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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.

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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 commentors 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 verfication 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 employees 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 urainalysis 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 multispeciality 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 degee 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 commenters 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 commenters 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 commentors 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.

6. Several commentors 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 Schdule 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 commentors 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 commentors 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 sampe is given.

9. Several commentors 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 commentors 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 commentors 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)(6)).

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 commentor 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 commentor 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 commentor 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 commentors 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 commentors 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 commentors 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 commentors 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 where 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.
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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.
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3.9 One-Year Storage for Confirmed Positives.
3.10 Documentation.
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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 intitial 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 immunossay screen to eliminate "negative" urine specimens from further consideration.

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

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

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

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

1.3 Future Revisions.

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

Subpart B—Scientific and Technical Requirements

2.1 The Drugs.

(a) The President's Executive Order 12564 defines "illegal drugs" as those included in Schedule I or II of the Controlled Substances Act (CSA), but not when used pursuant to a valid prescription or when used as otherwise authorized by law. Hundreds of drugs are covered under Schedule I and II and while it is not feasible to test routinely for all of them, Federal drug testing programs shall test for drugs as follows:

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

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

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

(b) Any agency covered by these guidelines shall petition the Secretary in writing for approval to include in its testing protocols any drugs (or classes of drugs) not listed for Federal agency testing in paragraph (a) of this section. Such approval shall be limited to the use of the appropriate science and technology and shall not otherwise limit agency discretion to test for any drugs covered under Schedule I or II of the CSA.

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

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

2.2 Specimen Collection Procedures.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(17) Both the individual being tested and the collection site person shall keep the specimen in view at all times prior to its being sealed and labeled. If the specimen is transferred to a second bottle, the collection site person shall request the individual to observe the transfer of the specimen and the placement of the tamperproof seal over the bottle cap and down the sides of the bottle.

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

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

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

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

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

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

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

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

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

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

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

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

2.3 Laboratory Personnel.

(a) Day-to-Day Management.

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

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

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

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

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

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

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

(B) Appropriate training and/or experience in forensic applications of analytical toxicology, e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors which qualify the individual as an expert witness in forensic toxicology.

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

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

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

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

(7) This individual shall be responsible for taking all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual shall ensure that sample results are not reported until all corrective actions have been taken and he or she can assure that the tests results provided are accurate and reliable.

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

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

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

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

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

2.4 Laboratory Analysis Procedures.

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

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

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

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

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

(d) Specimen Processing. Laboratory facilities for urine drug testing will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its workload. When conducting either initial or confirmatory tests, every batch shall contain an appropriate number of standards for calibrating the instrumentation and a minimum of 10 percent controls. Both quality control and blind performance test samples shall appear as ordinary samples to laboratory analysts.

(e) Initial Test. (1) The initial test shall use an immunoassay which meets the requirements of the Food and Drug Administration for commercial distribution. The following initial cutoff levels shall be used when screening specimens to determine whether they are negative for these five drugs or classes of drugs:

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

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

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

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

	Confirmatory test level (ng/ml)
Marijuana metabolite [1]	15
Cocaine metabolite [2]	150
Opiates:	
Morphine	[3] 300
Codeine	[3] 300
Phencyclidine	25
Amphetamines:	
Amphetamine	500
Methamphetamine	500

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

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

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

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

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

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

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

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

(i) Initial Testing:

(A) Number of specimens received:

(B) Number of specimens reported out: and

(C) Number of specimens screened positive for:

Marijuana metabolites
Cocaine metabolites
Opiate metabolites
Phencyclidine
Amphetamines

(ii) Confirmatory Testing:

(A) Number of specimens received for confirmation;

(B) Number of specimens confirmed positive for:

Marijuana metabolite

Cocaine metabolite
Morphine, codeine
Phencyclidine
Amphetamine
Methamphetamine

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2.5 Quality Assurance and Quality Control.

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

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

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

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

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

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

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

(1) Urine specimens certified to contain no drug;

(2) Urine specimens fortified with known standards; and

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

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

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

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

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

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

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

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

2.6 Interim Certification Procedures.

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

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

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

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

2.7 Reporting and Review of Results.

(a) Medical Review Officer Shall Review Results. An essential part of the drug testing program is the final review of results. A positive test result does not automatically identify an employee/applicant as an illegal drug user. An individual with a detailed knowledge of possible alternate medical explanations is essential to the review of results. This review shall be performed by the Medical Review Officer prior to the transmission of results to agency administrative officials.

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

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

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

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

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

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

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

2.8 Protection of Employee Records.

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

2.9 Individual Access to Test and Laboratory Certification Results.

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

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

3.1 Introduction.

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

3.2 Goals and Objectives of Certification.

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

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

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

3.3 General Certification Requirements.

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

3.4 Capability to Test for Five Classes of Drugs.

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

3.5 Initial and Confirmatory Capability at Same Site.

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

3.6 Personnel.

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

3.7 Quality Assurance and Quality Control.

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

3.8 Security and Chain of Custody.

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

3.9 One-Year Storage for Confirmed Positives.

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

3.10 Documentation.

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

3.11 Reports.

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

3.12 Certification.

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

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

(1) The adequacy of the laboratory facilities;

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

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

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

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

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

3.13 Revocation.

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

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

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

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

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

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

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

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

3.14 Suspension.

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

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

3.15 Notice; Opportunity for Review.

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

receipt requested. This notice shall state the following:

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

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

(3) The period of suspension or proposed revocation.

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

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

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

3.16 Recertification.

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

3.17 Performance Test Requirement for Certification.

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

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

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

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

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

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

3.18 Performance Test Specimen Composition.

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

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

3.19 Evaluation of Peformance Testing.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3.20 Inspections.

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

3.21 Results of Inadequate Performance.

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

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