity - The degree to which an antibody interacts with antigens other than the one used to produce the antibody. This is a property of nearly all naturally derived antibodies.

Cutoff Level (Threshold) - Value serving as an administrative breakpoint (or cutoff point) for labeling a result positive or negative.

False Negative - A test result which states that no drug is present when, in fact, a tested drug or metabolite is present in an amount greater than the threshold or cut-off amount.

False Positive - A test result which states that a drug or metabolite is present when, in fact, the drug or metabolite is not present or is in an amount less than the threshold or cut-off value.

Gas Chromatography/Mass Spectrometry (GC/MS) - The instrumental technique which couples the powerful separation potential of gas chromatography with the specific characterization ability of mass spectroscopy.

Immunoassay - The measurement of an antigen-antibody interaction utilizing such procedures as immunofluorescence, radioimmunoassay, enzyme immunoassay or other nonradioisotopic techniques. In drug testing, the antigen is a drug or metabolite and its

corresponding labeled analog; the antibody is a protein grown in an animal and directed towards a specific drug, metabolite or group of similar compounds.

Initial Testing Procedures - The initial test, or screening test, is used to identify those specimens which are negative for the presence of drugs or their metabolites. These specimens need no further examination and need not undergo a more costly confirmation test.

Mass Spectrometry - Analysis using an analytical instrument that provides accurate information about the molecular mass and structure of complex molecules. This technique can identify and quantify extremely small amounts of drugs or metabolites by their mass-fragment spectrum.

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.

Metabolite - A compound produced from chemical changes of a drug in the body.

ng/ml - Nanogram per milliliter. A nanogram is one billionth of a gram.

Split Specimen - The practice of dividing a urine specimen into two portions, one of which may be submitted for analysis and the other preserved by freezing for the confirmation analysis or reanalysis.

Verified Positive Test Result - A test result that was positive on both the initial and confirmatory tests, and reviewed and verified by the Medical Review Officer.

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State of California

Department of Justice

M E M O R A N D U M

To : Interested Agencies

Date: January 22, 1991

Norman C. Boehm
Norman C. Boehm
Executive Director

From : Commission on Peace Officer Standards and Training

Subject : Pre-Employment Drug Screening Survey Results

Thank you for taking the time to respond to the POST Survey of Local Agency Pre-Employment Drug Testing Policies And Practices.

Attached per your request is a summary of the survey results. As you will note, the overall return rate for the survey was a gratifying 78%.

The survey findings were presented to the Commission at its January 17, 1991 meeting. Upon review of the findings, the Commission directed staff to develop pre-employment drug screening **guidelines** for distribution to all agencies in the POST program. The guidelines will be drafted and presented to the Commission for final approval in late July. Assuming Commission approval is granted, a copy of the guidelines will be mailed to each agency in the POST program shortly thereafter.

Thank you again for your assistance. Should you have any questions about the survey methodology or results, please contact Dr. John Berner, at (916) 739-3872.

Attachment

SURVEY RESULTS

LOCAL AGENCY PRE-EMPLOYMENT DRUG SCREENING PRACTICES

Response Rate:

451 of the 580 agencies surveyed returned completed questionnaires, representing an overall return rate of 77.8%. The return rate for sheriffs' departments was 87.9%; for municipal police departments 78.8%.

Prevalence of Pre-Employment Drug Screening Programs:

Slightly over one-third of the responding agencies (35.9%) reported having a drug screening program. Drug testing was more frequently reported as being conducted by municipal police departments (46.4%) than by sheriffs' departments (33.3%) or "other" departments (12.4%).¹ Testing was also more frequently reported by agencies located in the southern part of the state (44.9%) than by agencies located in the central (34.2%) or northern (28.0%) regions. Among municipal police and sheriffs' departments, large departments more often reported drug testing (59.3%) than medium-sized departments (43.2%) or small departments (39.3%).²

Characteristics of Existing Pre-Employment Drug Screening Programs:

On average, existing drug screening programs have been in place 3.0 years.

The most frequently cited reasons for implementing a program were concerns over increased drug use by the public at large (83.3%) and dissatisfaction with other screening procedures for detecting past/current drug users (37.0%).

The vast majority of agencies with a program report being either "very satisfied" (45.3%) or "satisfied" (45.9%) with the program.

Urine specimens are analyzed in almost nine out of every ten programs (88.9%); blood specimens were reported as being collected as part of 22.8% of the programs (some agencies reported collecting either or both). Specimens are most often collected at the time of the pre-employment

¹"Other" agencies includes college/university police departments, state agencies, marshals' offices, etc.

²For purposes of data analysis, "large" agencies were defined as those with over 200 employees, "medium-sized" agencies as those with 50 to 200 employees, and "small" agencies as those with fewer than 50 employees.

medical examination (84.2%), and the candidate is typically given no advance notification that a specimen will be collected (42.0%), or is given less than one week's advance notification (19.1%).

The most common precautions used to ensure the integrity of testing are sealing the specimens in tamper-proof bags or with tamper-proof tape (56.2%); questioning the candidate at the time of specimen collection as to the use of prescription or non-prescription medications (53.1%); using chain-of-custody forms (46.3%); requiring photo identification at the time of specimen collection (41.4%); and observing the candidate during specimen collection (35.8%).

Typically only those specimens that test positive are retained, with the most common retention period being 12 months.

Approximately four out of ten survey respondents (40.7%) were unable to identify the specific test protocol used for initial screening. Among those who had this knowledge, the EMIT (Enzyme Multiplied Immunoassay Technique) protocol was most often reported (54.2%).

A like number of respondents (38.9%) were unaware of the protocol used for confirmatory testing. Gas Chromatography/Mass Spectrometry (GC/MS) was most often reported as the test used among those who knew (72.7%).

Very little reliable information was obtained regarding the costs to local agencies for testing, and thus no results are reported in the attachment by specific test. Best estimates based on the limited cost data that were provided are that per candidate costs average about \$30 for initial testing and \$37 for confirmatory testing. For those agencies that pay a flat per candidate fee (which covers both initial testing and confirmatory testing, if necessary) the average cost was found to be \$54. Fees were found to vary considerably, with larger agencies generally paying less per candidate. The lowest reported per candidate fees were \$7 for initial testing and \$17 for confirmatory testing.

The substances most often reported as being tested for were cocaine (89.5%), amphetamines (88.3%), barbiturates (83.3%), marijuana (83.3%), and phencyclidine (74.1%). Slightly more than one in five agencies (20.4%) reported that they also test for steroids. The specific substances tested for were "unknown" by 6.2% of the agencies.

Approximately one-third of the agencies were unable to provide estimates of the percentages of candidates who test positive for each of the various substances. For those who did provide this information, the average overall positive

test rate (i.e., "hit rate" for all substances combined) was .91%, and 74.5% of the agencies reported never having a candidate test positive. By individual substance, the highest average positive test result rates were for marijuana (.23%) and cocaine (.21%). In general, the reported percentages of candidates who test positive were not found to vary as a function of agency type, agency size, or geographic location.

Approximately half of the agencies (49.3%) reported that they have an appeal process for those candidates who test positive. The average reported appeal rate was less than one percent (.9%).

Slightly less than one in five (17.9%) of the agencies that reported not having a drug screening program indicated that they gave serious consideration to implementing such a program and then decided against doing so. The reasons most often cited for deciding against implementation were legal concerns (50.0%) and funding concerns (31.3%).

As shown in the responses to question #24 below, agency preferences with respect to POST involvement in pre-employment drug screening vary considerably. No significant differences in the pattern of responses to this question were found by agency type, agency size, or geographic location. Interestingly, those agencies that currently have a drug screening program more frequently expressed a preference for either alternative a (POST should take no action; 7.3%) or alternative d (POST should require drug screening, but leave the specifics to local agencies; 17.2%).

24. Check below the statement which best describes your preference with respect to POST involvement in pre-employment drug testing: (check one)
- a. POST should take no action [5.1%]
 - b. POST should provide general information to those agencies that wish to establish their own programs [24.9%]
 - c. POST should publish drug testing guidelines for use by local agencies [32.5%]
 - d. POST should require that all agencies conduct pre-employment drug testing, but leave the specifics as to testing procedures and screening criteria to the discretion of the local agency [11.8%]

- e. POST should require that all agencies conduct pre-employment drug testing and should further specify the testing procedures and screening criteria that must be used [24.7%]
- f. Other (specify) [1.2%]

Polygraph Testing:

Several questions were also asked about pre-employment polygraph examinations. Approximately half of the agencies (49.1%) reported using pre-employment polygraphs. Most frequently, the polygraph is administered to all candidates (82.5% of the time), as opposed to selectively. Seventy-one percent of the agencies reported that private firms conduct all or some of the exams. With few exceptions, questions about prior/current drug use are a routine part of the exams.

POST SURVEY OF LOCAL AGENCY PRE-EMPLOYMENT DRUG TESTING POLICIES AND PRACTICES

DEPARTMENT _____	DO NOT WRITE IN THIS SPACE
YOUR NAME _____	DATE _____
TELEPHONE NUMBER _____	

If your agency does not currently have a pre-employment drug testing program, check (✓) here and proceed to Question #22.

1. How long has your agency had a pre-employment drug testing program? AVG: years months

2. Approximately how many candidates have been tested to date? AVG: 275.7

3. Approximately what percentage of candidates fail to appear for drug testing? AVG: .56%

4. What prompted your agency to institute a drug testing program? (check all that apply)

- 83.3% a. Concerns over increased drug use by public at large
- 37.0% b. Dissatisfaction with other procedures for identifying past/current drug users (e.g., background investigation)
- 11.1% c. Instances of unlawful use/possession of illegal drugs by incumbent officers
- 10.5% d. Instances of misuse/abuse of controlled substances by incumbent officers (e.g., alcohol, prescription medications)
- 12.3% e. Action initiated by City Council, Board of Supervisors, etc.
- 6.2% f. Concerns from outside the agency (e.g., citizens' groups)
- 25.9% g. Experiences reported by other departments with drug testing programs
- 11.1% h. Costs to conduct such a program became reasonable
- 16.0% i. Concerns over legality of such programs lessened (case law decisions)
- 13.6% j. Other (specify) _____

5. Have there been any organized objections to the program? Please explain. _____

"YES" - 0.6% ; "NO" - 99.4%

6. In general, how satisfied are you with the program? (check one)

- 45.3% a. Very satisfied 0.6% c. Dissatisfied 7.5% e. Too early to tell
- 45.9% b. Satisfied 0.6% d. Very dissatisfied

7. With respect to your program, what type of specimen is collected and analyzed?

22.8% Blood 88.9% Urine 1.9% Other (specify) _____

8. How many specimens are collected from each candidate?

59.2% One 19.8% Two 21.0% Don't know

9. When are the specimens collected? (check one)

- 5.1% a. Just prior to the medical examination
- 84.2% b. At the time of the medical examination
- 0.6% c. Just prior to the background investigation
- 1.3% d. At the time of the background investigation
- 7.0% e. Timing of specimen collection varies
- 1.9% f. Other (specify) _____

10. How far in advance are candidates notified of the actual time and date when the specimen(s) will be collected? (check one)

- 42.0% a. No prior notification is given
- 57% b. 24 hours or less
- 6.4% c. 48 hours or less
- 7.0% d. 72 hours or less
- 19.1% e. One week or less
- 3.8% f. Two weeks or less
- 15.9% g. Other (specify) _____

11. Where are the specimens collected? (check one)

- 3.9% a. On site (at the department)
- 90.3% b. At the site of the medical examination
- 3.2% c. At the lab where the specimens are analyzed
- 1.3% d. Site varies depending on circumstances
- 1.3% e. Other (specify) _____

12. Who collects the specimens? (check one)

- 4.4% a. Department staff
- 86.1% b. Medical personnel (examining physician or physician's designee)
- 7.0% c. Staff from lab that analyzes the specimen
- 0.6% d. Varies depending on circumstances
- 1.9% e. Other (specify) _____

13. What precautions are taken to ensure the integrity of the testing process? (check all that apply)

- 23.4% a. Collection site is searched before collection of each specimen
- 35.8% b. Candidates are observed during specimen collection
- 41.4% c. Candidates are required to present photo ID at time of specimen collection
- 9.3% d. Candidates are advised in advance against use of certain non-prescription medications
- 53.1% e. Candidates are questioned at time of specimen collection concerning use of prescription and non-prescription medications
- 46.3% f. Custody of specimens is documented via chain of custody forms
- 36.2% g. Specimens are sealed in tamper-proof bags or with tamper-proof tape
- 14.8% h. Other (specify) _____

14. Who analyzes the specimens? (check one)

- 3.2% a. Department staff do initial testing, with confirmation testing done by outside source
- 72.8% b. Staff at privately owned lab do all testing
- 3.8% c. Staff at publicly owned lab do all testing
- 15.8% d. Staff at location of medical examination do all testing
- 4.4% e. Other (specify) _____

15. How long are the specimens kept? (check one)

- 10.9% a. All specimens are destroyed immediately after analysis
- 14.7% b. Only those specimens that test positive are retained--retention period unknown or varies
- 26.9% c. Only those specimens that test positive are retained--retention period is ____ months (specify) AVG: 13.9
- 6.4% d. All specimens are retained--retention period unknown or varies
- 7.7% e. All specimens are retained--retention period is ____ months (specify) AVG: 9.4
- 33.3% f. Don't know

16. What measures does your agency take to ensure the quality of the testing lab it uses? (check all that apply)

- 33.3% a. Require that lab be certified by the National Institute on Drug Abuse
- 14.2% b. Require that lab participate in the Inter-Lab Comparison Program sponsored by the College of American Pathologists
- 24.7% c. Require that lab be accredited by the College of American Pathologists
- 4.3% d. Require other certification (please specify) _____
- 14.2% e. Other (please specify) _____
- 39.5% f. Don't know

17. What initial drug screening test does your agency use? (for test used, please indicate approximate cost.)

- | | | |
|-----------------------------------|--|----------|
| 7.4% a. <input type="checkbox"/> | TLC (Thin Layer Chromatography) | \$ _____ |
| 2.5% b. <input type="checkbox"/> | HPTLC (High Performance Thin Layer Chromatography) | \$ _____ |
| 4.3% c. <input type="checkbox"/> | GLC (Gas Liquid Chromatography) | \$ _____ |
| 8.6% d. <input type="checkbox"/> | GC/MS (Gas Chromatography/Mass Spectrometry) | \$ _____ |
| 0.0% e. <input type="checkbox"/> | HPLC (High Pressure Liquid Chromatography) | \$ _____ |
| 6.2% f. <input type="checkbox"/> | RIA (Radioimmunoassay) | \$ _____ |
| 32.1% g. <input type="checkbox"/> | EMIT (Enzyme Multiplied Immunoassay Technique) | \$ _____ |
| 9.3% h. <input type="checkbox"/> | Other (please specify) _____ | \$ _____ |
| 40.7% i. <input type="checkbox"/> | Don't know | |

Cost per candidate

18. What confirmatory test does your agency use? (for test used, please indicate approximate cost.)

Cost per candidate

4.9%	a.	TLC (Thin Layer Chromatography)	\$	_____
3.1%	b.	HP TLC (High Performance Thin Layer Chromatography)	\$	_____
4.3%	c.	GLC (Gas Liquid Chromatography)	\$	_____
44.4%	d.	GCIMS (Gas Chromatography/Mass Spectrometry)	\$	_____
0.0%	e.	HPLC (High Pressure Liquid Chromatography)	\$	_____
0.0%	f.	RIA (Radioimmunoassay)	\$	_____
3.1%	g.	EMIT (Enzyme Multiplied Immunoassay Technique)	\$	_____
3.7%	h.	Other (please specify) _____	\$	_____
38.9%	i.	Don't know	\$	_____

19. For what substances does your agency test? (Please check all that apply.) For each substance tested for, indicate the approximate percentage of candidates who test positive.

	AVERAGES:	% who test positive
46.9% a.	Alcohol	.07%
98.3% b.	Amphetamines	.03%
83.3% c.	Barbiturates	.02%
67.3% d.	Benzodiazepines	.05%
89.5% e.	Cocaine	.21%
83.3% f.	Marijuana	.23%
88.3% g.	Opiates	.02%
74.1% h.	Phencyclidine	.00%
20.4% i.	Steroids	.00%
22.8% j.	Other (please specify) _____	.22%
6.2% k.	Don't know	

Percentage of candidates who test positive overall AVG: .91%
 (Note: Overall percentage should equal total of percentages reported for individual substances)

20. What standards for cutoff levels (nanograms per milliliter at which test results are considered positive) has your agency adopted?

- 3.3% a. | IACP standards
- 36.0% b. | National Institute on Drug Abuse standards
- 14.0% c. | Other standards (please name source and if possible attach copy of standard) _____
- 46.7% d. | Don't know

21. If an individual tests positive after the confirmatory test, does your agency have an appeals process?

49.3% Yes 50.7% No

If "yes," please describe the process: _____

Approximately what percentage of disqualified applicants appeal? AVG: .90%

Proceed to Question #23.

(Note: Answer this question only if your agency does not have a pre-employment drug testing program.)

22. Did your agency ever have a pre-employment drug testing program?

1 Yes 282 No

If "yes," indicate below the reasons why the program was discontinued: (check all that apply)

- a. Adverse legal decision
- b. Program was not cost effective
- c. Lack of funds to pay for program
- d. Dissatisfaction with lab service
- e. General concerns about integrity of program
- f. Suspicion that candidates were learning how to "beat the system"
- g. Program was difficult to administer properly
- h. Other (specify) Personnel department let it lapse

If "no," did your agency ever give serious consideration to implementing a drug testing program and then decide against doing so?

17.9% Yes 82.1% No

If "no," proceed to Question #23

If "yes," indicate below the reasons why you decided against implementation: (check all that apply)

- 31.3% a. Required funds not available
- 18.8% b. Concerns over cost effectiveness of such programs
- 50.0% c. Concerns over legality of such programs
- 12.5% d. No reputable labs in vicinity
- 29.2% e. Concerns over ability to administer program appropriately
- 18.8% f. Request for approval to implement program was denied (by City Hall, Board of Supervisors, etc.)
- 35.4% g. Other (specify) _____

Use of Polygraph

23. Do you currently conduct pre-employment polygraph examinations?

49.1% Yes 50.9% No

If "yes," who must take a polygraph examination? (check one)

- 82.5% a. All candidates who are ultimately hired
- 12.7% b. Some, but not all candidates who are ultimately hired (i.e., decision to administer polygraph is made on a case-by-case basis)
- 4.7% c. Other (specify) _____

Who administers the polygraph? (check all that apply)

- 21.3% a. We do (Departmental/Agency Personnel)
- 12.5% b. Personnel from another Law Enforcement Agency
- 71.3% c. Private Individual/Firm
- .9% d. Other (specify) _____

Are questions asked about prior/current drug use as part of the polygraph examination? (check one)

92.4% Yes, always 7.6% Sometimes No

24. Check below the statement which best describes your preference with respect to POST involvement in pre-employment drug testing: (check one)

- 5.1% a. POST should take no action
- 24.9% b. POST should provide general information to those agencies that wish to establish their own programs
- 32.5% c. POST should publish drug testing guidelines for use by local agencies
- 11.8% d. POST should require that all agencies conduct pre-employment drug testing, but leave the specifics as to the testing procedures and screening criteria to the discretion of the local agency
- 24.7% e. POST should require that all agencies conduct pre-employment drug testing and should further specify the testing procedures and screening criteria that must be used
- 1.2% f. Other (specify) _____

Thank you for taking the time and effort to complete the survey. If you would like to receive a copy of the results, please provide your name and address in the space provided. Please return the completed survey by November 9th in the envelope provided to POST, 1601 Alhambra Blvd., Sacramento, CA. 95816-7083.

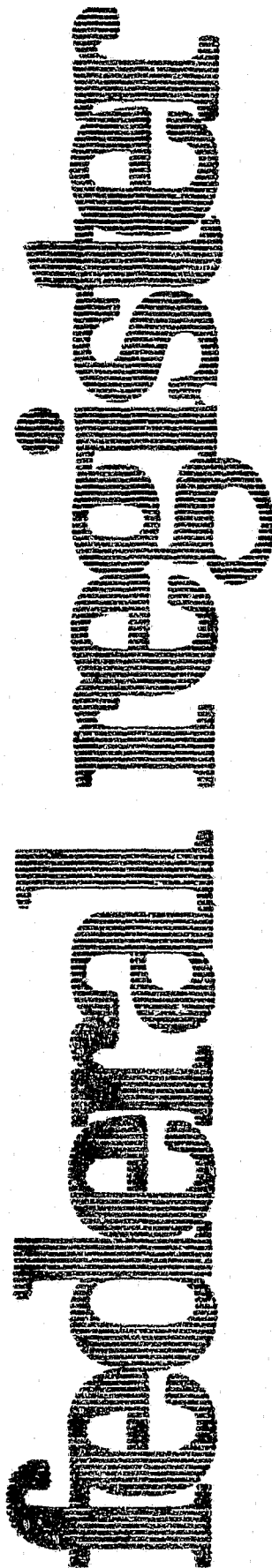
Monday
April 11, 1988

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**



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: National Institute on Drug Abuse, HHS.

ACTION: Final Guidelines.

SUMMARY: The Department of Health and Human Services (DHHS) adopts scientific and technical guidelines for Federal drug testing programs and establishes standards for certification of laboratories engaged in urine drug testing for Federal agencies.

EFFECTIVE DATE: April 11, 1988.

FOR FURTHER INFORMATION CONTACT: Maureen Sullivan (301) 443-6780.

SUPPLEMENTARY INFORMATION: These Final Guidelines, titled "Mandatory Guidelines for Federal Workplace Drug Testing Programs" were developed in accordance with Executive Order No. 12564 dated September 15, 1986, and section 503 of Pub. L. 100-71, the Supplemental Appropriations Act for fiscal year 1987 dated July 11, 1987. The statute specifically requires that notice of proposed mandatory guidelines be published in the Federal Register; that interested persons be given not less than 60 days to submit written comments; and that after review and consideration of written comments, final guidelines be published which:

I. Establish comprehensive standards for all aspects of laboratory drug testing and laboratory procedures to be applied in carrying out Executive Order No. 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 No. 12564.

Subpart A of this document contains general provisions. Subpart B, titled "Scientific and Technical Requirements," responds to the mandates in items I and II above. Subpart C, titled "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," responds to item III.

In substance, these Final Guidelines are very similar to those in the Notice of Proposed Guidelines published on August 14, 1987 (52 FR 30638). However, significant editorial and format changes have been made. The Guidelines have been edited as a single, integrated document organized in a more traditional format with subparts, numbered sections, and consistent paragraph designators. Definitions have been grouped together in Subpart A. Rather than repeat identical material, the document contains internal cross-references, particularly from Subpart C to Subpart B. This new organizational approach should add clarity to presentation of the material and aid the cross-referencing and citation of individual sections and paragraphs.

Prior to addressing comments on the specifics of the scientific and technical requirements and the certification program, it is worth noting that a number of commentors perceived the laboratory standards in these Guidelines as redundant, viewing existing regulations, guidelines, and certification/licensure mechanisms of the Medicare and Clinical Laboratory Improvement Act of 1967 (CLIA) interstate licensure program—also administered by DHHS—as sufficient to provide quality assurance for urine drug testing laboratories.

The Medicare and CLIA certification requirements apply to laboratories conducting a wide range of medical tests, having been designed for any medical testing laboratory receiving Medicare/Medicaid reimbursement or performing testing on specimens in interstate commerce, respectively.

The laboratory portion of the President's Drug-Free Federal Workplace Program can be distinguished from the Medicare/CLIA programs by important differences in policies, procedures, and personnel arising from standards appropriate to the application of analytical forensic toxicology for this program. Unique distinguishing features include:

- Rigorous chain of custody procedures for collection of specimens and for handling specimens during testing and storage.
- Stringent standards for making the drug testing site secure, for restricting access to all but authorized personnel, and providing an escort for any others who are authorized to be on the premises;
- Precise requirements for quality assurance and performance testing specific to urine assays for the presence of illegal drugs; and
- Specific educational and experience requirements for laboratory personnel to

ensure their competence and credibility as experts on forensic urine drug testing, particularly to qualify them as witnesses in legal proceedings which challenge the finding of the laboratory.

Medicare and CLIA laboratory certification procedures do not provide for quality assurance and performance testing specific to urine drug testing laboratories. With few exceptions, the Medicare and CLIA certification programs do not have employees specifically trained in toxicology to perform the on-site surveys and evaluations of the laboratories and the technologies employed in the laboratories. The Medicare and CLIA standards do not address issues such as cutoff limits for drug detection, grading criteria for the performance testing programs, blind performance testing requirements, specifications for the analytical techniques to be employed, types of drugs to be detected (including metabolites), and detailed outcome measures of performance such as requiring assays of quality control samples and a large number of performance test samples as an initial and ongoing requirement for certification.

The need to assure the protection of individual rights within the context of a drug testing program—linked to both employee assistance programs and the management potential for taking adverse action against an employee—makes essential the development of a separate laboratory certification program to respond to the unique requirements of the program mandated by the President and the Congress. These Guidelines set standards for such a certification program.

The Final Guidelines make clear that they do not apply to drug testing under any legal authority other than E.O. 12564, including testing of persons under the jurisdiction of the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees (see § 1.1(e)). The testing of persons in the criminal justice system is different than testing under E.O. 12564 for several reasons: (1) The overriding purpose of the criminal justice system is to protect community safety through the apprehension, adjudication, and punishment of law violators; (2) the incidence of drug use among those under the jurisdiction of the criminal justice system is high; and (3) the legal interests at issue in the criminal justice system, including liberty, privacy, and property interests, are different and, therefore, are subject to established practices, constitutional protections, and evidentiary rules specific to the criminal

justice system. The Guidelines also do not apply to military testing of service personnel or applicants to the military.

Response to Comments

Written comments to the Notice of Proposed Guidelines published August 14, 1987, were received from approximately 150 individuals, organizations, and Federal agencies. All written comments were reviewed and taken into consideration in the preparation of the Final Guidelines. This section summarizes major comments and the Department's response to them. Similar comments are considered together.

1. Several commenters requested that the Guidelines require a split sample technique in which a second sample or a portion of a sample could be saved for further testing. Although this possibility was considered, it is viewed as a cumbersome and expensive process involving the collection of two separate sets of samples and the retention of one for an indefinite period of time in some type of secured long term refrigerated storage. The use of a split sample was suggested as a mechanism to overcome perceived problems arising out of situations such as sample mixups, erroneous identification of samples, and lost samples. The Department does not agree that split or additional sample proposal would have any scientific advantage over the current system nor would they increase reliability. In fact, such a system could increase the risk of administrative error by doubling the labeling, initialing, storage, and accountability requirements. Furthermore, the Guidelines already include sufficient safeguards to eliminate the problems the use of split or additional samples are thought to address; e.g., detailed safeguards for labeling and chain of custody of the urine sample. Accordingly, we do not project any real scientific, chain of custody, or reliability benefits sufficient to justify placing the added requirement of collection and storage of split samples of Federal agencies and have rejected the split sample requirement. Furthermore, these Guidelines specifically reject allowing the tested employee or anyone else from presenting to the Medical Review Officer a split sample or private sample that does not fully comply with these Guidelines.

2. A number of commenters said that specific educational and experience requirements for laboratory directors and supervisors were too restrictive and that specific board certifications, experience, and degree requirements were also too restrictive and did not

provide any additional quality assurance. In many cases these individuals recommended that the current Medicare and CLIA personnel standards be used in place of the standards proposed in the Guidelines. Other individuals and organizations stated that the proposed personnel standards in the Guidelines were not stringent enough. Some recommended that specific standards also be adopted for the personnel performing the tests.

The Department carefully considered the comments about the personnel standards proposed in the Guidelines—most of which came from employees of clinical laboratories or organizations representing those employees—from the perspective of the intent of the Guidelines. It is not possible to reconcile the divergent viewpoint represented in the comments. In this connection it should be noted that credentialing standards for laboratory personnel have been an issue for a number of years in other laboratory programs administered by DHHS, as well as among those who commented on the Notice proposing these Guidelines.

The laboratory personnel requirements in the Guidelines are designated to assure that any individual responsible for test-review and result-reporting is qualified to perform the function and could appear as an expert witness in a court challenge of the results. This requires familiarity with a wide range of material related to test selection, quality assurance, interferences with various tests, maintenance of chain of custody, documentation of findings, interpretation of test results, validation and verification of test results, and the ability to testify as an expert in legal proceedings. The Guidelines set personnel requirements for the individuals responsible for day-to-day management and operation of laboratories engaged in urine drug testing for Federal agencies aimed at ensuring those competencies.

While a consultant may be able to carry out some of these specialized functions, it is essential that comprehensive oversight and control of the responsibilities cited above be exercised by those who are directly responsible on a day-to-day basis for the laboratory, who are accountable for the test results, and who may be called on to consult with the agency for which testing is performed as well as to appear at any legal proceeding to defend the quality of testing in the laboratory. Therefore, the Guidelines set functional employee qualification standards which are essential to the mission of a drug

testing laboratory and require that laboratory employees meet those standards. For the purpose of meeting laboratory personnel requirements, no provision is made for the use of consultants who are not involved in the day-to-day management or operation of the laboratory.

The Final Guidelines set functional requirements for individuals engaged in the day-to-day management and operation of laboratories engaged in urine drug testing for Federal agencies. They do not specify requirements for other personnel, including employees who perform the assays, but rather depend on the ability of those responsible individuals to select and oversee properly qualified employees in each specific laboratory, and they depend on outcome measures of laboratory performance such as performance testing. The individual responsible for day-to-day laboratory management is responsible for determining staffing needs and types of personnel required to perform particular functions in a specific facility. The individual responsible for day-to-day laboratory operations is responsible for supervision of analysts performing drug tests and related duties. Outcome measures will provide the responsible individual with feedback on the performance of laboratory employees. Within this framework, the Guidelines do not establish qualifications for additional laboratory positions.

The individuals who perform the tests are a vital part of any laboratory operation, and there is no intent to minimize their importance by omitting qualifications for them. However, by holding the appropriate laboratory officials responsible for review and certification of all test results before they are sent forward and by relying on various quality control and quality assurance measures, performance testing and on-site evaluations to provide direct measures of the quality of testing, the Department expects to ensure a standard of excellence in drug testing without setting additional personnel requirements. This reliance on the qualifications of the individuals responsible for the day-to-day management and operation of urine drug testing laboratories does not prohibit the laboratories themselves from setting additional employee standards which may include specific credentials, certifications, licenses, registries, etc., for specific functions.

However, once a laboratory is certified in accordance with these Guidelines, laboratory employees whose functions are prescribed by these

Guidelines are deemed qualified. These Guidelines establish the exclusive standards for qualifying or certifying these employees involved in urinalysis testing. Certification of a laboratory under these Guidelines shall be a determination that all appropriate qualification requirements have been met. Agencies may not establish or negotiate additional requirements for these laboratory personnel.

Some commentors felt that references to director, supervisor of analysts, certifying officials, and other analysts did not clearly distinguish between those positions. Other commentors criticized the establishment of specific position titles. We have clarified laboratory employee functions and dropped the use of specific position titles in 2.3 Laboratory Personnel. A laboratory engaged in urine drug testing for Federal agencies must have personnel to perform the following functions:

- Be responsible for the day-to-day management and for the scientific and technical performance of the drug testing laboratory (even where another individual has overall responsibility for an entire multispecialty laboratory).

- Attest to the validity of the laboratory's test reports. This individual may be any employee who is qualified to be responsible for the day-to-day management or operation of the drug testing laboratory.

- Be responsible for the day-to-day operation of the drug testing laboratory and for the direct supervision of analysts performing drug tests and related duties.

In response to those commentors who were concerned about the proposed requirement for a Ph.D. to qualify as a laboratory director, the Final Guidelines provide that the individual responsible for the day-to-day drug testing laboratory management may have education and experience in lieu of a Ph.D. to demonstrate an individual's scientific qualifications in analytical forensic toxicology (see 2.3(a)(2)(iii)). Together with the specific analytical forensic toxicology experience required in 2.3(a)(2)(iv), scientific qualifications may be demonstrated by showing "training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree and in addition have training and laboratory or research experience in biology, chemistry, and pharmacology or toxicology." This Ph.D. comparability provision eliminates the utility of the "grandfather" clause in the proposed guidelines, a clause which would have qualified incumbent laboratory directors who have a graduate degree in the

natural sciences followed by extensive experience (6 years postgraduate), in analytical forensic toxicology. Thus, the Final Guidelines omit the "Grandfather" clause.

The Ph.D. comparability provision, while not requiring specific research experience, recognizes research as one mechanism for demonstrating scientific competency to be responsible for day-to-day laboratory management. Lack of research experience does not disqualify an individual for that function if he or she has other appropriate training or experience. The Ph.D. comparability provision also makes explicit that a medical degree is an acceptable alternative to the Ph.D. for this purpose, provided, of course, that the M.D. has the other requisite training and experience.

The Final Guidelines do not require specific board certification for any laboratory employees. Some commentors were concerned particularly that individuals who supervise analysts would have to be on the registry of the American Society for Clinical Pathologists (ASCP). The proposed guidelines cited the ASCP registry, but only as an example of the type of experience and education that would qualify an individual to oversee the day-to-day operations of a urine drug testing laboratory, including the supervision of analysts. The important factors associated with day-to-day operation and supervision of analysts in a forensic toxicology laboratory are captured in 2.3(c). Therefore, the Final Guidelines omit any reference to a registry as a factor in qualifying an individual for this function. Likewise, the Guidelines do not refer to a registry for the individual responsible for day-to-day laboratory management or the individual responsible for attesting to the validity of the laboratory's test reports, but rely instead on education and experience qualifications set out in 2.3 (a) and (b), respectively.

Consistent with editorial revisions throughout the Final Guidelines, editorial changes in the personnel provisions are intended to clarify specific education, training, and experience requirements for individuals to carrying out vital laboratory functions, to simplify by adopting consistent terminology, and to eliminate the need to compare similar provisions by using identical provisions when appropriate. In this regard, the personnel provisions in Subpart B, which sets out the scientific and technical requirements, and in Subpart C, which sets out the standards for certification of laboratories, are identical: Subpart C

simply cross-references the personnel provisions in Subpart B.

3. A number of commentors said that it was unnecessarily restrictive to require that the screening and confirmation tests be performed at the same site. They believed that the majority of tests would be negative and that would reduce the number of samples that must be shipped to another site and would, in turn, prevent sample mixup and loss.

After having carefully reviewed this issue, the Department has determined that both screening and confirmatory testing must be performed at the same time (3.5). Although use of separate screening and confirmation laboratories may produce adequate results, Pub. L. 100-71 mandates that the Secretary set standards which "require . . . strict procedures governing the chain of custody of specimens collected for drug testing." Same-site screening and confirmation is the best method for maintaining such strict control in the chain of custody.

Requiring the two tests to be performed in the same laboratory will reduce problems inherent in having two test sites, such as problems maintaining chain of custody forms at two test sites; need for having two separate laboratory forms; possible mix-ups and loss of samples in transit between sites; potential delays in reporting results; and potential for having results reported only on the basis of an initial screening test.

Several commentors indicated that if screening were done on-site this would reduce the number of subsequent requirements for rescreening and result in fewer samples being sent to another site. The Federal work force testing program does not envision performing initial tests at the collection site. Therefore, considerations concerning on-site initial screening tests are not relevant to the current Federal testing program.

4. Several commentors indicated that a number of terms were not defined or that there was no single section defining terms used in the Notice of Proposed Guidelines. The Final Guidelines include a section to centralize the definitions that appeared in the proposed document and add definitions to several previously undefined terms (1.2). The term "proficiency testing" has been edited throughout to read "performance testing" as a more precise reflection of the nature of the testing with which these Guidelines are concerned.

5. A number of commentors said that the cutoff limits for the reporting of positive results should be higher or

lower than those proposed (see 52 FR 30641). There also were commentators who believed that the cutoff limits for the screening and confirmation tests should be set at the same level.

The initial immunoassay test cutoff is established at levels generally similar to those used by the Department of Defense and available with commercial immunoassays. These levels are consistent with detection of recent drug use.

The second set of cutoff levels is for the gas chromatography/mass spectrometry (GC/MS) confirmatory test, chosen so that the specimens determined to be positive by the first technique (screening technique) could be confirmed at a reasonable level of analytical accuracy.

The Final Guidelines retain all the proposed initial test cutoff values (2.4(e)). Confirmation for marijuana is changed by 5 ng/ml in accordance with DOD experience. Likewise, confirmation for amphetamines reflects the cutoff intended for the notice of proposed guidelines consistent with DOD levels. Cutoffs for specific opiates (morphine and codeine) and amphetamines (amphetamine and methamphetamine) are delineated for clarity (2.4(f)).

In finalizing both screening and confirmation cutoffs, among the matters considered were prevalence rate; cross-reactivity; state of the art in drug detection; and the experience of the Department of Defense and other groups in large-volume drug testing programs.

8. Several commentators indicated that alcohol should be included among the substances to be tested. The Department acknowledges the significance of alcohol and its use as well as its potential impact on performance in the workplace. In any event, alcohol is not an illegal substance, and Executive Order 12564, which these Guidelines implement, only authorizes testing for illicit drugs listed in Schedule I and Schedule II of the Controlled Substances Act. However, nothing in these Guidelines restricts the authority of agencies to test for alcohol under authorities other than E.O. 12564.

7. Several commentators indicated that photo identifications should be required at the testing site to ensure that the tested individual is properly identified. We concur that proper identification should be provided by the individuals at the test site to assure that the correct individual will be tested. Since most Federal agencies already issue photo identification cards to their employees and most employees have a driver's license with photo identification, it is not unreasonable to require this form of identification for individuals presenting

themselves for testing. In cases where the individual does not have a proper photo identification, the collection site person must get the employee's supervisor, coordinator of the drug testing program, or any other agency official who knows the employee to provide a positive identification (2.2(f)(2)).

8. Several commentators suggested that toilets, water faucets, and other sources of water which could be used as adulterants should be taped shut or sealed to prevent adulteration of the sample at the collection site. The Department acknowledges that sources of water should not be available which would enable an individual to adulterate the sample. However, there are also needs, such as hand washing, for a relatively convenient source of water. These Guidelines cannot anticipate the needs at each collection site and the hardship which would be imposed by sealing all sources of water at the site. However, the proposed and Final Guidelines do include in 2.2 precautions in specimen collection procedures to ensure the integrity and identity of the specimen. Because we have taken reasonable steps to ensure that specimens are not adulterated at the collection site and because there are practical reasons for having a convenient source of water, the Final Guidelines do not require that all sources of water be taped or sealed shut but rather require that precautions be taken to ensure that unadulterated specimens are obtained. Among the precautions included in 2.2(f) to ensure unadulterated specimens is a requirement to use a bluing agent so that the water in the toilet tank and bowl are colored blue and that there be no other source of water in the enclosure where the sample is given.

9. Several commentators requested more specific guidelines to define "unusual behavior" at the urine collection site which would give reason to believe a particular individual may alter or substitute the specimen to be provided which, in turn, would trigger the requirement to obtain a second specimen under direct observation of a same gender collection site person (see 2.2(f)(16)). The guidelines focus on whether there is "reason to believe" (see 1.2 for definition) that a sample is adulterated. Observations of unusual behavior may bear on whether there is a "reason to believe" and for that reason the Guidelines require such observations to be documented in the permanent record book. While it may be desirable to provide specific descriptions of or guidelines to identify "unusual behavior," the Department

cannot foresee or define every contingency which might occur. Thus, "unusual behavior" is not further defined in the Guidelines.

It should be noted, however, that other indicia of "reason to believe" are set out in 2.2(f). For example, 2.2(f)(12) and (13) require a temperature reading upon collection of the specimen and indicate those temperatures which would give rise to a reason to believe that a specimen may be altered or substituted. Elsewhere the Guidelines require the collection site person to inspect the sample for unusual color or other signs of contaminants (2.2(f)(14)). Likewise, if a collection site person sees unusual behavior which causes him or her to question the integrity of the sample such that it leads to a reason to believe that a particular individual may alter or substitute the specimen to be provided, the Guidelines require that such an observation be noted in writing in the permanent record book (2.2(f)(8)). The Final Guidelines also add a requirement that any "reason to believe" observation be concurred in by a higher level supervisor of the collection site person (2.2(f)(23)).

With regard to reason to believe that a particular individual may alter or substitute the specimen based on the specimen's temperature falling outside the acceptable range, the Final Guidelines permit an individual to volunteer to have an oral temperature reading to provide evidence that the temperature of the specimen was consistent with the individual's body temperature, i.e., an individual's fever could cause an elevation in the temperature of the specimen (2.2(f)(13)).

10. Several commentators said that if the first specimen is subject to a reason to believe that the particular individual may alter or substitute the specimen which would require a second specimen to be collected, the second specimen should be collected immediately. The Department concurs that the second specimen should be collected as soon as the need for it is established. Therefore, the Guidelines provide that the second specimen shall be collected as soon as possible whenever there is reason to believe that the particular individual may alter or substitute the specimen. (2.2(f)(16)).

11. Several commentators wanted to know the basis for the choice of cocaine and marijuana as the drugs required to be screened by all agencies. The requirement that all agencies screen for cocaine and marijuana was based on the incidence and prevalence of their abuse in the general population and the experiences of the Department of

Defense and the Department of Transportation in screening their work forces. The choice of cocaine and marijuana as the only substances for which all agencies must test takes into account that the predictive value of any positive diagnostic test is a function of prevalence in the tested population. Agencies have also been authorized to test for phencyclidine, amphetamines, and opiates because their high incidence and prevalence in the general population may warrant testing of particular agency work forces for these illegal substances (2.1(a)).

Federal agency requests for screening drugs other than the five authorized in these Guidelines must be made in writing to the Secretary. The Secretary will review the requests on a case-by-case basis and make a determination of the acceptability of the plans, cutoff limits, and testing protocols. The Secretary's determination shall be limited to the use of appropriate science and technology and shall not otherwise restrict agency authority to test for drugs included in schedules I and II of the Controlled Substances Act (2.1(b)).

12. Several commentors wanted clarification of the procedures for the Medical Review Officer's (MRO's) protocols for performing the review function. They also wanted to know if individual employees would have an opportunity to discuss the Medical Review Officer's findings with him or her. Procedures for the conduct of the medical review function, including a handbook to cover the activities of the MRO, will be disseminated to all Federal agencies. While there is agreement that there should be an opportunity for some type of medical interview between the medical review officer and the employee prior to the MRO's final decision concerning a positive test result, a face-to-face interview may not always be feasible or possible. For example, they may be in widely distant geographic areas, and it may be more practical to arrange a telephone or teleconference interview than a direct meeting. Therefore, we have provided for flexibility in the mechanism for this communication and have stated at 2.7(c) that prior to making a final decision to verify a positive result, the MRO shall give the individual employee an opportunity to discuss the test result with him or her. The Medical Review Officer shall not, however, consider the results of urine samples that are not obtained or processed in accordance with these Guidelines.

13. Several commentors indicated that color blindness measurements for laboratory workers were not necessary

since none of the currently approved methodologies involved the use of visual color measurements. The requirement that laboratories maintain files which include information on employee color vision was originally proposed because some immunoassay systems have color-coded components and the reliable manipulation of such systems requires good color vision. In view of the methodologies currently approved in the Guidelines, we agree that an across-the-board requirement to maintain files on color blindness is not warranted. However, the Department has a more general concern that laboratories employ individuals who have the ability to perform any necessary test procedures. Therefore, the Guidelines generally provide at 2.3(f) that laboratory personnel files shall include results of any tests which establish employee competency for the position he or she holds and provide, as a specific example, a test for color blindness if the employee will be using color coded analytical systems. Similarly, the final Guidelines do not require that laboratories maintain any other medical data about employees unless that data would be necessary to show the employee's competency to perform a specific job function.

While these Guidelines do not require laboratories to maintain general health or medical information in employee files, they do not preclude a laboratory from maintaining such files. What 2.3(f) is intended to do is require laboratories to maintain sufficient files to show employee competency for the position he or she holds.

14. One commentor requested that the laboratory notify agency management officials of a positive result at the same time the Medical Review Officer is notified, so that individuals in sensitive positions or in positions where they could pose a hazard to other individuals or the public could be temporarily removed from these positions, with no punitive action, until after the Medical Review Officer had completed the review process. After considering both the safety implications and the employee rights in this type of notification, the Department has determined that it would be inappropriate to report a result before the Medical Review Officer has the opportunity to review the facts and circumstances and make a decision on the meaning of the test results. In instances where an agency determines that it has a need for immediate action or might have such a need based on its mission, the agency should develop a mechanism to expedite the review

process or allow the Medical Review Officer to require review of the individual's general fitness to continue performing a specific function. Circumventing the review system would abridge necessary protections for employees and could result in prejudging an individual employee's case (2.7).

15. Several commentors called for a medical review board instead of a single Medical Review Officer. A primary purpose of the Medical Review Officer position is to provide for the privacy and confidentiality of the employee's personal medical history during the course of reviewing positive test results. To call together a board which would be privy to that private information would increase the exposure of the employee's medical history to several other individuals. Furthermore, the Department views the physician in the Medical Review Officer's role in retaining overall responsibility for reviewing and interpreting positive test results. There is no restriction on the Medical Review Officer's seeking advice on an ad hoc or a continuous basis from an individual or group if he or she does not breach employee confidentiality during the course of the review and interpretation of the employee's test results. Because the Department is vitally concerned with maintaining confidentiality and privacy and because the Medical Review Officer is not now limited in seeking advice from persons who might have served on the proposed medical review board (e.g., the drug program coordinator, employee assistance program officials, or any other agency employee), the Guidelines will continue to call for review by a single medical officer rather than a board (2.7).

16. Several commentors requested that the term "inexpensive immunoassay" to describe the initial test be eliminated since cost should be left to the agency and the laboratory and techniques other than immunoassay should be used to test for certain drugs. The term "inexpensive" was not intended to set specifications for price; that is a matter for negotiation between the laboratory and the contracting Federal agency. It was meant to serve as part of a generic description of the procedure and purpose of a screening assay. The term "initial test" has been revised in 1.2 and does not use the word "inexpensive".

17. Several commentors indicated that more specific guidelines should be issued to assure the security of test results whether sent by mail or by electronic means. The Guidelines clarify

that the laboratory must ensure the security of data transmission and limit access to any data transmission, storage, and retrieval system (2.4(g)(4)).

18. Several commentors stated that individuals should have access to all records, data, and documents relating to their test results and the certification of the laboratory which performed the urine drug test. Section 503 of Pub. L. 100-71 provides that 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. In response to this comment the provisions of the statute have been set out in a new paragraph at 2.9. The Department anticipates that individuals will be able to obtain information about their own test results from the agency's Medical Review Officer, employee assistance program, or other staff person designated by the agency. Any other relevant information will be made available in accordance with the statute.

19. Several laboratories indicated that the monthly statistical summary required of the testing laboratories would be costly and an excessive burden. The Department views the monthly data as necessary for several purposes including evaluating the laboratory testing program, gathering statistical data to evaluate the drug testing program's effectiveness, and providing demographic data on drug use by the Federal work force. The information will assist in making decisions concerning changes in policy or program implementation and identifying specific programs for attention. The Department anticipates that the cost of providing the data will be built into the contract the laboratory signs with each agency. Therefore, provision of the data will be a function for which the laboratory is duly compensated, not an undue cost or burden (2.4(g)(8)).

20. One commentor indicated that samples for which the initials on the specimen bottle and in the permanent record book do not match should not be rejected automatically, since that would provide an opportunity for individuals to attempt to have their specimens rejected when they knew the specimens would test positive. We have considered the fact that individuals might deliberately alter their initials in an attempt to have their samples rejected. However, we do not anticipate that samples should be thrown out solely on the basis of unmatched initials on the specimen

bottle and in the permanent record book. If unmatched initials provide reason to believe that a particular individual may have altered or substituted the specimen, both the proposed and the Final Guidelines provide that the specimen be forwarded for testing along with a second sample obtained as soon as possible after reason to believe the individual may have altered or substituted the specimen is established (2.2(f) (15) and (16)). The Final Guidelines ensure the identification of the person from whom the specimen is collected through the requirement for photo identification (see 2.2(f)(2)). In addition, a principal responsibility of the collection site person is to gather and verify information on site and to detect any problems with the identification of the specimen. Until experience in the program indicates that misidentified samples arising out of unmatched initials is a significant problem, the Guidelines will require that the individual initial the specimen bottle and sign the permanent record book to certify that the identified sample is the one collected from the individual.

21. One commentor asked if the Guidelines apply to Federal contract employees. The Guidelines do not apply to Federal contract employees; however, any agency may require a contractor to test its own employees following the procedures in the Guidelines by making the requirement a term or condition of the contract.

22. One commentor indicated that the proposed requirement for signing a procedure manual on an annual basis was in conflict with current DHHS efforts in the Medicare and CLIA programs to delete the annual signing requirement and replace it with a requirement that the manual be signed initially and whenever changes are made. We concur with the comment that the important factor is that the manual be signed by the responsible individual whenever a procedure is instituted or changed or whenever a new individual becomes responsible for the day-to-day management of the drug testing laboratory. The Guidelines do not require annual signing of the procedure manual.

The on-site review of the laboratory together with the assignment to an individual of the overall responsibility for the testing will assure that the procedures in the manual are current and followed. If the procedures in the manual are not current or followed, it is an indication that the responsible individual is not performing the

oversight function appropriate to the management of the laboratory.

We have also clarified that the individual responsible for the day-to-day management of the drug testing laboratory is the individual responsible for signing the manual (2.3(a)(5)). It is not appropriate for the individual who is responsible for day-to-day operations and supervision of analysts or for any other individual to be delegated this responsibility since the manual is the vehicle for selection of methodologies, and the approval of methodologies is a principal reason for requiring the individual responsible for day-to-day management of the drug testing laboratory to possess detailed knowledge in the area of toxicology.

23. One commentor indicated that laboratories should be notified when they may discard samples. We have reviewed the comment and concur that the agency should be able to notify the laboratory in writing if it determines that samples no longer need to be retained because no further action is pending which will require the samples. Both 2.4(g)(8) and 2.4(h) permit the agency to instruct or authorize storage for less than the period for which there is a storage requirement.

24. Several commentors indicated a discrepancy in the periods for maintenance of frozen samples in storage—1 year in the proposed guidelines and 6 months in Appendix B to the proposed guidelines. The time interval in the appendix was in error. The Final Guidelines consistently call for frozen storage of confirmed positive samples for 1 year (2.4(h)). Note that the Appendix has been omitted, although pertinent provisions from it are integrated in the Final Guidelines.

25. In response to concern that specimens may be misused to test for physiological states other than drug abuse (e.g., pregnancy), a provision has been added to the Final Guidelines to prohibit the specimens collected for urine drug testing from being used for any other types of analyses unless otherwise authorized by law. It is important to the integrity and goals of the President's program to achieve a drug-free work place that any specimens collected for that purpose not be analyzed or used for inappropriate purposes. To ensure that outcome, a paragraph has been added at 2.1(c) stating that specimens may be used only to test for those drugs included in the agency drug-free workplace plan and may not be used to conduct any other analysis or test unless the agency is authorized by law to perform other analyses.

26. One commentator indicated that the individuals permitted in the "secure test area" should include routine service and maintenance personnel and that these individuals should not require escorts. While providing escorts for all employees, including service and maintenance personnel, may cause considerable inconvenience, unless the facilities are secured at night and all materials locked away with no possible access, there is always the potential for tampering with the specimens or test results. The Guidelines make no provision for routine service and maintenance personnel to enter the secure test area without an escort (2.4(a)).

27. One commentator suggested that collection personnel be provided with gloves or other protective garments to prevent contamination of the personnel from the urine. The Department encourages a protected work environment for collection site personnel, including any necessary protective garments. Various State and Federal guidelines provide for the health and safety of employees. Collection agents are expected to be aware of and to comply with such provisions to safeguard their own health and the health and safety of employees. However, no requirement was added to the Guidelines to require provision of protective garments to collection personnel.

28. One commentator recommended that DHHS use its own personnel to investigate any quality assurance problems which arise with a particular laboratory instead of requiring each agency to have its own investigative staff. Other commentators viewed agencies as lacking the in-house expertise to perform this analysis, and it was not clear to them who in each agency should carry out such an investigation. The Final Guidelines reflect a decision that the Secretary (which might include a DHHS contractor or DHHS recognized certification program) shall assume this investigative responsibility and carry out the related coordinating activities. A coordinating mechanism within the National Institute on Drug Abuse (NIDA) will ensure that all agencies are aware of problems with any given laboratory. Conducting investigations and coordinating findings through DHHS will eliminate the need to provide a more complex mechanism for agencies to notify each other about laboratory performance (2.5(d)(4)).

29. Several commentators said that the format for reporting employee drug test results was not sufficiently clear and that while there was a discussion of the

mechanism for reporting performance test results, there was no comparable discussion on reporting employee test results. 2.4(g), Reporting Results, clarifies that laboratories will not report quantitation on test results but will report whether a result is positive or negative and that this is indicative of a result being above or below a particular cutoff limit. A negative report does not signify the absence of a particular drug or metabolite but only that the particular drugs or metabolites screened for were not detected at a specified concentration (i.e., cutoff level).

Quantitation will not be reported to the agency for confirmed positive reports in order to provide for identical reporting by the laboratory of performance test specimens and employee specimens. However, quantitation may be obtained by the Medical Review Officer on request from the laboratory. In the case of the opiates, we have indicated that the particular opiate to be reported will depend on the amounts of morphine and codeine detected by the confirmation test. We have included the reporting scheme in the scientific and technical requirements as well as in the revision of the requirements for reporting performance test results (2.4(g), 3.11 which cross-references 2.4(g), and 3.17(f)).

30. The Final Guidelines attempt to clarify the purpose of the certification program, since the comments reflect uncertainty as to what certification implies and what would be surveyed in the process of certifying a laboratory. Subpart C permits DHHS to recognize certification programs run by other organizations. These programs may be private accrediting organizations that are recognized by the Secretary to determine whether laboratories meet the Guideline requirements. Any laboratory accredited by these organizations in accordance with these Guidelines is deemed to be a certified laboratory, thus making it eligible to perform urine drug testing for Federal agencies. DHHS is contemplating publishing standards for recognition of private accrediting organizations in the near future.

The provisions of Subpart C apply to any laboratory which has or seeks a contract to perform, or otherwise performs urine drug testing for Federal agencies under a drug testing program conducted under E.O. 12564. Only certified laboratories will be authorized to perform urine drug testing for Federal agencies. However, in order to create a pool of qualified laboratories to bid on agency contracts to perform such testing, the Secretary may certify

laboratories as contract eligible that meet the requirements of Subpart C. This pool of qualified laboratories will lead to competitive pricing and better services for Federal agencies.

The certification process 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 drugs using the methods specified herein. The Guidelines require that a certified laboratory must inform its non-Federal clientele when testing procedures are to be those specified by these Guidelines. Non-Federal purchasers are free to bargain with a certified laboratory for any standards they may deem appropriate.

31. The Guidelines delete the checklist in Appendix B of the proposed certification standards. The checklist was initially intended to provide a tool for the inspectors of laboratories to use in conducting their on-site inspections and to enumerate the standards contained in the section on the certification program published in the Federal Register. However, there was confusion regarding whether the checklist represented an additional or different set of requirements. Relevant portions of the checklist have been integrated in the Guidelines. The checklist itself will be revised to correspond to the requirements in the Guidelines and will be made available to laboratories by the DHHS-recognized certification program(s).

32. Several commentators asked that the specific criteria used by the group(s) who will perform the certification function for the Department be detailed in these Guidelines. In response, the Guidelines include a new section explaining how performance testing will be evaluated for initial certification as well as for previously certified laboratories (3.19 (a) and (b)). All major aspects of the certification program, including personnel and quality assurance and quality control requirements, are included in Subpart C of these Guidelines. With the addition of 3.19 (a) and (b), we believe the Guidelines are appropriately specific and there is no need to include additional detail in the Guidelines concerning the certification process.

33. Some commentators indicated that the number of blind performance test samples required to be run by the

laboratories (i.e., 1,000) for initial certification and (i.e., 250 per quarter) for continuing certification was excessive and would be too costly. The commentors also indicated that it was not clear whether the laboratory or the submitting organization would bear the cost of the samples and if it were necessary for each submitting organization to submit this number of samples to each laboratory. In response to the comments, we have revised this section to indicate that 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) during the initial 90-day period of program implementation and a minimum of 10 percent of all samples (to a maximum of 250) submitted per quarter thereafter. The Final Guidelines also clarify that approximately 80 percent of the blind performance test samples are to be blank (i.e., certified to be drug free) and the remaining samples are to be positives (2.52(d)(3) and 3.7). The cost of the blind performance test samples will be borne by the submitting agency.

34. Several commentors requested corrective action and reanalysis of previously run specimens in the case of discovered laboratory administrative error. They also requested that the union and all employees who tested positive be notified of the error in writing. The recommendation was to notify all employees with positive results who were tested between the time of resolution of the error and the preceding cycle of correct results. In the case of an administrative error, there are no plans to automatically have all specimens retested. The decision on whether to retest will be dependent on the type and extent of the error. For example, if a single employee's test results were transcribed incorrectly, nothing would be gained from rerunning all the specimens in a given timeframe since it would not change the values attributed to the specimens. If an error occurred such that it was not clear whose specimen was being tested and which results belonged to which specimen, this would require retesting of the group for which the values were uncertain and for those analytes for which the values were uncertain. However, it would be unproductive to require the automatic retesting of all specimens for any error.

Agency policy under which individuals are notified of errors will depend on the circumstances. If the error is corrected before the results are reported to any employee, it is

unnecessary to notify each employee that an error was discovered and subsequently corrected. If a discovered error affects an employee after results have been reported, the Medical Review Officer will be notified and the affected employee will also be notified through the appropriate mechanisms established by each agency.

35. Several commentors indicated that the laboratory contract should be suspended if the laboratory committed the same administrative error twice and that the designated reviewing official's discretion to continue a laboratory in the program should be more limited or more clearly defined. The Department has reviewed the comments concerning the point at which a contract should be suspended because of an administrative error and submits that the current policy allows sufficient flexibility and protection to the employee and the laboratory and that it should not be changed. There are no circumstances under which administrative or human error can be entirely eliminated. The major assurance of accuracy in the overall program is the series of checks to assure that such errors are detected and corrected. The reviewing official has been given the necessary flexibility and definition of authority to make the appropriate technical and program judgments concerning the status of each facility and to assure that reasonable and responsible decisions are made. Nevertheless, the Final Guidelines add several features to put greater responsibility on the individual responsible for the day-to-day management of the drug testing laboratory for the quality assurance program and ensuring that quality assurance procedures are followed. These Guidelines also more clearly describe what constitutes a quality assurance and quality control program to detect and correct errors (2.5) and a program of performance testing (3.17-3.19).

We have chosen not to include a formal definition of administrative or clerical error in the Guidelines as was suggested. Among the errors to which either term refers are incorrect transcription of test results or errors in recording specimen identities, i.e., errors that are not due to the analysis of the specimens with regard to analytical accuracy, precision, interpretation of test results, or calibration of equipment. Clearly analytical errors are not considered "administrative." While it is not possible to write guidelines that cover every possibility, at no place in these Guidelines are incorrect analyses considered administrative error but

rather are consistently treated as a basis for prompt action against the laboratory by the responsible officials.

36. Several commentors indicated that laboratory inspections should be conducted unannounced and that union representatives should be permitted to accompany the inspection teams. The Guidelines neither require nor prohibit unannounced inspections. They contemplate that agencies will, through their contract with a certified laboratory, specify the terms and conditions of inspections in accordance with the requirements in the Guidelines. If individuals other than members of the inspection team were entitled to accompany the inspectors, it would significantly complicate coordination and conduct of the inspections. More importantly, we see additional participants in the inspection as inhibiting the laboratory's freedom to provide complete cooperation out of concern for protecting proprietary information. While some laboratories may be willing to provide escorted tours to union officials to illustrate the quality of their processes, the Guidelines do not establish a right for union officials to participate in inspections incident to certification of laboratories under these Guidelines (2.4(1) and 3.20).

37. One commentor indicated that any of the five general factors indicated in 3.13(b) as a possible basis for revocation in the certification requirements should inevitably lead to revocation without any further determination that the revocation is "necessary." The issue of how many potential grounds for revocation are necessary to determine that revocation of a laboratory is necessary was considered when the list of grounds was developed. The Department views the nature and seriousness of the facts concerning the grounds for revocation as factors to be weighed in deciding to revoke a certification. It is difficult and would not contribute to the maintenance of high quality testing standards to develop *a priori* statements about the magnitude of an offense or a combination of violations and to formulate necessary actions in response to each possible violation of the provisions of 3.13. All five factors listed are considered serious violations of these certification criteria, and it is not necessary for more than one factor to be violated to take action against a laboratory. However, the Guidelines retain the flexibility for the Secretary to determine that revocation is necessary to ensure the full reliability and accuracy of drug tests and the accurate reporting of test results (3.13(b)).

38. Several commentors indicated that when a laboratory fails a performance test it would be inordinately expensive (especially in high volume laboratories) to retest all samples since the last performance test the laboratory passed and to test for all analytes rather than for the one analyte for which the laboratory had failed performance testing. The reason for retesting all positive samples since the last successful performance test is that the quality of the test results has been called into question. In order to verify test results for the period between a successful performance testing and the failed testing, it will be necessary to retest all specimens tested positive for which an incorrect analysis may have been performed. It is not routinely necessary to retest for all analytes but only for those on which the laboratory failed its performance testing. However, the laboratory may be required to test for other analytes if the performance test failure reflects broader problems (3.19(b)(1)(v)).

39. Several commentors indicated that performance testing every other month is excessive and that quarterly testing would be sufficient to assure the quality of the testing. Others indicated that fewer challenges per shipment would be adequate to determine the quality of the laboratory. Still other individuals stated that the limits for acceptable performance on performance tests were too high in terms of the concentrations used. Others said that the grading criterion of failure based on one false positive was too strict. We have reviewed the concerns that bimonthly performance testing is excessive and maintain that the use of performance tests is a valid outcome measure of performance and will assist in the evaluation of quality of the laboratory performance. If future experience with the program indicates that a lesser frequency will assure the quality of the testing, we will revise the frequency and the number of specimens accordingly. Relatively frequent performance testing reduces the time period for which samples may have to be rerun in case of performance test failure (3.17).

To the extent that the Guidelines amended the cutoff limits for drugs for which employees may be tested for consistency with those currently used by the Department of Defense, it was necessary to modify the values of the various performance test samples correspondingly. We have clarified that a laboratory must achieve an overall grade of 90 percent on the first three cumulative shipments of performance tests and that if such a poor grade is

obtained on the first or second challenge that a laboratory cannot achieve an overall grade of 90 percent on the three successive performance test challenges, then the laboratory will fail at that point. Laboratories already in the program must achieve a grade of 90 percent on each shipment of performance testing. It was unclear in the proposed notice whether the grade of 90 percent referred only to the positive samples. We intend that the 90 percent refer only to positive samples, since any negative sample giving rise to a false positive would be the basis for automatic disqualification for initial certification. It also was unclear whether the 90 percent referred to performance on all drugs in the shipment, not on each drug tested. We have clarified the Guidelines in both these areas. We adopted a strategy requiring 90 percent for all drugs because it is not always feasible to have a sufficient number of challenges for each drug in each shipment to avoid a single failure on a drug leading to a failing grade of less than 90 percent (3.19(b)(2)).

40. Some commentors thought laboratories should be required to notify all users if their certification was revoked. Since the requirements in these Guidelines only apply to certification for Federal drug testing programs, it would be inappropriate to require laboratories to notify non-Federal users of revocation or suspension.

41. We have not adopted the recommendations that any changes in the Guidelines be accomplished by publication of a notice, review of comments, and then publication of final changes. (Section 503 of Pub. L. 100-71 required such steps for initial development of these Guidelines.) The time required for this process would not permit rapid adjustment to changes in technology. Accordingly, the Guidelines retain the provision permitting final revision of these Guidelines by publication of a notice in the Federal Register (1.3).

42. One commentor suggested that only positive tests be certified as to accuracy and validity before reporting. Although this practice would reduce paperwork, it does not reflect the potential impact on public safety of false negative results. The Guidelines continue to require that negative results be reviewed carefully and attested to by the proper officials in the same way as positive results (2.4(g)).

43. One commentor wanted us to specify the time the individual responsible for day-to-day management must spend in the laboratory. No change

has been made in the Guidelines. The critical factor here is the quality of the work and not the absolute number of hours spent. The Department views the use of outcome measures of performance for the laboratory as more effective in assuring accurate and reliable test results than attempting to set hours for the responsible individual particularly in view of the qualifications which the Guidelines set for the individual responsible for day-to-day management of the drug testing laboratory.

44. The criterion for retesting specimens (i.e., those being challenged) was clarified to indicate that in performing a retest the laboratory must confirm the presence of the substance but does not have to confirm that it is present above the cutoff level. Since the drug levels may deteriorate with time, it is only necessary to show that the drug (or its metabolite) is present to reconfirm its presence during retesting (2.4(i)).

45. A provision has been added to the Guidelines requiring that laboratories be capable of testing for at least the five classes of drugs specified in the Guidelines. The laboratories are being required to possess the flexibility to test for all the specified classes of drugs in order to assure that they have a sufficient range of capabilities to respond to the agencies' testing protocols, including testing for reasonable suspicion (3.4).

46. Several Federal agencies commenting on the proposed guidelines sought waivers of particular provisions in reliance on the original Scientific and Technical Guidelines issued February 13, 1987, which provided that, "Agencies may not deviate from the provisions of these Guidelines without the written approval of the Secretary, Health and Human Services or his designee." This waiver statement, which was not explicit in the proposed guidelines, is included at 1.1(f). Absent such a waiver, these Guidelines represent the exclusive standard for urinalysis testing and agencies may not deviate from these established procedures.

In order to clarify that the laboratory certification standards apply to laboratories which have or seek certification to perform urine drug testing for Federal agencies, a paragraph was added to the applicability section, 1.1(c), stating that Subpart C of the Guidelines applies to any laboratory which has or seeks such certification and that certification is required to perform urine drug testing for Federal agencies.

Section 4(d) of E.O. 12564 states that "agencies shall conduct their drug testing programs in accordance with [scientific and technical] guidelines" promulgated by the Secretary of Health and Human Services. Since the Guidelines impose mandatory requirements on a Government-wide basis, they are exempt from the duty to bargain under section 7117(a)(1) of the Federal Service Labor-Management Relations Statute.

Information Collection Requirements

Information collection and recordkeeping requirements which would be imposed on laboratories engaged in urine drug testing for Federal agencies concern quality assurance and quality control; security and chain of custody; documentation; reports; performance testing; and inspections as set out in 3.7, 3.8, 3.10, 3.11, 3.17, and 3.20. To facilitate ease of use and uniform reporting, standard forms have been developed for chain of custody records and the permanent record books as referenced in 2.2(c) and (f).

The information collection and recordkeeping requirements contained in these Final Guidelines have been approved by the Office of Management and Budget under section 3504(h) of the Paperwork Reduction Act of 1980 and have been assigned control number 09300130, approved through April 30, 1989.

Date: April 1, 1988.

Robert E. Windom,
Assistant Secretary for Health.

Date: April 1, 1988.

Otis R. Bowen,
Secretary.

These Final Mandatory Guidelines are hereby adopted in accordance with Executive Order 12564 and section 503 of Pub. L. 100-71 as set forth below:

MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS

Subpart A—General

- 1.1 Applicability.
- 1.2 Definitions.
- 1.3 Future Revisions.

Subpart B—Scientific and Technical Requirements

- 2.1 The Drugs.
- 2.2 Specimen Collection Procedures.
- 2.3 Laboratory Personnel.
- 2.4 Laboratory Analysis Procedures.
- 2.5 Quality Assurance and Quality Control.
- 2.6 Interim Certification Procedures.
- 2.7 Reporting and Review of Results.
- 2.8 Protection of Employee Records.
- 2.9 Individual Access to Test and Laboratory Certification Results.

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

- 3.1 Introduction.
- 3.2 Goals and Objectives of Certification.
- 3.3 General Certification Requirements.
- 3.4 Capability to Test for Five Classes of Drugs.
- 3.5 Initial and Confirmatory Capability at Same Site.
- 3.6 Personnel.
- 3.7 Quality Assurance and Quality Control.
- 3.8 Security and Chain of Custody.
- 3.9 One-Year Storage for Confirmed Positives.
- 3.10 Documentation.
- 3.11 Reports.
- 3.12 Certification.
- 3.13 Revocation.
- 3.14 Suspension.
- 3.15 Notice: Opportunity for Review.
- 3.16 Recertification.
- 3.17 Performance Test Requirement for Certification.
- 3.18 Performance Test Specimen Composition.
- 3.19 Evaluation of Performance Testing.
- 3.20 Inspections.
- 3.21 Results of Inadequate Performance.

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 immunosay 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 8°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.....	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."

	Confirma- tory 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 Benzoylcegonine.

(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 acceptable 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 made 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 notified 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 medication.* 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 8-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 Positive

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 Performance 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 90 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 90 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 occurrence 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 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 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 criteria 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.

DRUG FACT SHEETS

CANNABIS (Marijuana)

Effects

All forms of cannabis have negative physical and mental effects. Several regularly observed physical effects of cannabis are increase in heart rate, bloodshot eyes, dry mouth and throat, and hunger.

Use of cannabis may impair or reduce short-term memory and comprehension, alter sense of time, and reduce ability to perform tasks requiring concentration and coordination, such as driving a car. Research shows that knowledge retention may be lower when information is given while the person is "high." Motivation and cognition are altered, making the acquisition of new information difficult. Marijuana can also produce paranoia and psychosis.

Because users often inhale the unfiltered smoke deeply and then hold it in their lungs as long as possible, marijuana is damaging to the lungs and respiratory system. The tar in marijuana smoke is highly irritating and carcinogenic. Long-term users may develop psychological dependence and tolerance.

Type	What is it called? What does it look like? How is it used?		
Marijuana	Pot Grass Weed Reefer Dope Mary Jane Acapulco Gold	Dried parsley mixed with stems that may include seeds	Eaten Smoked
Tetrahydro- cannabinol	THC	Soft gelatin capsules	Taken orally Smoked
Hashish	Hash	Brown or black cakes or balls	Eaten Smoked
Hashish oil	Hash oil	Concentrated syrupy liquid varying in color from clear to black	Smoked—mixed with tobacco

Source: U.S. Dept. of Labor

INHALANTS

Effects

A variety of psychoactive substances have been inhaled as gases or volatile liquids. Many popular commercial preparations such as paint thinners and cleaning fluids are mixtures of volatile substances making it difficult to be specific about their various effects. There is no single "Inhalant Syndrome."

Immediate negative effects of inhalants may include nausea, sneezing, coughing, nose bleeds, fatigue, lack of coordination, and loss of appetite. Solvents and aerosol sprays may also decrease the heart and respiratory rates and impair judgement. Amyl and butyl nitrite cause rapid pulse, headaches, and involuntary passing of urine and feces. Long term use may result in hepatitis or brain damage.

Long-term use can cause weight loss, fatigue, electrolyte imbalance, and muscle weakness. Repeated sniffing of concentrated vapors over time can lead to permanent damage of the nervous system.

Type	What is it called?	What does it look like?	How is it used?
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Nitrous Oxide	Laughing gas Whippets Buzz bomb	Propellant for whipped cream in aerosol can Small 8-gram metal cylinder sold with a balloon or pipe	Vapors inhaled
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Amyl-Nitrite	Poppers Snappers	Clear yellowish liquid in ampules	Vapors inhaled
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Butyl-Nitrite	Rush Bolt Locker room Bullet Climax	Packaged in small bottles	Vapors inhaled
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Chloro-hydro-carbons	Aerosol sprays	Aerosol paint cans Containers of cleaning fluid	Vapors inhaled
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Hydro-carbons	Solvents	Cans of aerosol propellants, gasoline, glue, paint thinner	Vapors inhaled
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COCAINE

Effects

Cocaine stimulates the central nervous system. Its immediate effects include dilated pupils, elevated blood pressure, increased heart rate, and elevated body temperature. Occasional use can cause stuffy or runny nose. Chronic use can cause ulceration of the mucous membrane in the nose. Injecting cocaine with unsterile equipment can transmit AIDS, hepatitis, and other infections. Preparation of freebase, which involves the use of highly volatile solvents, can result in fire or explosion. Cocaine can produce psychological dependency, a feeling that the user cannot function without the drug.

Crack or freebase rock, a concentrated form of cocaine, is extremely potent. Its effects are felt within ten seconds of administration. Physical effects include dilated pupils, increased pulse rate, elevated blood pressure, insomnia, loss of appetite, tactile hallucinations, paranoia, and seizures.

Cocaine use may lead to death through disruption of the brain's control of heart and respiration.

Type	What is it called?	What does it look like?	How is it used?
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Cocaine	Coke Snow Flake White Nose Candy Big C Snow Bird Lady	White crystalline powder, often diluted with other ingredients	Inhaled through the nose Injected Smoked
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Crack or-cocaine	Crack Freebase rocks Rock	Light brown or beige pellets-or crystalline rocks that resemble coagulated soap; often packaged in small vials	Smoked
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OTHER STIMULANTS

Effects

Stimulants can cause increased heart and respiratory rates, elevated blood pressure, dilated pupils, and decreased appetite. In addition, users may perspire, experience headache, blurred vision, dizziness, sleeplessness, and anxiety. Extremely high doses can cause rapid or irregular heartbeat, tremors, loss of coordination, and even physical collapse. An amphetamine injection creates a sudden increase in blood pressure that can result in stroke, very high fever, or heart failure.

In addition to the physical effects, users report feeling restless, anxious, and moody. Higher doses intensify the effects. Persons who use large amounts of amphetamines over a long period of time can develop an amphetamine psychosis that includes hallucinations, delusions, and paranoia. These symptoms usually disappear when drug use ceases.

Type What is it called? What does it look like? How is it used?

Amphetamines	Speed Uppers Ups Black Beauties Pep Pills Copilots Hearts Benzedrine Dexadrine Biphetamine	Capsules Pills Tablets	Taken orally Injected Inhaled through the nose
Methamphetamines	Crank Crystal Meth Methedrine Speed	White powder Pills Resembles a block of paraffin	Taken orally Injected Inhaled through the nose
Additional Stimulants	Ritalin Cylert Preludin Didrex Pre-State Voranyl Tenuate Tepanyl Pondimin Sandrex Plegine	Pills Capsules Tablets	Taken orally Injected

DEPRESSANTS

Effects

The effects of depressants are similar to those of alcohol in many ways. Small amounts can produce calmness and relaxed muscles, but larger doses can cause slurred speech, staggering gait, and altered perception. Very large doses can cause respiratory depression, coma, and death. The combination of depressants and alcohol can increase the effects of the drugs, thereby multiplying the risks.

The use of depressants can cause both physical and psychological dependence. Regular use over time may result in tolerance to the drug, leading the user to increase the quantity consumed. When regular users stop taking depressant drugs, they may develop withdrawal symptoms ranging from restlessness, insomnia and anxiety to convulsions and death.

Babies born to mothers who abuse depressants during pregnancy may be physically dependent on the drugs and show withdrawal symptoms shortly after they are born. Birth defects and behavioral problems have been associated with these children.

Type	What is it called?	What does it look like?	How is it used?
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Barbiturates	Downers	Capsules of many colors: Red, yellow, blue, or red and blue	Taken orally
	Barbs		
	Blue devils		
	Red devils		
	Yellow Jacket		
	Yellows		
	Nembutal		
	Seconal		
	Amytal		
	Tuinal		

Metha- qualone	Quaaludes	Tablets	Taken orally
	Ludes		
	Sopors		

Tranquilizers	Valium	Capsules	Taken orally
	Librium		
	Equanil		
	Miltown		
	Serax		
	Tranxene		

HALLUCINOGENS

Effects

Phencyclidine (PCP) produces behavioral alterations that are multiple and dramatic. Because the drug blocks pain receptors, violent PCP episodes may result in self-inflicted injuries. The effects of PCP vary, but users generally report a sense of distance and space estrangement. Time and body movement are slowed. Muscular coordination worsens and senses are dulled. Speech is blocked and incoherent.

Chronic users of PCP report persistent memory problems and speech difficulties. Mood disorders - depression, anxiety, and violent behavior - also occur. In later stages, chronic users often exhibit paranoid and violent behavior and experience hallucinations. Large doses of PCP may produce convulsions, coma, heart and lung failure, or ruptured blood vessels in the brain.

Lysergic acid (LSD), mescaline, and psilocybin cause illusions and hallucinations. The physical effects may include dizziness, weakness, tremor, nausea, and drowsiness.

Sensations and feelings may change rapidly. It is common to have a bad psychological reaction to LSD, mescaline, and psilocybin. The user may experience panic, confusion, suspicion, anxiety, and loss of control. Delayed effects, or flashbacks, can occur even after the use has ceased.

Type	What is it called?	What does it look like?	How is it used?
Phencyclidine	PCP	Liquid	Taken orally
	Angel dust	Capsules	Injected
	Loveboat	White crystalline powder	Smoked - can be sprayed on cigarettes, parsley, and marijuana
	Lovely	Pills	
	Hog Killer weed		
Lysergic Acid diethylamide	LSD	Brightly colored tablets	Taken orally
	Acid	Impregnated blotter paper	Licked off paper
	Green or red dragon	Thin squares of gelatin	Eaten
	White lightning	Clear liquid	Gelatin and liquid can be put in eyes
	Blue heaven		
	Sugar cubes Microdot		
Mescaline & Peyote	Mesc	Hard brown discs	Chewed, swallowed, smoked
	Buttons	Tablets	
	Cactus	Capsules	
Psilocybin	Magic mushrooms	Fresh or dried mushrooms	Taken orally

NARCOTICS

Effects

Narcotics initially produce a feeling of euphoria followed by drowsiness, nausea, and vomiting. Users may experience constricted pupils, watery eyes, and itching. An overdose may produce slow and shallow breathing, clammy skin, convulsions, coma, and death.

Tolerance to narcotics develops rapidly and dependence is likely. The use of unsterilized syringes may result in transmission of diseases such as AIDS, endocarditis, and hepatitis. Addiction in pregnant women can lead to premature, stillborn, or addicted infants.

Type What is it called? What does it look like? How is it used?

Heroin	Smack	Powder, white to dark	Injected
	Horse	brown	Inhaled through
	Brown sugar	Tar-like substance	the nose
	Junk		Smoked
	Mud Big H		
Methadone	Dolophine	Solution	Taken orally
	Methadoşé		Injected
	Amidone		
Codeine	Empirin	Tablets	Taken orally
	compound with codeine	Capsules	Injected
	Tylenol with co- deine	Dark liquid varying in thickness	
	Codeine in cough medicines		
Morphine	Pectoral syrup	White crystals	Injected
		Hypodermic tablets	Taken orally
		Solutions	Smoked
Meperidine	Pethidine	White powder	Taken orally
	Demerol	Solution	Injected
	Mepergan	Tablets	
Opium	Paregoric	Dark brown chunks	Smoked
	Dover's Powder	Powder	Taken orally
Other Narcotics	Percocet	Tablets	Taken orally
	Pecodan	Capsules	Injected
	Tussionex	Liquid	
	Fentanyl		
	Darvon		
	Talwin Lomotil		

DESIGNER DRUGS

Effects

Illegal drugs are defined in terms of their chemical formulas. To circumvent these legal restrictions, underground chemists modify the molecular structure of certain illegal drugs to produce analogs known as designer drugs. These drugs can be hundreds of times stronger than the drugs that they are designed to imitate.

The narcotic analogs can cause symptoms such as those seen in Parkinson's disease - uncontrollable tremors, drooling, impaired speech, paralysis, and irreversible brain damage. Analogs of amphetamines and methamphetamines cause nausea, blurred vision, chills or perspiration, and faintness. Psychological effects include anxiety, depression, and paranoia. As little as one dose can cause brain damage. The analogs of phencyclidine cause illusions, hallucinations, and impaired perception.

Type What is it called? What does it look like? How is it used?

Analogs of Fentanyl (Narcotic)	Synthetic heroin China white	White powder resembling heroin	Inhaled through nose Injected
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Analogs of Meperidine (Narcotic)	Synthetic heroin MPTP (New heroin) MPPP PEPAP	White powder	Inhaled through nose Injected
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Analogs of Amphetamines & Methamphetamines (Hallucinogens)	MDMA (Ecstasy, XTC, Adam, Essence) MDM STP PMA 2,5-DMA TMA DOM DOB	White powder Tablets Capsules	Taken orally Injected Inhaled through nose
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Analogs of Phencyclidine (Hallucinogens)	PCPy PCE TCP	White powder	Taken orally Injected Smoked
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Alcohol, Drug Abuse and
Mental Health Administration
Rockville MD 20857

August 1, 1991

Dear Sir or Madam:

Enclosed is the most recent information on laboratories certified by the National Institute on Drug Abuse (NIDA) of the Department of Health and Human Services (HHS) to perform urine drug testing. These laboratories meet the minimum criteria established in the Mandatory Guidelines for Federal Workplace Drug Testing Programs, Subpart C, published on April 11, 1988 and have been certified by NIDA for HHS.

Also, there are numerous other laboratories at various applicant stages of NIDA's National Laboratory Certification Program (NLCP). It may be anticipated that many of these laboratories will be certified and added to future listings.

Laboratories which claim to be in the applicant stage of NIDA certification are not to be considered as meeting the minimum requirements expressed in the NIDA Guidelines. A laboratory must have its letter of certification from HHS/NIDA which attests that it has met minimum standards.

The Federal Register listing will be updated and published on or about the first workday of the month. Please arrange to review future issues of the Federal Register to obtain this information. Should you have any questions regarding the list or the NLCP program, please contact me at (301) 443-6014.

Sincerely,

Donna M. Bush, Ph.D.
Chief, Drug Testing Section
Division of Applied Research
National Institute on Drug Abuse

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Alcohol, Drug Abuse, and Mental Health Administration

Current List of Laboratories Which Meet Minimum Standards To Engage In Urine Drug Testing for Federal Agencies

AGENCY: National Institute on Drug Abuse, ADAMHA, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (53 FR 11979, 11988). A similar notice listing all currently certified laboratories will be published during the first week of each month, and updated to include laboratories which subsequently apply for and complete the certification process. If any listed laboratory's certification is totally suspended or revoked, the laboratory will be omitted from updated lists until such time as it is restored to full certification under the Guidelines.

FOR FURTHER INFORMATION CONTACT: Denise L. Goss, Program Assistant, Drug Testing Section, Division of Applied Research, National Institute on Drug Abuse, room 9-A-53, 5600 Fishers Lane, Rockville, Maryland 20857; tel.: (301)443-0014.

SUPPLEMENTARY INFORMATION: Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12584 and section 503 of Public Law 100-71. Subpart C of the Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards which laboratories must meet in order to conduct urine drug testing for Federal agencies. To become certified an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification a laboratory must participate in an every-other-month performance testing program plus periodic, on-site inspections.

Laboratories which claim to be in the applicant stage of NIDA certification are not to be considered as meeting the minimum requirements expressed in the NIDA Guidelines. A laboratory must have its letter of certification from HHS/NIDA which attests that it has met minimum standards.

In accordance with subpart C of the Guidelines, the following laboratories

meet the minimum standards set forth in the Guidelines:

Alpha Medical Laboratory, Inc., 405 Alderson Street, Schofield, WI 54478, 800-827-8200

American BioTest Laboratories, Inc., Building 15, 3350 Scott Boulevard, Santa Clara, CA 95054, 408-727-5525

American Medical Laboratories, Inc., 11091 Main Street, P.O. Box 188, Fairfax, VA 22030, 703-891-0100

Associated Pathologists Laboratories, Inc., 4230 South Burnham Avenue, Suite 250, Las Vegas, NV 89110-6412, 702-733-7806

Associated Regional and University Pathologists, Inc. (ARUP), 500 Chipeta Way, Salt Lake City, UT 84106, 801-583-2787

Bayshore Clinical Laboratory, 4555 W. Schroeder Drive, Brown Deer, WI 53223, 414-355-4444/800-877-7018

Bellin Hospital-Toxicology Laboratory, 2710 Allied Street, Green Bay, WI 54304, 414-496-2487

Bio-Analytical Technologies, 2356 North Lincoln Avenue, Chicago, IL 60614, 312-800-0900

Bioran Medical Laboratory, 415 Massachusetts Avenue, Cambridge, MA 02139, 617-547-8900

Cedars Medical Center, Department of Pathology, 1400 Northwest 12th Avenue, Miami, FL 33138, 305-325-5810

Center for Human Toxicology, 417 Wakara Way-Room 290, University Research Park, Salt Lake City, UT 84106, 801-581-5117

Columbia Biomedical Laboratory, Inc., 4700 Forest Drive, Suite 200, Columbia, SC 29206, 800-846-4245/803-782-2700

Clinical Pathology Facility, Inc., 711 Bingham Street, Pittsburgh, PA 15203, 412-488-7500

Clinical Reference Lab, 11850 West 85th Street, Lenexa, KS 66214, 800-445-8917

CompuChem Laboratories, Inc., 3308 Chapel Hill/Nelson Hwy., P.O. Box 12852, Research Triangle Park, NC 27709, 919-549-8280/800-833-3984

Damon Clinical Laboratories, 140 East Ryan Road, Oak Creek, WI 53154, 800-365-3840 (name changed; formerly Chem-Bio Corporation; CEC Clinilab)

Damon Clinical Laboratories, 8300 Esters Blvd., Suite 800, Irving, TX 75063, 214-929-0535

Doctors & Physicians Laboratory, 801 East Dixie Avenue, Leesburg, FL 32748, 904-787-9008

Drug Labs of Texas, 15201 I 10 East, Suite 125, Channelview, TX 77530, 713-457-3784

DrugScan, Inc., P. O. Box 2960, 1119 Mearns Road, Warminster, PA 18974, 215-674-9310

Eagle Forensic Laboratory, Inc., 950 North Federal Highway, Suite 308, Pompano Beach, FL 33062, 305-948-4324

Eastern Laboratories, Ltd., 95 Seaview Boulevard, Port Washington, NY 11050, 516-825-8600

ElSohly Laboratories, Inc., 1215 1/2 Jackson Ave., Oxford, MS 38855, 801-236-2809

General Medical Laboratories, 38 South Brooks Street, Madison, WI 53715, 608-287-8267

HealthCare/Preferred Laboratories, 34451 Telegraph Road, Southfield, MI 48034, 800-225-9414 (outside MI)/800-328-4142 (MI only)

Laboratory of Pathology of Seattle, Inc., 1229 Madison St., Suite 500, Nordstrom Medical Tower, Seattle, WA 98104, 206-380-2072

Laboratory Specialists, Inc., P. O. Box 670, Woodland Hills, CA 91365, 818-718-0100/800-331-8670 (outside CA)/800-464-7081 (CA only), (name changed; formerly Abused Drug Laboratories)

Laboratory Specialists, Inc., 113 Jarrell Drive, Belle Chasse, LA 70037, 504-392-7901

Mayo Medical Laboratories, 200 S.W. First Street, Rochester, MN 55905, 800-533-1710/507-284-3831

Med-Chek Laboratories, Inc., 4900 Perry Highway, Pittsburgh, PA 15229, 412-931-7200

MedExpress/National Laboratory Center, 4022 Willow Lake Boulevard, Memphis, TN 38175, 901-795-1515

MedTox Laboratories, Inc., 402 W. County Road D, St Paul, MN 55112, 612-636-7466

Mental Health Complex Laboratories, 9455 Watertown Plank Road, Milwaukee, WI 53226, 414-257-7439

Methodist Medical Center, 221 N.E. Glen Oak Avenue, Peoria, IL 61638, 309-672-4928

MetPath, Inc., 1355 Mittel Boulevard, Wood Dale, IL 60191, 708-595-3888

MetPath, Inc., One Malcolm Avenue, Teterboro, NJ 07608, 201-393-5000

MetWest-BPL Toxicology Laboratory, 18701 Oxnard Street, Tarzana, CA 91358, 800-492-0800/818-343-8191

National Center for Forensic Science, 1901 Sulphur Spring Road, Baltimore, MD 21227, 301-247-9100 (name changed; formerly Maryland Medical Laboratory, Inc.)

National Drug Assessment Corporation, 5419 South Western, Oklahoma City, OK 73109, 800-749-3784 (name changed; formerly Med Arts Lab)

National Health Laboratories Incorporated, 13900 Park Center Road, Herndon, VA 22071, 703-742-3100/800-572-3734 (inside VA)/800-338-0391 (outside VA)

National Health Laboratories Incorporated, d.b.a. National Reference Laboratory, Substance Abuse Division, 1400 Donelson Pike, Suite A-15, Nashville, TN 37217, 615-360-3992/800-800-4522

National Health Laboratories Incorporated, 2540 Empire Drive, Winston-Salem, NC 27103-6710, 919-760-4820/800-334-8827 (outside NC)/800-842-0894 (NC only)

National Psychopharmacology Laboratory, Inc., 9320 Park W. Boulevard, Knoxville, TN 37923, 800-251-9492

National Toxicology Laboratories, Inc., 1100 California Avenue, Bakersfield, CA 93304, 805-322-4250

Nichols Institute Substance Abuse Testing (NISAT), 8985 Balboa Avenue, San Diego, CA 92123, 800-446-4728/819-694-5050, (name changed; formerly Nichols Institute)

Northwest Toxicology, Inc., 1141 E. 3900 South, Salt Lake City, UT 84124, 800-322-3381

Oregon Medical Laboratories, P.O. Box 972, 722 East 11th Avenue, Eugene, OR 97440-0972, 503-687-2134

Parke DeWitt Laboratories, Division of Comprehensive Medical Systems, Inc., 1810 Frontage Rd., Northbrook, IL 60062, 708-480-4680

Pathlab, Inc., 18 Concord, El Paso, TX 79906, 800-999-7284

Pathology Associates Medical Laboratories,
East 11804 Indiana, Spokane, WA 99208,
509-928-2400

PDLA, Inc., 100 Corporate Court, So.
Plainfield, NJ 07080, 201-789-8500

PharmChem Laboratories, Inc., 1505-A
O'Brien Drive, Menlo Park, CA 94025, 415-
328-8200/800-448-5177

Poisonlab, Inc., 7272 Clairemont Mesa Road,
San Diego, CA 92111, 619-279-2900

Precision Analytical Laboratories, Inc., 13300
Blanco Road, Suite #150, San Antonio, TX
78216, 512-493-3211

Regional Toxicology Services, 15505 NE, 40th
Street, Redmond, WA 98052, 206-882-3400

Roche Biomedical Laboratories, 1801 First
Avenue South, Birmingham, AL 35233, 205-
581-3537

Roche Biomedical Laboratories, 6370 Wilcox
Road, Dublin, OH 43017, 614-889-1061

The certification of this laboratory
(Roche Biomedical Laboratories, Dublin,
OH) is suspended from conducting
confirmatory testing of amphetamines.
The laboratory continues to meet all
requirements for HHS/NIDA
certification for testing urine specimens
for marijuana, cocaine, opiates and
phencyclidine. For more information,
see 55 FR 50589 (Dec. 7, 1990).

Roche Biomedical Laboratories, Inc., 1912
Alexander Drive, P.O. Box 13973, Research
Triangle Park, NC 27709, 919-361-7770

Roche Biomedical Laboratories, Inc., 89 First
Avenue, Raritan, NJ 08869, 800-437-4986

Roche Biomedical Laboratories, Inc., 1120
Stateline Road, Southaven, MS 38871, 601-
342-1286

S.E.D. Medical Laboratories, 500 Walter NE.,
Suite 500, Albuquerque, NM 87102, 505-
848-8000

Sierra Nevada Laboratories, Inc., 888 Willow
Street, Reno, NV 89502, 800-848-5472

SmithKline Beecham Clinical Laboratories,
506 E. State Parkway, Schaumburg, IL
60173, 708-885-2010 (name changed:
formerly International Toxicology
Laboratories)

SmithKline Beecham Clinical Laboratories,
400 Egypt Road, Norristown, PA 19403, 800-
523-5447 (name changed: formerly
SmithKline Bio-Science Laboratories)

SmithKline Beecham Clinical Laboratories,
3175 Presidential Drive, Atlanta, GA 30340,
404-934-9205 (name changed: formerly
SmithKline Bio-Science Laboratories)

SmithKline Beecham Clinical Laboratories,
6000 Sovereign Row, Dallas, TX 75247, 214-
638-1301 (name changed: formerly
SmithKline Bio-Science Laboratories)

SmithKline Beecham Clinical Laboratories,
7600 Tyrone Avenue, Van Nuys, CA 91045,
818-378-2520

South Bend Medical Foundation, Inc., 530
North Lafayette Boulevard, South Bend, IN
46801, 219-234-4176

Southgate Medical Laboratory, Inc., 21100
Southgate Park Boulevard, 2nd Floor,
Maple Heights, OH 44137, 800-338-0180
outside OH/800-382-8913 inside OH

St. Anthony Hospital (Toxicology
Laboratory), P.O. Box 205, 1000 North Lee
Street, Oklahoma City, OK 73102, 405-272-
7052

St. Louis University Forensic Toxicology
Laboratory, 1205 Carr Lane, St. Louis, MO
63104, 314-577-8628

Toxicology & Drug Monitoring Laboratory,
University of Missouri Hospital & Clinics,
301 Business Loop 70 West, Suite 208,
Columbia, MO 65203, 314-882-1273

Toxicology Testing Service, Inc., 5428 NW,
79th Avenue, Miami, FL 33166, 305-593-
2260

Charles R. Schuster,

Director, National Institute on Drug Abuse.

[FR Doc. 91-18238 Filed 7-31-91; 8:45 am]

BILLING CODE 4160-20-M

Model Policy

Effective Date May 1, 1989		Number
Subject Drug Testing—Sworn Employees		
Reference		Special Instructions
Distribution	Reevaluation Date April 30, 1990	No. Pages

I. PURPOSE

The purpose of this policy is to provide all sworn employees with notice of the provisions of the department drug-testing program.

II. POLICY

It is the policy of this department that the critical mission of law enforcement justifies maintenance of a drug free work environment through the use of a reasonable employee drug-testing program.

The law enforcement profession has several uniquely compelling interests that justify the use of employee drug-testing. The public has a right to expect that those who are sworn to protect them are at all times both physically and mentally prepared to assume these duties. There is sufficient evidence to conclude that the use of controlled substances, and other forms of drug abuse will seriously impair an employee's physical and mental health, and thus, their job performance.

Where law enforcement officers participate in illegal drug use and drug activity, the integrity of the law enforcement profession, and public confidence in it are destroyed. This confidence is further eroded by the potential for corruption created by drug use.

Therefore, in order to ensure the integrity of the department, and to preserve public trust and confidence in a fit and drug-free law enforcement profession, this department shall implement a drug-testing program to detect prohibited drug use by sworn employees.

III. DEFINITIONS:

- A. *Sworn Employee*—Those employees who have been formally vested with full law enforcement powers and authority.
- B. *Supervisor*—Those sworn employees assigned to a position having day-to-day responsibility for supervising subordinates, or who are responsible for commanding a work element.
- C. *Drug Test*—The compulsory production and submission of urine by an employee in accordance with departmental procedures, for chemical analysis to detect prohibited drug usage.
- D. *Reasonable suspicion*—That quantity of proof or evidence that is more than a hunch, but less than probable cause. Reasonable suspicion must be based on specific, objective facts and any rationally derived in-

ferences from those facts about the conduct of an individual that would lead the reasonable person to suspect that the individual is or has been using drugs while on- or off-duty.

- E. *Probationary Employee*—For the purposes of this policy only, a probationary employee shall be considered to be any person who is conditionally employed with the department as a law enforcement officer.

IV. PROCEDURES/RULES

A. Prohibited Activity:

The following rules shall apply to all applicants, probationary and sworn employees, while on and off duty:

1. No employee shall illegally possess any controlled substance.
2. No employee shall ingest any controlled or other dangerous substance, unless as prescribed by a licensed medical practitioner.
 - a. Employees shall notify their immediate supervisor when required to use prescription medicine which they have been informed has the potential to impair job performance. The employee shall advise the supervisor of the known side effects of such medication, and the prescribed period of use.
 - b. Supervisors shall document this information through the use of an internal memorandum and maintain this memorandum in a secured file.
 - c. The employee may be temporarily reassigned to other duties, where appropriate.
3. No employee shall ingest any prescribed or over-the-counter medication in amounts beyond the recommended dosage.
4. Any employee who unintentionally ingests, or is made to ingest a controlled substance shall immediately report the incident to their supervisor so that appropriate medical steps may be taken to ensure the officer's health and safety.
5. Any employee having a reasonable basis to believe that another employee is illegally using, or in possession of any controlled substance shall immediately report the facts and circumstances to their supervisor.
6. Discipline of sworn employees for violation of this policy shall be in accordance with the due process rights provided in the department's discipline and grievance procedures.

B. Applicant Drug-Testing:

1. Applicants for the position of sworn law enforcement officer shall be required to take a drug test as a condition of employment during a pre-employment medical examination.
2. Applicants shall be disqualified from further consideration for employment under the following circumstances:
 - a. Refusal to submit to a required drug-test; or
 - b. A confirmed positive drug-test indicating drug use prohibited by this policy.

C. Probationary Employee Drug-Testing:

1. All probationary employees shall be required as a condition of employment to participate in any unannounced mass/mandatory drug tests scheduled for the probationary period. The frequency and timing of such tests shall be determined by the chief or his/her designee.
2. In addition, where the probationary employee has a past history of drug use, he/she shall be required to submit to random-testing until the probationary period is successfully completed. The frequency and timing of such testing shall be determined by the chief or his/her designee.

D. Employee Drug Testing:

Sworn officers will be required to take drug tests as a condition of continued employment in order to ascertain prohibited drug use, as provided below:

1. A supervisor may order an employee to take a drug test upon documented reasonable suspicion that the employee is or has been using drugs. A summary of the facts supporting the order shall be made available to the employee prior to the actual test.
2. A drug test will be administered as part of any regular physical examination required by this department.
3. All sworn officers shall be uniformly tested during any unannounced, mass/mandatory testing required by the department.
 - a. The chief or his/her designee shall determine the frequency and timing of such tests.
 - b. Testing will be done on a unit by unit basis.
4. A drug test shall be considered as a condition of application to the specialized units within the department, and shall be administered as part of the required physical examination for that position.

E. Drug-Testing Procedures:

1. The testing procedures and safeguards provided in this policy to ensure the integrity of department drug-testing shall be adhered to by any personnel administering drug tests.
2. Personnel authorized to administer drug tests shall require positive identification from each employee to be tested before they enter the testing area.
3. A pre-test interview shall be conducted by testing personnel with each employee in order to ascertain and document the recent use of any prescription or non-prescription drugs, or any indirect exposure to drugs that may result in a false positive test result.
4. The bathroom facility of the testing area shall be private and secure.
 - a. Authorized testing personnel shall search the facility before an employee enters it to produce a urine sample, and document that it is free of any foreign substances.

- b. The employee to be tested shall disrobe before entering the bathroom facility, and be provided a light robe.
- c. Testing personnel of the same sex as the employee shall observe production of the urine sample.

5. Where the employee appears unable, or unwilling to give a specimen at the time of the test, testing personnel shall document the circumstances on the drug-test report form. The employee shall be permitted no more than eight hours to give a sample, during which time he/she shall remain in the testing area, under observation. Reasonable amounts of water may be given to the employee to encourage urination. Failure to submit a sample shall be considered a refusal to submit to a drug-test.
6. Employees shall have the right to request that their urine sample be split and stored in case of legal disputes. The urine samples must be provided at the same time, and marked and placed in identical specimen containers by authorized testing personnel. One sample shall be submitted for immediate drug-testing. The other sample shall remain at the facility in frozen storage. This sample shall be made available to the employee or his attorney should the original sample result in a legal dispute or the chain of custody be broken.
7. Specimen samples shall be sealed, labeled and checked against the identity of the employee to ensure the results match the tested specimen. Samples shall be stored in a secured and refrigerated atmosphere until tested or delivered to the testing lab representative.
8. Whenever there is a reason to believe that the employee may have altered or substituted the specimen to be provided, a second specimen shall be obtained immediately, under direct observation of the testing personnel.

F. Drug-Testing Methodology:

1. The testing or processing phase shall consist of a two-step procedure:
 - a. Initial screening test, and
 - b. Confirmation test.
2. The urine sample is first tested using the initial drug screening procedure. An initial positive test result will not be considered conclusive; rather, it will be classified as "confirmation pending." Notification of test results to the supervisor or other departmental designee shall be held until the confirmation test results are obtained.
3. A specimen testing positive will undergo an additional confirmatory test. The confirmation procedure shall be technologically different and more sensitive than the initial screening test.
4. The drug screening tests selected shall be capable of identifying marijuana, cocaine, and every major drug of abuse including heroin, amphetamine and barbiturates. Personnel utilized for testing will be certified as qualified to collect urine samples or adequately trained in collection procedures.
5. Concentrations of a drug at or above the following levels shall be considered a positive test result when using the initial immunoassay drug screening test:

	<i>Initial Test Level ng/ml</i>
Marijuana metabolite	100
Cocaine metabolite	300
Opiate metabolites	300*
Phencyclidine	25
Amphetamines	1000
* 25ng/ml if immunoassay specific for free morphine.	

Concentrations of a drug at or above the following levels shall be considered a positive test result when performing a confirmatory GC/MS test on a urine specimen that tested positive using a technologically different initial screening method:

	<i>Confirmatory Test Level (ng/ml)</i>
Marijuana metabolite	15 (1)
Cocaine metabolite	150 (2)
Opiates:	
Morphine	*300
Codeine	*300
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine	500
(1) Delta-9-tetrahydrocannabinol-9-carboxylic acid	
(2) Benzoylcegonine	

6. The laboratory selected to conduct the analysis shall be experienced and capable of quality control, documentation, chain-of-custody, technical expertise, and demonstrated proficiency in urinalysis.

7. Employees having negative drug test results shall receive a memorandum stating that no illegal drugs were found. If the employee requests such, a copy of the letter will be placed in the employee's personnel file.
8. Any employee who breaches the confidentiality of testing information shall be subject to discipline.

G. Chain of Evidence-Storage:

1. Each step in the collecting and processing of the urine specimens shall be documented to establish procedural integrity and the chain of custody.
2. Where a positive result is confirmed, urine specimens shall be maintained in secured, refrigerated storage for an indefinite period.

H. Drug-Test Results:

1. All records pertaining to department required drug tests shall remain confidential, and shall not be provided to other employers or agencies without the written permission of the person whose records are sought.
2. Drug test results and records shall be stored and retained in compliance with state law, or for an indefinite period in a secured area where there is no applicable state law.

BY ORDER OF

CHIEF OF POLICE

This model Drug-Testing policy was developed under the auspices of the Advisory Board to the IACP/BJA National Law Enforcement Policy Center.

This model policy is intended to serve as a guide for the police executive who is interested in formulating a written procedure to govern drug-testing. The police executive is advised to refer to all federal, state and municipal statutes or ordinances, regulations, and judicial and administrative decisions to ensure that the policy he or she seeks to implement meets the unique needs of the jurisdiction.



IACP/BJA National Law Enforcement Policy Center



Model Drug-Testing Policy

Concepts and Issues Paper

May 1, 1989

I. PURPOSE OF DOCUMENT

Just as law enforcement has been the vanguard in the war on drugs, so must the law enforcement community now take a leadership role on the issue of the drug testing of its own members. No other group can better balance its employees' privacy rights against the unique and compelling interests of the law enforcement profession to determine the precise and proper scope of officer drug testing.

The goal of law enforcement drug testing must be to send a message that *any* drug use by officers, at any time, is unacceptable, and that each agency is prepared to enforce that philosophy by utilizing drug-testing technology to the fullest extent. Half measures are inadequate when the stakes are raised by the potentially corrupting influence of drugs on law enforcement.

The purpose, then, of the National Law Enforcement Policy Center Model Drug-Testing Policy is to take a leadership stance in the formulation of the proper scope of this employment practice for law enforcement officers.

The Law Enforcement Drug-Testing Concepts and Issues Paper was developed to accompany the Model Drug-Testing Policy promulgated by the IACP/BJA National Law Enforcement Policy Center. This document provides basic background information on drug testing, and identifies and discusses relevant issues, in order to aid each law enforcement executive in rendering appropriate decisions for this critical policy.

II. BACKGROUND

In the early 1980s, employee drug testing seemingly burst onto the scene, fast becoming one of the most controversial employment practices of the decade. The controversy stemmed not from the newness of this practice, but from its increased use, and adoption by employers that had not previously utilized drug testing as a means of screening employees.

The cause of this surge in employee drug testing can be directly traced to the dramatic increase in drug use in American society. It has been estimated that approximately 25 million people regularly use drugs. Employee drug use, in turn, costs employers an estimated \$33 billion per year in lost wages and

productivity. In order to counter this loss, employers turned to drug testing as a means of screening out high-risk job applicants and employees.

It is an unfortunate fact that the law enforcement profession has not remained immune to the drug problem. Indeed, the profession has been hit twice—by officer drug use and drug corruption.

No statistics are available as to how many law enforcement officers use controlled substances, or have become entangled in drug corruption. While many police executives argue that those officers using drugs represent a discrete minority, many argue that law enforcement is but a microcosm of society. Thus, the number of officers using drugs would mirror the high drug use in society as a whole. Some state that a higher than average number of officers use drugs, due to the increased contact with drugs inherent in police work. Whatever the number is, the eradication of drug use within the law enforcement profession is compelling and necessary for the protection of the public.

A. Explanation of Terminology

A preliminary explanation of several legal terms is necessary to enhance full comprehension of some of the language used by the courts and throughout this paper.

In determining whether a given drug test is an illegal search or not, the courts weigh the department's interests or justifications for conducting the drug test against the employee's right of privacy and the amount of intrusion on this right the drug test will present. While the department may have many such interests that it hopes to serve by conducting drug tests, not all such interests are "valid." A "valid interest" represents a judicial determination that the asserted interest is a reasonable and permissible one for the department to attempt to fulfill by means of drug testing. Those interests currently deemed valid for purposes of justifying police drug testing are discussed in the next section.

In addition, courts assign a symbolic weight to these interests by referring to them as "important," "significant," or "compelling" interests. A compelling interest signifies the highest qualitative weight used by courts.

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1110 North Glebe Road, Suite 200, Arlington, Virginia 22201

On the other side of the scales, the right of privacy is also assigned an extremely high weight, due to its status as one of the fundamental rights guaranteed by the Constitution. The diminished expectation of privacy held by public employees somewhat lessens this weight. The ultimate goal in gaining judicial acceptance of a drug test is for the department's interests to outweigh the employee's interests.

Law enforcement executives deciding to implement a drug-testing program need to become familiar with these terms. Should the plan be challenged in court, the law enforcement agency bears the burden of justifying its use of drug testing. While courts are aware that legal phrases are not terms of common usage, the law enforcement executive will want to communicate his concerns in the manner that will gain the fullest impact. Stating that "we've got some pretty good reasons for drug-testing" will not convey the proper significance to the court. By contrast, stating that "we have several valid, and what we think are compelling interests that support departmental drug testing" immediately communicates to the judge that critical information is about to be imparted, that the department views these interests as crucial to the law enforcement mission, and that the speaker has a professional attitude toward drug testing and has taken some time to research it. While the judge will ultimately determine whether an interest is compelling, how the department characterizes its justifications can often play a large part in that determination.

B. Making a Decision to Implement a Drug-Testing Program

The law enforcement profession has several valid and compelling reasons that justify use of a strong employee drug-testing program. The most urgent concern is the threat to public safety and the destruction of the public trust that are posed by officer drug use. Drug use has been shown to adversely affect the physical senses and thought processes. The officer with impaired senses and decision-making skills presents a threat of unjustified shootings, or other misuses of force, and increased vehicular accidents. The public has a right to expect that its law enforcement personnel are both physically and mentally fit to assume their duties, and drug testing serves this expectation.

Public trust and confidence in the integrity of the law enforcement profession is threatened by officer drug use. The public expects officers to enforce the law in a fair and impartial manner. The specter of police involvement in drug corruption and illegal drug use has cast a shadow on this expectation.

The law enforcement profession has compelling internal reasons to diminish officer drug use through the practice of drug testing. The safety of each officer is threatened by the drug-impaired state of a fellow officer. Each department has a duty to protect its employees from such dangers. In addition, each department has the right to take necessary measures to protect the internal discipline and esprit de corps vital to carrying out the law enforcement mission. Just as public trust is eroded by officer drug use, so too is each officer's pride in his profession.

Finally, officer drug use impacts potential departmental civil liability, a matter of vital concern. Each

department has a valid interest in taking measures to forestall litigation based on the negligent actions of a drug-impaired officer.

C. Pre-Drug Test Planning

1. Documentation of Drug Environment. The law enforcement executive considering implementation of drug testing for his agency is advised to do strategic planning well in advance of the actual implementation of drug testing.

The most important step is an analysis of the department itself. The size of a department is not always indicative of how much drug use occurs among officers. As drug use over the general population has expanded, small towns have increasingly found themselves in the middle of a drug problem. Shifting drug-dealing and drug shipment patterns have also affected previously "safe" areas such as the Midwest. For example, the increased use of drug dogs at airports on the traditional Miami to New York City drug shipment routes has forced drug dealers to find alternate routes and modes of transportation. This has led to the increased presence of drugs in areas where no airport drug dogs are used, or the law enforcement presence and alertness to drug dealing is *perceived* by dealers as minimal.

As drug dealers search for bigger profits, the natural response has been to increase the market area. Increased drug demand is also symptomatic in areas of high unemployment, notably in industrial towns hit by the closing of an automobile or other major factory.

The reasons for both drug use and the increase in drug use are so many and confusing that it is entirely consistent to hear of small or medium-sized law enforcement agencies with serious drug problems. Thus, each agency should take a serious look at the environment within which it operates. A written analysis of these external influences should be prepared as a foundation to the drug-testing program. Should the departmental drug-testing program be challenged, this analysis may be able to be used in court as evidence to support the dimensions of the potential drug problems within the agency.

A written analysis of potential employee drug use should also be prepared, based on those officers already exhibiting a problem or a potential drug problem. Courts have determined that there must be a demonstrable reason for drug testing. Written documentation of existing drug use is compelling evidence. Documentation of officer involvement in drug dealing, bribery, or other forms of drug corruption may also be used. The department need not show that a majority of the work force is involved in drug activity to justify drug testing of employees. However, more intrusive types of drug testing, such as random testing, would require a significant demonstration of employee drug use.

2. Consultation. The law enforcement executive should consult with various professional groups before implementing drug testing. Extensive legal assistance will be necessary from the beginning stages. A preliminary analysis of the permissible types of drug testing in the jurisdiction should be conducted before rendering the decision on who will be tested and when. The final written policy should be analyzed to ensure all legal requirements have been met, and that the policy is clear. Legal information should be shared with the officers,

although it may be readily available through the local union. However, department-provided information helps neutralize any negative feelings from the officers concerning management-initiated drug testing.

Medical personnel should be consulted for a full explanation of the various drug tests available and their capabilities. No existing drug test is infallible, although DNA testing appears to be highly accurate. The department should determine which drugs will be tested for, and which tests will best serve their specific need.

Finally, the department should work closely with any collective bargaining units of the employees to be tested. Several cases have held that drug testing may be a mandatory subject of bargaining.¹ While labor organizations have initiated much of the current litigation concerning police drug testing, the focus has generally been to ensure that the tests are fair and not an attempt to prohibit the drug-testing program. Thus, cooperation of all involved collective bargaining units in formulating department drug-testing provisions can ultimately gain vital employee acceptance of the program.

III. PRELIMINARY LEGAL ANALYSIS OF POLICE DRUG TESTING

The sudden profusion of compulsory employee drug testing caught lawyers as much by surprise as the tested employees. No clear body of case law existed to easily accommodate the sudden onslaught of drug-testing cases.

To date, the Supreme Court has not issued a decision on the legality of employee drug testing. However, several cases are currently docketed for decision or consideration over the next two years.² The drug-testing case law which does exist has, for the most part, developed region by region at the federal court level. While *some* measure of uniformity can be gleaned from these decisions, each federal district's decisions are only binding on that district. Thus, until the Supreme Court decides these cases, certain methods of drug testing may be permissible in one state, but not in another state. The law enforcement executive contemplating implementation of a drug-testing program is advised to consult local legal counsel to determine the specific decisions on drug testing for his jurisdiction.

Police drug-testing programs have been challenged on various legal grounds. To date, the most successful challenges have derived from Fourth Amendment and Fourteenth Amendment due process and equal protection analyses. A brief explanation of these legal theories is necessary to familiarize the executive with those legal standards that must be met before initiating a drug-testing program. A more detailed analysis of the validity of certain methods of testing or drug-testing procedures is contained in the appropriate section of this paper.

A. Fourth Amendment Analysis

Fourth Amendment analysis is initially applied to a drug-testing program to determine whether the test itself constitutes an illegal search, or a permissible intrusion on employee privacy rights based on significant governmental interests. The Fourteenth Amendment then ensures that the overall program is implemented in a fair and impartial manner.

The Fourth Amendment prohibits both unreasonable governmental searches and seizures into those areas in

which a person holds a societally recognized expectation.³ Not surprisingly, most courts have held that urine, and the act of urination, are entitled to such a societally recognized expectation of privacy.⁴

However, it is important to note the rationale behind this extension of a right of privacy, as vital employee concerns are implicated. As urine is routinely discharged from the body, some departments have argued that the plain view doctrine bars a drug test from being a search or seizure. However, this argument has failed, as it is felt that people do not expect other people to gather their urine for analysis. In addition, urine contains personal medical information such as evidence of pregnancy, epilepsy, and other medical conditions. It has been established that a person may have a right of privacy in this information and its nondisclosure.⁵ Legally unfettered drug testing would have the potential to allow a random governmental search into areas beyond drug use. The information gained could form the basis for unlawful termination.

The act of urination itself is vested with an expectation of privacy. It has been argued that men do not have this expectation, as they do have the option in public restrooms to urinate in front of other persons.

Aside from the obvious argument that women do not urinate in front of others, and equal protection rights would not allow women to have more privacy rights than men on such a thin social custom, a more sophisticated analysis has prevailed. No one urinating in front of another person expects the other person to watch them, under a compulsion to produce urine.⁶ A sense of fair play requires that urination be given the dignity of privacy rights protection.

Thus, courts have almost unanimously determined that a drug test is a search. And, as the officer is ordered to give a urine specimen or be terminated, a seizure of the urine occurs.⁷

As the Fourth Amendment only prohibits "unreasonable" searches or seizures, all drug-testing programs must be reasonable in order to be permitted. What constitutes a "reasonable" drug test lies at the heart of much controversy.

The parameters for discerning the reasonableness of a search of a public employee's workplace were first addressed by the Supreme Court in *O'Connor v. Ortega*.⁸ While *O'Connor* does not address the issue of drug-testing, it is currently being used in drug testing cases because it is the only applicable Supreme Court pronouncement on public employee searches.

Initially, *O'Connor* establishes that for the purpose of workplace searches, public employees retain some semblance of their Fourth Amendment rights. However, the extent of these rights is dependent upon the context in which they are asserted. Due to the nature of their work, public employees have a diminished expectation of privacy. In order to determine the scope of the privacy right, the governmental interest in conducting the search must be balanced against the intrusiveness of the search. Thus, a case-by-case approach will be used to determine the extent of the privacy right retained and the reasonableness of the search, based on such factors as the type of search to be conducted, the reasons for the search, the workplace environment, and the type of public employment involved.

Looking at workplace searches performed to discover work-related employee misconduct, *O'Connor* held that for the search to be deemed reasonable, it must have been both reasonable at its inception, and reasonable in scope. This test has been applied to drug tests of police officers, where conducted to detect the prohibited use of drugs.

Essentially, this test requires two conditions to be satisfied before approving a drug test as proper under the Fourth Amendment. First, the drug test must be reasonable at its inception. No warrant will be required before the department may order a drug test, as this would place an undue burden on the department. And, while warrantless searches generally require a probable cause foundation, certain limited exceptions to the probable cause requirement have been permitted. As employee searches for work-related misconduct are not ultimately aimed at criminal prosecution, the lesser standard of reasonable suspicion would suffice to support a warrantless search. Application of this crucial part of *O'Connor* is the basis for legal projections that drug testing will only be permitted upon reasonable suspicion by the Supreme Court. However, the case-by-case approach advised by *O'Connor* could prove this projection incorrect.

The *O'Connor* case left open for decision the question of whether reasonable suspicion requires an individualized suspicion that the particular person to be tested is using drugs, or whether a more generalized suspicion about employee drug use will suffice. This current ambiguity lies at the heart of the controversy as to when drug tests may be required.

Second, the *O'Connor* test would require that a drug-test "search" be reasonably executed. The drug test may only be used to search for prohibited controlled substance use, and must be conducted in a reasonable manner.⁹

While courts seem to overuse the word reasonable, and leave little guidance for those who must implement it, the key to drug testing is fairness. The law enforcement profession has especially compelling interests that may ultimately allow them to use drug testing in ways that other employers may not. Where possible, the employee should be extended as much dignity and protection as possible without compromising the test.

B. Due Process Requirements

The Fourteenth Amendment guarantees that no person shall be deprived of his liberty or property interests without due process of law.¹⁰ Law enforcement officers, unlike private sector employees, generally enjoy a property interest in their job. Any actions that will deprive them of their job, through suspension or termination, must comply with due process requirements that ensure that the actions are taken in a fair and evenhanded manner.¹¹

Employees also have a liberty and property interest in their reputations that is also protected by the due process clause. Employees have a right to be free from any unwarranted stigma attached to termination that would hurt their future employment chances.¹²

As applied to police drug-testing programs, due process essentially requires conformity with two principals. First, the drug test and drug-testing

procedures must be fairly conducted. Notice must be given to the employee that a drug-testing program exists, when tests will be given, and how the test will be implemented. The test may not be administered based on individual discretion, or in an arbitrary and capricious manner.¹³ Second, termination for drug use should remain confidential. The department should not release to future employers, other police agencies, or newspapers information that confirms that the employee was fired for drug use.¹⁴

C. Miscellaneous Legal Challenges

Drug testing has been challenged as a Fifth Amendment violation, as the officer is being forced to produce evidence of his own misconduct. As the Fifth Amendment only applies to oral inculpatory evidence, drug testing is not a Fifth Amendment violation.

Termination for drug testing does not constitute cruel and unusual punishment under the Eighth Amendment. Termination is not considered excessive or unreasonable in light of the offense.¹⁵

Termination of drug addicts does not constitute a violation of the Federal Rehabilitation Act of 1973.¹⁶ While drug addiction is considered a handicap protected by the act, no violation occurs if the addiction substantially impairs the employee's ability to perform their job. The illegality of drug use and the debilitating effect of drugs constitute a substantial impairment of a police officer's ability to perform essential duties. The threat to public safety from drug use also constitutes substantial impairment.

Termination of drug users, but not alcoholics, does not constitute a violation of the Fourteenth Amendment Equal Protective clause, for similar reasons. Drug use is illegal; alcohol use is not.¹⁷

The most potent threat to police departments comes from private citizens. Where a department retains a drug-using officer who harms a citizen due to their drug use, the department can be sued for negligent retention of an employee.¹⁸

IV. MODEL DRUG-TESTING POLICY

A. Framework of Policy

1. *Necessity for Written Policy.* The need for a written policy is especially critical for those departments developing a drug-testing program for officers. The majority of courts deciding drug-testing cases has analyzed the soundness of drug-testing programs based on the amount of information the officer is given concerning department drug-testing procedures.¹⁹ Thus, the agency should develop a written drug-testing policy that will inform employees of all relevant information.

2. *Stated Governmental Interests.* Any policy that regulates an officer's conduct must be related to achieving a valid departmental interest. Where the policy regulates a fundamental right such as privacy, the policy must be more narrowly drawn, and related to achieving a significant, or compelling departmental interest.²⁰

The significant law enforcement interests that justify the use of employee drug testing were discussed earlier in this paper. These interests should be discussed in the written drug-testing policy. This will provide any court perusing the document with a clear picture of

why the department is justified in generating a drug-testing program.

In addition, where the department explains in the policy why drug testing is important and necessary to the department, the practice itself is more palatable to the collective bargaining unit and the employee. Drug testing is reduced from the status of spying and interfering with the officer's life, to a tool to protect both the officer and the public.

For these reasons, the model policy places a discussion of the departmental interests justifying a drug-testing program in the policy statement. This immediately tells the reader, judge, or officer why this program is necessary, and describes those concerns it is meant to address.

3. Prohibited Activity. Law enforcement executives that favor lean, sparsely written policies and procedures are encouraged to suspend this practice when promulgating a drug-testing policy. As far as the courts are concerned, the more information provided to the officer, the more reasonable the policy. And, details which may seem obvious, and are thus omitted, may take on a startling importance and not be as obvious to courts reviewing the policy.

An excellent example of this is the prohibition against drug use in the model policy. As an officer cannot be terminated for nonprohibited behavior, termination for drug use pursuant to a positive drug test could be held impermissible where the policy manual does not state that drug use is prohibited.

Most departments prohibit drug use in their Rules of Conduct. However, it is important that when establishing a drug-testing policy, this rule is clearly worded to advise the officer of that activity which is prohibited.

For this purpose, the model policy provides clear instruction as to departmental prohibition of drug use. Two specific types of activity are prohibited. First, the model policy prohibits the ingestion of any controlled or other dangerous substance unless upon a doctor's orders. Ingestion covers all forms of introduction of drugs to the body such as sniffing, injecting, inhaling, oral administration, or the placing of acid onto the eyeball. Second, the model policy prohibits ingestion of prescription or over-the-counter drugs in amounts beyond the recommended dosage, where this would impair job performance. This section addresses abuse of drugs such as Percodan, cough syrup, decongestants, and tranquilizers. Increased dosages of such drugs can also impair the officer's perceptions and reactions and prove just as addictive as street drugs.

The model policy prohibits these uses of drugs whether the officer is on or off duty. Some departments may choose to prohibit drug use only for on-duty officers. Many courts and labor organizations protest limitations on off-duty conduct as an unacceptable privacy violation. However, the majority of courts have upheld the type of blanket drug use prohibition embodied in the model policy as a reasonable restriction on a police officer's rights of privacy.²¹ In reaching this conclusion, courts have based their decision on the lingering affects of drug use, and the illegal status of controlled substances.

Drug testing is not sophisticated enough to discern the intent with which drugs were used. The drug test

merely reports the presence in certain amounts of the drugs for which it screens. However, the practice of drug testing is only meant to discipline or terminate officers who intentionally use or abuse dangerous substances.

In order to protect innocent employees, the law enforcement executive should include in the written policy the following provisions found in the model policy. First, officers who have been taking prescribed medication that contains a narcotic base such as codeine should report this fact to their supervisor. In case of a subsequent positive drug test, or accusation of drug use, the officer will be protected from termination or suspension.

Another important provision relates to unintentional drug ingestion that can result in a positive drug test. In both the social and work environment, the officer may "passively inhale" drug smoke that could later register as a positive drug test. A narcotics unit officer may be forced ultimately to use a drug in a drug dealer's presence in order to establish credibility. Passive inhalation and unintentional use of a controlled substance should immediately be reported to the supervisor to avoid later misunderstandings.

The department is not looking for, and is not justified in punishing, an officer for these types of unintentional drug activity. Thus, as provided in the model policy, departments seeking to implement drug-testing policies should protect their officers by narrowly crafting the prohibited drug use provisions.

B. Scope of Testing

The amount of notice or information that an officer is provided pertaining to when he will be required to submit to a drug test is a key consideration in the overall determination of the reasonableness of a drug-testing program. Of similar importance, the policy must state who may order that an officer be required to take a drug test.

The model policy permits compulsory urinalysis in a number of clearly defined instances:

1. Applicant Drug Screening. The model policy requires that all applicants for the position of sworn police officer submit to a drug test during a preemployment physical as a condition of employment.

Preemployment drug screening has been approved by the courts as a valid means of ensuring fit, drug-free employees.²² As such, it is a valid condition of employment.

Stringent due process requirements are not generally applicable to applicants rejected on the basis of a positive drug test, or the types of drug tests permitted.²³ The applicant is not an employee of the agency with discernible rights. Submission to the drug test is considered to have been done and accepted on a voluntary basis.

A recent case rejected an argument that drug screening of police applicants disproportionately impacted minority populations.²⁴ Where the test is administered as part of a general preemployment physical administered by the municipal doctor, no doctor-patient confidentiality rights are triggered. The doctor is an employee of the administering entity.²⁵

Preemployment drug screening can be a strategically crucial means of assuring a drug-free work force. While

drug testing is not a perfect means of projecting which employees will use drugs in the future, it remains a powerful tool in detecting possible candidates—those currently using drugs on a regular basis.

An important issue that each agency must initially consider is how much past drug use it will accept in applicants. The Miami Police Department rejects all applicants with a past history of drug use. However, due to widespread drug use by society, many departments are finding it harder and harder to find applicants with no past drug use experience. Thus, some departments accept applicants with a minimal past history. This raises the issue of what is an "acceptable" past history of drug use. A law enforcement executive may want to delimit this based on type of drug used, frequency, and how long ago the drug use occurred. For example, the executive may decide that infrequent marijuana use is an acceptable condition, but infrequent heroin use is not. Once the department delimits acceptable past use standards, this standard must be applied equally to all applicants.

2. *Probationary Employee Testing.* Given the costs involved in drug testing, smaller agencies may wish to limit testing to the applicant stage. This plan has a potential drawback. It has been argued that an applicant can beat a drug test by refraining from use of drugs for a specified period before the test. As the goal of applicant screening is to eliminate persons with drug problems, such subterfuge undermines the process.

In order to prevent this potential subterfuge, the model policy additionally permits mandatory testing of all probationary employees throughout the probationary period prescribed by the department. Mandatory or mass testing requires that all persons be tested an equal number of times in a testing period. This is often accomplished by testing the entire group on one day. The model policy requires that the chief or his designee determine the timing and frequency of the mandatory testing of probationary officers.

Finally, the model policy permits random testing of probationary individuals throughout the probationary stage where the individual has a past history of drug use. This is necessary to ensure that the probationary employee does not continue his habit after becoming a law enforcement officer.

It is important to ascertain the legal status of the recruit or probationary officer under state law or pertinent collective bargaining agreements before using these more legally complex testing methods. Important due process rights may be involved that must be considered in planning the drug test.

3. *Reasonable Suspicion.* The model policy permits the department to administer a compulsory drug test upon reasonable suspicion that an officer is currently using, or has been using, drugs.

The vast majority of federal courts has clearly held that law enforcement is constitutionally limited to drug testing upon reasonable suspicion.²⁶ While making the choice easier for agencies seeking to implement drug testing, it should be noted that this type of testing is the most difficult to implement. A drug-testing program that requires testing only upon reasonable suspicion may still hold legal pitfalls for agencies in the following areas:

- *Individualized or General?* Testing may only be done upon reasonable suspicion of drug use. As discussed earlier in this paper, it is unclear whether reasonable suspicion must be founded upon individualized or generalized suspicion. The model policy has chosen to use a definition of reasonable suspicion based on a particularized suspicion. This complies more closely with Fourth Amendment guidelines. However, some departments may choose to incorporate the generalized suspicion for their policy. This choice presents a legal pitfall for departments should the Supreme Court decide this issue in the opposite way than the department may have chosen.
- *What Evidence Constitutes Reasonable Suspicion?* The second danger in reasonable suspicion testing is one familiar to law enforcement—whether the facts that instigated the decision to test an officer amounted to reasonable suspicion. The generally accepted definition of reasonable suspicion, as reflected in the model policy, is "specific and objective facts about the conduct of an individual, and any rational inferences that would cause the reasonable police officer to believe that the individual has been using drugs."

In assessing reasonable suspicion, law enforcement personnel are given great leeway due to their status as trained observers. As police are trained to assess drug use in citizens, their observations concerning drug use by a fellow employee are considered fairly trustworthy.²⁷ However, to ensure validity of the drug-testing program, it is suggested that departments either state in the policy, or circulate to employees, a list of observable characteristics of drug use.

Reasonable suspicion can also be formulated from nonobserved information about the officer suspected of drug use.²⁸ Again, law enforcement is considered to have a tremendous intelligence-gathering and investigational edge over other industries that will allegedly immediately net information about officer drug use. In calculating reasonable suspicion, informants' tips and citizen complaints concerning an officer's drug use or involvement in drug dealing may provide an adequate basis for a drug test.²⁹

Finally, less direct information can be considered in determining reasonable suspicion. Increased absenteeism, use of force incidents, accidents, or disciplinary problems may indicate drug use. Evidence that an officer is clearly living beyond his means may bolster other evidence that the officer may be involved in drug activity.

Aside from eyewitness observation of drug use, each of these factors alone may not be enough to amount to a reasonable suspicion. Where, as in the model policy, an individualized suspicion standard is to be used, a balancing test suggested by courts in several recent decisions may prove useful in instructing employees on reasonable suspicion. This test suggests that before requiring a drug test, the department assess the quality of its reasonable suspicion by weighing (1) the nature of the tip or information; (2) the reliability of the informant or information; (3) the degree of corroboration; and (4) any other facts contributing to the presence, or lack thereof, of reasonable suspicion.³⁰ This analysis may aid employees in separating a mere hunch from the actual proof needed.

- **Incident Testing as Reasonable Suspicion?** Some drug-testing plans, notably those adopting a generalized reasonable suspicion standard, include "incident testing" as a type of testing for reasonable suspicion. Incident testing refers to compulsory testing of an officer after an accident, use of force, or similar critical incident to determine whether it was caused by drug use. The incident alone is considered reasonable suspicion. While incident testing has been strongly upheld in cases concerning the transportation industry, it is unclear at this point whether the case-by-case approach to employee searches discussed in *O'Connor* would support it for police officers. In addition, it is important to note that drug tests can not adequately be used to determine if an accident or use of force can be attributed to drug use. The drug test will show if drugs were used, but it cannot tell when they were used. Thus, an officer with a positive drug test after a critical incident may not have been drug impaired at the time of the incident. The model policy would only permit a drug test here if additional factors tended to prove that the incident was caused by drug use.
- **When Can a Test be Ordered?** It is especially critical to formulate clear procedures for reasonable suspicion testing in order to ensure that employees are not subjected to arbitrary or biased testing. In order to circumvent these problems, the model policy requires that testing may only be initiated upon documented evidence, and at the order of a supervisor. Any employee observing potential drug use characteristics should immediately notify his supervisor. The supervisor should then begin the documentation and investigation process.

Where there are strong indications of current on-the-job drug use, the supervisor may temporarily relieve the employee of his duties and order an immediate drug test. Where evidence of drug use is ambiguous or weak, more investigation and documentation are prudent.

Departments may wish to include more supervisory layers in the reasonable suspicion review process in order to provide better checks and balances. For example, some departments require the chief to give final approval to order a drug test after analysis of the documented suspicion and investigation by several successive supervisors. Another method often used is to only permit employee observations to serve as a basis for a test when corroborated by other employees. This prevents an officer from being tested wrongfully due to a spiteful co-worker.

Procedures detailing when an officer may be tested upon reasonable suspicion must be narrowly crafted in order to eliminate the possibility of arbitrary testing. The department must ensure that testing is not conducted on ambiguous evidence of drug use, a mere hunch, or as a result of personal vendetta, but upon meaningful evidence of drug use.

4. Physical Exams. The model policy permits a drug test as part of a regularly scheduled physical examination required by the department.

To date, drug screening during a departmentally required general physical examination has received strong support from those courts examining such practices.³¹ No expectation of privacy can be asserted, as the officer is submitting his body for medical analysis

for any conditions. Thus, the governmental interest in ensuring healthy, fit police officers outweighs any negligible employee interests.

The crucial consideration in determining test validity is whether the physical is truly a regularly scheduled physical exam. The exam cannot be a thinly veiled excuse to do drug testing. There must be a clear connection between the physical exam and the employer's legitimate safety concerns.³² Thus, a provision requiring a six-month checkup by city doctors that only involved urinalysis would probably be prohibited.

Department practices concerning physical examinations vary due to their expense. Some departments require an annual physical, while others base the timing of the required exam on the officers age or upon promotion. For example, officers over 35 may be required to have annual exams, while officers under 35 may only be required to be examined every other year. However, law enforcement has begun to place increased emphasis on fitness and medical exams in order to reduce potential employee cardiorespiratory problems. Thus, drug testing may be conducted during these regularly scheduled physical examinations.

Some departments have required a general physical examination that incidentally requires a drug test, after certain incidents. For example, in *Wrightsell v. City of Chicago*, the court upheld the use of compulsory physical exams that included drug tests: (1) to identify the cause of an officer's illness or incapacitation; or (2) where an officer has excessive sick leave; or (3) where an officer has been ordered to submit to a psychiatric examination; or (4) the officer is returning to work after a 30-day leave of absence due to suspension, to receive extra training, re-employment pursuant to court order, or any other reason. Thus, the focus of the test is on the officer's general health, and is not primarily a broad-based general search to ascertain any prohibited drug use.

Where departments choose to initiate drug testing as part of a physical exam, this should be clearly stated in the policy. The policy should explain the connection between the exam and the department's concern for the officer's general health and fitness.

5. Specialized Unit Tests. Finally, the model policy requires a drug test as a condition of application and acceptance to specialized units within the department. This section would apply to such units as the narcotics, organized crime, SWAT, or bomb squad units.

Drug testing of specialized unit members is merited by the inherent nature of these assignments. In units where great technical expertise, split-second timing, and decision-making ability are required, drug use by unit members presents a heightened potential of danger for both the unit members and the public. In narcotics and organized crime units, drug testing may prove especially critical. It has been speculated that the continual exposure to drugs and the drug culture has often led to drug use by narcotics unit members. In addition, these officers are particularly vulnerable to forms of drug corruption by members of organized crime.

Specialized unit litigation generally has focused on narcotics unit testing. For the reasons cited above, the majority of courts have upheld drug tests of all applicants to specialized units, where conducted as a condition of application and acceptance.³³ In addition,

such testing has gained approval because application is made on a voluntary basis by the officer. Thus, applicants are deemed to have knowingly and freely consented to be tested.

In order to ensure the continuing integrity of narcotics or other specialized units, some department drug-testing plans have contained a provision requiring random drug tests of all unit members at specified intervals after acceptance in the unit. The case law on random testing of narcotics unit members is particularly unclear.³⁴ The seminal case of *Caruso v. Ward*, which originally produced the spate of cases prohibiting random testing of narcotics unit members as unconstitutional, was recently reversed. Random testing was upheld because unit membership was voluntary, thus the members had a choice to submit to drug testing.³⁵ In addition, applicants were not penalized if they withdrew their application rather than submit to a drug test or random testing.

By contrast, cases prohibiting this type of random testing have stated that testing upon reasonable suspicion, and police observation and intelligence techniques, provide more than adequate means of determining potential unit member drug use, without the intrusiveness.

The Supreme Court will have an opportunity to determine the constitutional parameters of special unit testing this term in *National Treasury Employees Union v. Von Raab*.³⁶ This case concerns the testing of Customs officials applying for positions with increased exposure to drugs. Before implementing random or mandatory testing of specialized unit members then, the law enforcement executive is urged to consult state case law, and watch for the decision of this case.

6. Mass/Mandatory Testing. Finally, the model policy permits mandatory or mass testing of officers. The timing and frequency of such tests should be determined by the chief or his designee.

Mandatory or mass testing requires that all officers undergo a drug test, whether on one specified date or within a certain period of time. The model policy suggests that testing be conducted on a unit-by-unit basis until all officers have been tested. At present, the majority of courts have not permitted this type of testing because it is initiated on no articulable suspicion that any particular officer is involved in prohibited drug activity.³⁷ Instead, it is a far-reaching search to find out just this information. However, some courts have suggested that more intrusive measures such as mandatory testing may be permitted where there is evidence that the drug problem cannot be adequately addressed through such measures as internal investigations, citizen complaints, and employee observation.

As stated in the introduction to this paper, law enforcement executives must play a leadership role in eliminating drugs from the law enforcement profession. Use of mandatory testing is a necessary and effective tool in achieving this goal. It strikes the correct balance between employer and employee rights. Employees have no right to use drugs and endanger others.

Mandatory testing allows the department to quickly ascertain which employees are using drugs. Given the insidious effects of drugs on the law enforcement profession, time is of the essence. Ordinary means of discovering officer drug use have come too late to

prevent corruption and accidents caused by drugs, and cannot be said to have begun to identify all drug users. Thus, use of mandatory testing is advocated as the only means to eliminate officer drug use, while providing consideration for employee rights.

B. Random Testing

The model policy prohibits random drug testing of sworn officers. For the purpose of this paper, a distinction is made between mandatory and random testing, although courts often use the terms interchangeably to denote drug tests conducted without any basis for belief that the person to be tested has used or is using drugs.

Random drug testing, as first discussed in *Shoemaker v. Handel*,³⁸ can take several different forms. Obviously, the person to be tested is chosen at random. However, in a classic random test, no attempt is made to test all officers equally over a specified period. While each officer has an equal chance to be tested at each draw, unless the names of those already tested are withdrawn, officers can be subjected to double testing or no testing. Random drug testing of law enforcement officers has been almost unanimously prohibited by the courts as an unconstitutional search and seizure and a violation of due process.³⁹ As with mandatory tests, random tests are considered a prohibited "general" search because the officer is tested without any actual suspicion of drug use.

As discussed earlier, an important question in drug testing concerns the nature and quality of the suspicious evidence upon which a drug test must be founded. This ambiguity may provide a means to approve random testing at a future date. Several courts ruling against random drug testing of police have noted that they would approve a random testing plan if the department could prove that officer drug use had reached such proportions that testing upon reasonable suspicion and normal police intelligence and investigative techniques to detect officer drug use were no longer a viable option.⁴⁰

Random drug testing has generally been upheld only for heavily regulated industries such as the horse-racing and nuclear power industries.⁴¹ While each police drug-testing case has argued that law enforcement qualifies as a regulated industry due to statutory and internal restrictions, this argument has been rejected in all but one case.⁴²

Due process objections to random testing have focused on the selection procedures. Random choice may permit an official to target for testing an officer who is disliked. It has been held that any approved random test must be set up to eliminate human intervention and prejudices. Thus, where random testing has been permitted, a computer-generated random program has been used to eliminate arbitrary official discretion.

C. Testing Procedures

1. Chain of Custody. The most critical part of the drug test itself is maintenance of a strict chain of custody for the urine specimen. Where it may be shown that a positive drug test could have resulted from human error or tampering or a broken chain of custody, the courts may invalidate any disciplinary action taken as a result of the positive drug test. Thus, urine specimens

should be subject to the same chain of custody procedures as any other piece of evidence. Preservation of the chain of custody should begin before the test itself is administered. The first step is to ensure the reliability of personnel responsible for the administration of the test and the analysis of the specimens. Some departments have the capacity to perform the drug test and analysis in-house. However, the majority of departments hire an outside lab to either conduct both steps, or the analysis only, after department personnel oversee the taking of the specimen.

Careful and thorough training should be given to any departmental personnel involved in administration or analysis of drug tests. Proper chain of custody procedures should be emphasized, as well as confidentiality and compassion.

The model policy requires that the agency choose an experienced and reliable laboratory to conduct analysis of the urine specimen. Given law enforcement budget constraints, the temptation is to choose the lowest bidder for the job, and trust that they are competent. The department should carefully scrutinize the laboratory's procedures for documentation and handling of the specimen, and request references to determine the reliability of the laboratory.

The model policy further protects the integrity of the drug test by requiring that the room in which the specimen is given be searched for foreign substances and documented as secure. Departments should be warned that employees have proven ingenious in creating ways to circumvent drug tests. The sale of "clean" urine has prompted many employers to require that the employee be searched before the specimen is given.

The urine specimen should be given in a private, medical setting. The safest procedure is to have a "dry" room, with no running water available from the sink or toilet. This prevents contamination of the specimen with water. Certain chemicals or dyes may be placed in toilet bowl water to show that a specimen has been tampered with, where it is not practical to use a dry room. The room should have nothing in it where an employee could hide contaminants. For example, an employee could carry contaminating liquid or clean urine in a body cavity and hide it in a waste paper basket, Kleenex box, or other place for use by a fellow employee to be tested at a later time.

Each step of the test should be carefully documented. As required in the model policy, specimen containers should be clearly marked with the employee's identifying number and the date and time the specimen was submitted. The employee giving the urine sample should provide positive identification before giving a sample.

Prior to the test, the employee should be given a questionnaire concerning recent drug use. This asks the employee to list those medications or passive exposures to drugs that may trigger a positive test.

2. Employee Comfort. The model policy requires that the urine specimen be collected in a manner that will not embarrass, demean, or cause physical discomfort to employees.

Most drug-testing policies require that the employee disrobe before entering the bathroom to produce a specimen. This ensures that no items will be carried

in to contaminate the sample. The employee should be provided a light robe to wear into the testing area, and be given a light pat-down search to ensure these items have not been placed in the robe.

Use of witnesses to the act of urination has been upheld by courts as necessary to ensure the integrity of the test. However, the amount of actual visual observation of the act is up to the department. The more demeaning the procedure, the higher the chance it will be held unreasonable. For this purpose, it is suggested that medical personnel be used to monitor the proceedings.

The observer must be of the same sex as the employee. While it is perfectly proper to have the observer watch the urine being discharged, some departments permit the observer to turn their back or avert their eyes in order to permit the employee some privacy. Where the employee has been searched before entering the collection site, and the observer is able to listen for any abnormal sounds that may indicate sample falsification, visual scrutiny may be unnecessary.

Where department personnel will be observing the urine discharge, personal concerns should be taken into account. Where the department has knowledge that certain employees do not like each other, one employee should not be permitted to observe the other while urinating. A supervisor should not be required to submit to observation by one of his employees. Command staff should be given observers of their own rank or the next highest rank.

The employee should be made as comfortable through the entire process as possible. While a natural body function, it is not uncommon for an employee to "freeze up" upon being presented with a specimen cup with orders to fill it. However, it should be noted that such "freezes" may be an attempt to stall, in hopes the test will not be administered. Extra time also provides the employee a better chance that the body will be naturally erasing signs of drug use.

The policy should set a certain period, such as eight hours, in which the urine specimen must be given. The time period should be a reasonable one, as time pressures can worsen the sudden inability to urinate. Consideration should be shown where the observer feels that his presence is probably causing the freeze. Failure to produce a specimen should be considered refusal to submit to the drug test.

3. Sample Splitting. The model policy permits sample splitting, as long as the samples are collected at the same time, and marked immediately. Sample splitting permits the employee to have a urine sample divided and stored for future analysis. In cases where the initial sample is lost or shows a positive result, the employee can challenge the positive result if the split sample remainder shows negative for drug use. It is unclear at this point whether due process absolutely requires that sample splitting be permitted. However, a sense of fairness dictates that the employee be able to use what means are available to defend against a false positive result. As the rest of the sample remains refrigerated, this practice costs the department little.

After a specimen is given, it must be immediately sealed, labeled, and refrigerated until tested. The model policy requires that each step in the collection and processing of the sample be documented in order to

ensure validity. The sample should be stored in a secured refrigerator. Access to this refrigerator should be limited to those personnel testing the samples, or those who must retrieve samples from it.

D. Screening of Urine Samples

The model policy requires that a urine sample taken as part of a compulsory drug test be subjected to two technologically different drug-screening methods in order to ensure the accuracy of a positive drug-test result. While this may seem to impose an expensive and repetitious burden on the law enforcement agency, this requirement results from the state of drug-screening technology, and can actually prove cost effective in the long run.

There are several types of drug-screening processes currently in use. These processes differ based on cost, accuracy, sensitivity, the way the process detects the presence of drugs, and the types of drugs that can be detected by the process. Not surprisingly, the cheaper screening processes are less accurate, less sensitive, and may not be able to detect the full range of drugs an agency may wish to screen for in its drug-testing program.

No drug-screening process currently in use is completely accurate in detecting the presence of drugs. While early statistics on drug screening by DNA analysis from body hair have been impressive, this technique has not yet been fully proven.

The most common combination of drug tests are the immunoassay tests, confirmed by the gas chromatography/mass spectrometry (GC/MS) technique. The immunoassay-type tests are cheaper, and fairly reliable, but not reliable enough to be used alone. Thus, many agencies use the immunoassay or radioimmunoassay techniques initially, to isolate only the positive test results. Then, the more expensive and sensitive GC/MS method will only be needed for a few specimens. It is important to use a technologically different and more sophisticated screening method to ensure the accuracy of a positive result, and cross-check the sample.

Drug-screening methods can produce different types of inaccurate results. A "false positive" result means that the test indicated that certain drugs were present, when they actually were not. False positives can be caused by human error, faulty procedures, and the technology itself. In addition, false positives can be created by cross-reactivity. Cross-reactivity occurs when certain non-prescriptive drugs or substances interact to create a positive test result for a drug that is not actually there.

By contrast, "false negatives" report the presence of no drugs, when drugs are actually present. False negatives can occur due to the addition of certain substances to the urine, or where the urine goes stale due to age.

Finally, false negatives may occur due to the cut-off levels of a screening method. Cut-off levels are the concentration of drugs in the urine that will reliably be detected by the drug-screening method. Naturally, the smaller the amount desired to be detected, the lower the reliability factor. Manufacturers usually set cut-off levels for their tests. Thus, if a person has a lower concentration of a drug in their system than the cut-off level, it will register as negative for drug use, although drugs may have actually been used.

The model policy has included the cut-off levels currently prescribed by the federal government as an example.⁴³ Each department should carefully study the drug-screening methods available, and determine which drugs they need to test for and the appropriate cut-off levels.

E. Confidentiality

The model policy requires that all records pertaining to an applicant's or employee's drug-test history remain confidential. This applies to pre-test consent forms, interviews containing lists of prescribed drugs used, preliminary test results, and any other written documentation of the drug test.

These documents cover the type of personal employee information that is considered confidential under most state public record laws. In addition, the stigmatizing aura of drug testing, given for any reason, provides a basis for a due process deprivation of reputation suit, should the information be released. Thus, the model policy specifically states that an employee's drug-testing information cannot be passed on to future employers. To enhance this, release of such information is a disciplinable offense.

All drug-testing records should be kept in a separate, secure file area, in order to ensure confidentiality. The records should be retained as required by state law. Access to the records should be strictly limited to those personnel with an absolute need to know.

V. ACCREDITATION STANDARDS

No accreditation standards on drug testing are available at this time.

Endnotes

¹*Railway Labor Executives v. Long Island R. Co.*, 651 F. Supp. 1284 (E.D.N.Y. 1987); *Fraternal Order of Police (Miami Lodge No. 20) v. City of Miami* Case No. CA-85-041, Public Employees Relations Commission, Florida.

²*Eg., Copeland v. Philadelphia Police Department*, No. 88-66; *NTUE v. Von Raab*, No. 86-1879.

³U.S. Const. Amend. IV.

⁴*Lovvorn v. City of Chattanooga*, —F.2nd—, 3 IER Cases 673 (No. 86-6281, May 23, 1988).

⁵*Feliciano v. City of Cleveland*, 661 F. Supp. 578 (N.D. OH. 1987).

⁶*Id.* at 588.

⁷*Chappelle v. Rice*, —F. Supp.—, 3 IER Cases 1372 (No. 87-C 4494, April 19, 1988).

⁸—U.S. —, 107 S. Ct. 1492 (1987).

⁹*Id.*

¹⁰U.S. Const. Amend. XIV.

¹¹*Cleveland Bd. of Education v. Loudermill*, 470 U.S. 532 (1985).

¹²*Board of Regents v. Roth*, 408 U.S. 564 (1972).

¹³*Capua v. City of Plainfield*, 643 F. Supp. 1507 (D.N.J. 1986).

¹⁴*Copeland v. Philadelphia Police Department*, 840 F.2d 1139 (2nd Cir. 1988).

¹⁵*Bostic v. McClendon*, 650 F. Supp. 245 (N.D. Ga. 1986).

¹⁶*Copeland*, 840 F.2d at 1149.

¹⁷*Id.* at 1147.

¹⁸*Cf., Bonsignore v. City of New York*, 521 F. Supp. 394 (S.D. N.Y. 1981).

¹⁹*Capua*, 643 F. Supp. at _____.

²⁰16A McQuillan, *Municipal Corporations*, Sec. 45.07C (3rd ed.).

²¹*City of Palm Bay v. Bauman*, 475 So. 2d 1322 (Fla. Dist. Ct. App. 1983).

²²*Id.* at 1325.

²³*Cardona v. Ward*, 673 F. Supp. 120 (S.D. N.Y. 1987); *Chappelle*, 3 IER Cases at 1375.

²⁴*Shield Club v. City of Cleveland*, 647 F. Supp. 274 (N.D. OH. 1986) (toxicologist's theory that high concentration of melanin in members of Negro race may invalidate drug tests not proven sufficiently to support adverse impact argument).

²⁵National Institute of Justice, *Police Drug Testing* (May 1987).

²⁶See, e.g., *Turner v. Fraternal Order of Police*, 500 A. 2d 1005 (D.C. App. 1985).

²⁷*Capua*, 643 F. Supp. at _____.

²⁸*Allen v. Passaic County*, 219 N.J. Super. 352 (1986).

²⁹*Louvorn*, 647 F. Supp. at 883.

³⁰*Copeland*, 840 F. 2d at 1144.

³¹*Wrightsell v. City of Chicago*, 678 F. Supp. 727 (N.D. Ill. 1988).

³²*Id.*

³³*Cf.*, *National Treasury Employees Union v. Von Raab*, 816 F. 2d 170 (5th Cir. 1987), *cert. granted*, 108 S. Ct. 1972 (1988).

³⁴Compare, *Caruso v. Ward*, —N.Y. 2d —, No. 216, Slip op. (Oct. 25, 1988) (random testing of narcotics unit members permissible due to their voluntary transfer to position) with *Fraternal Order of Police v. City of Newark*, 216 N.J. Super. 461

(1987) (reasonable suspicion testing only constitutionally permitted type of test).

³⁵*Caruso v. Ward*, —N.Y. 2d at —.

³⁶*Supra* at note 33.

³⁷E.g., *Penny v. Kennedy*, —F.2d. —, 3 IER Cases 692 (No. 86-6280, May 23 (1988)).

³⁸*Shoemaker*, 795 F. 2d 1136 (3rd Cir. 1986), *cert. den.* —U.S. —, 107 S. Ct. 577.

³⁹*Guiney v. Roache*, —F. Supp. —3 IER Cases 598 (D. Mass., May 18, 1988).

⁴⁰*City of East Point v. Smith*, 258 GA. Ill. 365 S.E. 2d 432 (1988).

⁴¹*Shoemaker*, *Supra* at note 41.

⁴²*Policemen's Benev. Assn. of N.J. v. Washington Tp.*, 672 F. Supp. 779, *rvsd*, 3 IER Cases 699 (No. 87-5793, June 21, 1988).

⁴³*Mandatory Guidelines for Federal Workplace Drug-Testing Programs*, 53 Fed. Reg. 11970 (April 11, 1988). These guidelines were promulgated pursuant to President Reagan's Executive Order No. 12564, in which he called for a drug-free America.

Drug Detection Periods

Drug	Category	Detection Period*
Amphetamines	Stimulants	
Amphetamine		2-4 days
Methamphetamine		2-4 days
Barbiturates	Sedative Hypnotics	
Amobarbital		2-4 days
Butalbital		2-4 days
Pentobarbital		2-4 days
Phenobarbital		Up to 30 days
Secobarbital		2-4 days
Benzodiazepines	Sedative Hypnotics	
Diazepam (Valium®)		Up to 30 days
Chlordiazepoxide (Librium®)		Up to 30 days
Cocaine	Stimulants	
Benzoyllecgonine		12-72 hours
Cannabinoids (Marijuana)	Euphoriants	
Casual Use		2-7 days
Chronic Use		Up to 30 days
Ethanol	Sedative Hypnotics	Very short†
Methadone	Narcotic Analgesics	2-4 days
Methaqualone (Quaalude®)	Sedative Hypnotics	2-4 days
Opiates	Narcotic Analgesics	
Codeine		2-4 days
Hydromorphone (Dilaudid®)		2-4 days
Morphine (for Heroin)		2-4 days
Phencyclidine (PCP)	Hallucinogens	
Casual Use		2-7 days
Chronic Use		Up to 30 days

- * Detection periods vary; rates of metabolism and excretion are different for each drug and user. Detection periods should be viewed as estimates. Cases can always be found to contradict these approximations.
- † Detection period depends on amount consumed. Alcohol is excreted at the rate of approximately one ounce per hour.

