DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Revised mandatory guidelines.

SUMMARY: The Department of Health and Human Services (''HHS'' or ''Department'') is establishing standards for determining the validity of urine specimens collected under the Mandatory Guidelines for Federal Workplace Drug Testing Programs. These standards ensure that specimen validity testing (SVT) and reporting procedures are uniformly applied to all Federal agency urine specimens when a validity test is conducted.

DATES: *Effective Date:* November 1, 2004.

Comment Date: Submit comments on or before June 14, 2004.

ADDRESSES: You may submit comments, identified by (insert docket number and/or RIN number), by any of the following methods:

- E-mail: *wvogl@samhsa.gov.* Include docket number and/or RIN number in the subject line of the message.
- Fax: 301–443–3031.
- Mail: 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857.
- Hand Delivery/Courier: 5515 Security Lane, Suite 815, Rockville, Maryland 20852.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments will be available for public review at 5515 Security Lane, Suite 815, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Walter F. Vogl, Ph.D., Division of Workplace Programs, CSAP, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, telephone (301) 443–6014, fax (301) 443–3031, or e-mail: *wvogl@samhsa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) establish the scientific and technical guidelines for Federal workplace drug testing programs and standards for certification of laboratories engaged in urine drug testing for Federal agencies, under authority of section 503 of Pub. L. 100–71, 5 U.S.C. 7301 note, and E. O. No. 12564. The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11979), and revised on June 9, 1994 (59 FR 29908), and on November 13, 1998 (63 FR 63483).

The Department is revising the Mandatory Guidelines here concerning the determination of the validity of urine specimens. In another document published along with this revision, the Department is proposing to revise the Mandatory Guidelines again to add alternative specimens, instrumented initial test facilities, and point of collection testing.

The alternative specimen proposal will be subject to a 90-day comment period after which the Department will consider the comments received and issue a final revision. Until the final revision on alternative specimens is issued, the Mandatory Guidelines as contained in this revision govern.

This revision becomes effective 180 days after the date of publication so that laboratories have an opportunity to purchase and become familiar with testing equipment to be used in assessing the validity of a urine specimen.

The revision of the Guidelines is subject to further comment only on the creatinine criterion that is part of the requirement to report a urine specimen as substituted because the Department has based this criterion on information received after the comment period closed on October 22, 2001.

II. Summary of the Proposed Revised Mandatory Guidelines

On August 21, 2001, HHS published a notice in the **Federal Register** (66 FR 43876), proposing that the Mandatory Guidelines be revised to include standards for determining the validity of urine specimens collected by Federal agencies under the Federal Workplace Drug Testing Program. These proposed revisions to the Mandatory Guidelines establish the analytical standards for determining the validity of urine specimens in order to ensure that SVT and reporting procedures are uniformly applied to all Federal agency urine specimens. Set forth below is a description of the major provisions of the proposed revision of the Mandatory Guidelines, including, among other things, definitions for certain terms associated with SVT, a discussion of the specific SVT requirements and how validity testing results should be reported, clarification of the qualifications and responsibilities of a Medical Review Officer (MRO), how a donor may challenge the accuracy of a validity testing result, and an expansion of the existing performance testing program and laboratory inspection program.

Provisions of the Proposed Revisions to the Mandatory Guidelines

1. Definitions

The proposed revisions added definitions specifically associated with specimen validity testing. These include the definitions for adulterated specimen, confirmatory validity test, dilute specimen, initial validity test, invalid result, non-negative specimen, oxidizing adulterant, and substituted specimen.

2. SVT Requirement

The proposed revisions require each Federal agency to have specimen validity tests conducted on all urine specimens collected under the Mandatory Guidelines.

3. Split Specimen Testing

The proposed revisions grant the donor the right to request that a split (Bottle B) specimen be tested to confirm an adulteration or substitution result that was reported by the primary laboratory on the primary (Bottle A) specimen.

4. SVT Reporting Criteria

The proposed revisions add a new section, entitled ''Validity Testing,'' to the Mandatory Guidelines. The new section requires a laboratory to conduct validity testing and establishes the criteria that must be used by a laboratory to report a specimen as adulterated, substituted, invalid, or dilute.

5. Cutoff Levels

The proposed revisions establish a pH cutoff for reporting a specimen as adulterated and establish a creatinine cutoff and a specific gravity cutoff for reporting a specimen as substituted. The creatinine concentration cutoff is proposed to be less than 5 mg/dL. The specific gravity cutoff is proposed to be less than 1.002. The pH cutoff is proposed to be less than 3.

6. Retesting

The proposed revisions require a second laboratory to conduct validity tests when it is unable to reconfirm the drug or drug metabolite that was originally reported positive in a single specimen or primary (Bottle A) specimen. The proposed revisions also add criteria for retesting a specimen for adulterants and substitution.

7. Quality Control

The proposed revisions establish specific quality control criteria and other procedural and test requirements for performing each individual validity test.

8. MRO Qualifications and Duties

The proposed revisions clarify the qualifications and responsibilities of the MRO and expand the MRO's duties to review adulteration, substitution, and invalid test results reported by a laboratory.

9. Donor's Right To Challenge Results

The proposed revisions provide that a donor has the same right to challenge the accuracy of a positive, adulterated, or substituted result reported for a single specimen collection as for a split specimen collection.

10. HHS Notification of Results

The proposed revisions state that an MRO will notify the designated regulatory office that is responsible for the laboratory certification program when a second laboratory fails to reconfirm a positive, adulterated, or substituted result reported by a first laboratory.

11. Performance Testing and Laboratory Inspection Programs

The proposed revisions expand the performance testing program and the laboratory inspection program. The performance testing program will include performance testing samples to challenge each certified laboratory's ability to correctly perform validity tests. The inspection program will include inspecting and evaluating the SVT procedures used by the laboratories in a manner similar to that for all other laboratory operations.

III. Summary of Public Comments and HHS's Response

The August 21, 2001, **Federal Register** notice proposing revisions to the Mandatory Guidelines set forth a 60-day public comment period, ending on October 22, 2001. During the public comment period, the terrorist strikes of September 11 occurred, which have demanded a new focus and resolve from our government and citizens, that continue undiminished to date. Initially, there was concern that the public comment period would need to be extended, or that some comments might be delayed due to temporary disruptions in the delivery of documents. In light of the national emergency, the Department determined that public comments would be considered, even if they were received a few days after the formal ending date. That proved to be unnecessary. The Department received 23 public comments by October 22nd on the proposed changes from Federal agencies, individuals, organizations, laboratories, and companies that were then made available for public view on our Internet Web site (*www.drugfreeworkplace.gov*). All written comments were reviewed and taken into consideration in the preparation of the revised Mandatory Guidelines. Set forth below is an overview of the various comments and recommendations received and the Department's responses to those concerns. Similar comments are considered together.

Over the past several years, there has been an increasing number of chemical adulterants marketed on the Internet and in counter-culture, pro-drug use magazines. These adulterants are advertised as able to prevent laboratories from detecting drugs or metabolites in physiological specimens (*e.g.*, urine, hair, oral fluid) that are collected as part of a drug testing program. These products are often toxic or corrosive and are sold to be added to a specimen in order to mask the presence of any drugs or metabolites. Examples of adulterants include various nitrites (Klear, Whizzies), pyridinium chlorochromate (Urine Luck, LL481, Sweet Pee's Spoiler), surfactant (Mary Jane SuperClean 13), and acid (Amber-13, THC–Free). As of this time, approximately 400 different products (although many contain the same adulterant) are available for adulterating urine specimens.

Even more blatant are recent increases in openly marketed promises to conceal current illicit drug use by substituting a "clean'' urine specimen for the drug-user's "dirty'' one. Some products actually advertise a prosthetic device in a range of skin tones complete with waistband, fluid reservoir, thermocouple heating device, and externally formulated and color-dyed solution marketed as synthetic urine. These devices and systems are targeted for use by individuals who want to conceal their illicit drug use by using such a system to suborn a drug test.

The final requirements that make up the revisions to the Mandatory Guidelines are based on seven years of experience with SVT. These revisions are the collective product of a broad community of medical, forensic, research, and production laboratory testing experts who have contributed their knowledge, determination, and problem-solving skills to address those who would cheat on a drug test.

In reviewing different specimen validity test procedures and methods, the Department learned from mistakes made by participants. The Department corrected these mistakes as they occurred, including making corrections or canceling test results in cases where laboratory inspectors, contractor staff, and Federal program staff were not certain about the ability of a laboratory forensically to defend a test result in court. This approach is a practice the Department will continue.

The Department has established these final requirements for SVT to produce the most accurate, reliable, and correctly interpreted test results. In a national system that has reduced the number of detected adulterated and substituted specimens to the current levels of about three one-hundredths of one percent of all federally mandated workplace tests performed in the past year, some may ask if it is worth the effort to prevent this very small number of individuals from masking their personal use of illicit drugs. The answer is yes. The purpose of the entire program has been to prevent and deter the use of illicit drugs in the Federal workplace. It has been vitally important to always project a sure and certain standard that Federal employees will be held personally accountable regarding employment selection or even job retention should they choose to use illicit drugs.

The Department intends to decrease or remove opportunities to subvert a workplace drug test through these revisions to the Mandatory Guidelines and will seek to hold all individuals accountable for their choices.

1. Mandatory SVT (Paragraph 2.1(a)(4))

The Department specifically requested comments from Federal agencies and employees covered by E.O. 12564 and Pub. L. 100–71 regarding the proposal to require SVT as part of their drug testing programs. Only one Federal agency submitted a comment on this issue. The comment submitted concurred with the proposal to make SVT mandatory on urine specimens collected by all Federal agencies. Because there were no comments submitted by Federal agencies or Federal employees opposed to the proposal, the Department believes it is appropriate to require each Federal agency to make SVT a required part of its workplace drug testing program.

2. Donor Right To Request a Retest of an Adulterated or Substituted Specimen (Sections 2.2(h) and 2.6(e))

One commenter suggested that the proposed requirement for the donor to request a retest on a single specimen or

a test of a split specimen within 72 hours after being notified by the MRO that his or her specimen was reported positive, adulterated, or substituted was insufficient. The 72-hour rule has been in the Guidelines since 1994 and the Department is not aware of any occasion in which the donor was unable to request a test of a split specimen within this time frame. Additionally, MROs have the discretion to extend the 72-hour time frame when necessary. The proposed revision to this section of the Mandatory Guidelines simply expands the donor's ability to request a retest when a specimen is identified as adulterated or substituted. The donor shall be allowed the same ability to request through the MRO a retest of a single specimen that is reported either drug positive, adulterated, or substituted. In cases where a split specimen was collected consistent with agency policy, the donor shall be allowed the same ability to request through the MRO a retest of the split (Bottle B) specimen when the primary specimen is reported either drug positive, adulterated, or substituted. Based on our experience, the Department continues to believe that 72 hours is a sufficient period of time for a donor to request a retest on a single specimen or a test of the split specimen after being notified by the MRO that his or her specimen was reported positive, adulterated, or substituted.

The same commenter also suggested that a Federal agency should have the authority to direct a retest of a single specimen or the test of a split specimen at any time. The Department believes that limiting the ability to request a retest to the donor ensures that each donor is offered the same chance to dispute the reported test results. However, the Guidelines do not preclude a judge from issuing a court order to retest a specimen, an administrative law judge from ordering a retest of a specimen, or a Federal agency from retesting a specimen as part of a legal or administrative proceeding to defend a test result when the donor elected not to request a retest of a specimen reported positive, adulterated, or substituted. A new paragraph 2.6(e)(4) has been included to ensure that a Federal agency may conduct a retest under this limited situation.

3. SVT (Section 2.4(g))

One commenter suggested that it is unnecessary for all laboratories to have the capability to identify and quantitate oxidizing adulterants and recommended establishing a list of laboratories that would specialize in adulteration testing. The Department does not agree with this recommendation. The Department believes that all laboratories must have the capability and actually test all specimens for one or more oxidizing adulterants. This is especially critical for those specimens where a drug test result or other evidence indicates that a specimen may be adulterated. Otherwise, many specimens adulterated with oxidants may simply be reported as negative. This action is consistent with the Federal Workplace Drug Testing Program goal of ensuring an accurate and reliable result on every specimen tested, whether the result is positive or negative for drugs, adulterated, substituted, or invalid.

One commenter suggested there is no value in determining the pH for every specimen because the number of specimens reported with a pH that is too low or too high is extremely low. The Department believes that the elimination of this requirement would allow the use of adulterants that alter the pH causing it to be out of the normal physiological range, and hence interfere with obtaining a valid drug test or adulterant result. Therefore, as was proposed, the revisions to the Mandatory Guidelines shall require that a laboratory determine the pH for every specimen tested.

One commenter suggested the requirement that a laboratory must test a specimen for oxidizing adulterants did not clearly state that the test(s) was to be performed on each specimen. The Department agrees that the statement of the requirement in the proposed revisions was unclear. As a result, paragraph 2.4(g)(4) has been revised to indicate that one or more validity tests for oxidizing adulterants must be performed on each specimen.

One commenter recommended either to define abnormal color or odor or to delete any reference to abnormal physical characteristics as a condition to perform additional validity tests. The Department believes there are physical characteristics that can be used to identify specimens that may require some additional validity tests. However, definitions cannot be developed to specifically describe all the possible abnormal characteristics that may be observed by laboratory personnel. In response to this comment, the parenthetical reference to color, odor, or excessive foaming has been deleted in the Mandatory Guidelines to avoid limiting the possible characteristics that may be used to trigger additional validity tests. Because of the large number of adulterants being marketed to mask the presence of or remove drugs or metabolites from a specimen, the Department fully intends for color, odor, and excessive foaming, among others, to remain as abnormal physical characteristics that can be evaluated at a laboratory and prompt additional testing as specified in paragraph 2.4(g)(5). However, a laboratory may choose not to test the specimen if the laboratory believes that testing the specimen may damage its instruments. For example, a specimen that is gelatinous may possibly clog the tubing used in an immunoassay analyzer, thereby shutting down the instrument and requiring extensive maintenance. In such a case, the laboratory may assume that the urine specimen is not a valid urine specimen and must report an invalid result to the MRO. This invalid result is then used by the MRO to direct the agency to have the donor immediately submit another urine specimen using a direct observed collection. *See* section 2.6(c).

One commenter stated that insufficient data exists to support the proposed requirement that a specimen be reported as an "invalid result'' if validity testing performed on the specimen shows creatinine concentration and specific gravity results that are considered to be inconsistent with normal human physiology. The Department believes that the conditions given for creatinine concentration and specific gravity results that are inconsistent with normal range values indicate possible tampering with the specimen. The requirement to report these inconsistent values as "invalid results'' ensures the collection of another specimen to determine if the donor did provide a valid specimen or, in fact, did tamper with the first specimen collected.

With regard to the proposal to establish the lower specific gravity cutoff as less than 1.002 for the substitution criteria, the Department has reconsidered this proposal and is establishing the specific gravity cutoff as less than or equal to 1.0010. Note that this cutoff is stated to four decimal places. This will retain the specific gravity cutoff that the laboratories have been using since HHS issued guidance for all laboratories in determining the validity of a specimen (Division of Workplace Programs Memorandum dated September 28, 1998, Subject: Guidance for Reporting Specimen Validity Test Results, Program Document #35). At the time the Program Guidance was issued and the proposed changes to the Mandatory Guidelines were published in August 2001, the refractometers that were in use read the values to three decimal places (*i.e.*, 1.001). Since the time that the Department published the proposed

cutoff of less than 1.002, a new series of electronic refractometers have been made available that measure specific gravity to four decimal places. The use of a refractometer that measures specific gravity to four decimal places allows a laboratory to report and display specific gravity values that are within one ten-thousandth from the cutoff rather than being essentially a "yes'' or "no'' answer (that is, 1.000 or 1.001 for a "yes'' answer, 1.002 for a "no'' answer when using a three decimal place refractometer). Therefore, the Department directs that all laboratories must use refractometers that report and display specific gravity to four decimal places. These instruments also have electronic and hard copy reporting peripheral device capability and thus allow machine generated documentation, which recent administrative and legal proceedings have advocated.

After the close of the public comment period, and prior to the publication of a final notice in the **Federal Register** that would have established the criteria used to report a specimen as substituted, the Department became aware of supplemental information from a Congressionally-mandated study by the Department of Transportation (DOT) Federal Aviation Administration (FAA) indicating that the Department's treatment of substitution should be reconsidered. The information was presented at a conference sponsored by the FAA in Tampa, Florida, on February 4–6, 2003, that brought together toxicologists, nephrologists and other physicians, MROs, technical experts in various fields, and HHS and DOT officials. Attendees at the conference generally agreed that it would be appropriate to lower the creatinine criterion that is part of the requirement to report a urine specimen as substituted. This information lead DOT to publish an interim final rule in the **Federal Register** (68 FR 31624) on May 28, 2003, that changed the way MROs were expected to interpret substitution results reported by the laboratories.

This supplemental information strongly suggested that if the Department adopted the proposed cutoffs as written, in rare, but very real circumstances, it might be possible to misidentify an individual as providing a substituted specimen, when in fact the specimen was actually produced by the individual. To date, to the best of our knowledge, there have not been any Federal employees who have raised a challenge to the specific creatinine decision point of less than or equal to 5 mg/dL *and* specific gravity less than or equal to 1.001 or greater than or equal to 1.020 as defining a "substituted specimen.'' After careful consideration of the supplemental information, the Department believes that it is appropriate to propose lowering the creatinine decision point to identify a substituted specimen to less than 2 mg/dL and specific gravity to less than or equal to 1.0010 or greater than or equal to 1.0200. With regard to the proposal in August 2001 to establish the lower specific gravity cutoff as less than 1.002 for the substitution criteria, the Department has reconsidered this proposal and is requiring to establish the specific gravity cutoff as less than or equal to 1.0010. Note that this cutoff is now stated to four decimal places. This will retain the specific gravity cutoff that the laboratories have been using since HHS issued guidance for all laboratories in determining the validity of a specimen (Division of Workplace Programs memorandum dated September 28, 1998, Subject: Guidance for Reporting Specimen Validity Test Results, Program Document #35). At the time the Program Guidance was issued and the proposed changes to the Mandatory Guidelines were published in August 2001, the refractometers that were in use read the values to three decimal places (*i.e.*, 1.001). Since the time that the Department published the proposed cutoff of less than 1.002, a new series of electronic refractometers have been made available that measure specific gravity to four decimal places. Therefore, the Department is requiring that all laboratories must use refractometers that report and display specific gravity to four decimal places. These instruments also have electronic and hard copy reporting peripheral device capability and thus allow machine generated documentation, which recent administrative and legal proceedings have advocated.

4. Reporting Results (Section 2.4(h))

Three commenters expressed concern that the same test could be used for both the initial and confirmatory validity tests. The commenters believe that the initial validity test should use a different analytical methodology than the confirmatory validity test before a specimen can be reported adulterated or substituted. The Department agrees with the commenters' recommendation that initial and confirmatory validity tests use a different analytical methodology and has revised the reporting policy for adulterants to require that two different methods are used before a specimen can be reported as adulterated. If a laboratory uses the same test (*e.g.*, the same colorimetric test) for both the initial test and the confirmatory test, the laboratory may only report an "invalid result'' for a specimen rather than an adulterated result. Paragraph 2.4(h)(4) clearly describes the combination of methods that a laboratory must use to report a specimen as adulterated for a specific adulterant. The only exceptions to this requirement pertain to the tests used to measure the creatinine concentration, specific gravity, and pH.

To report a specimen as adulterated because the pH is too low or too high, a pH meter may be used for both the initial and confirmatory pH tests because it is considered a reference method by the scientific community, is a highly reliable instrument, and gives extremely accurate results when properly calibrated. Further, pH values represent a logarithmic scale and therefore represent very large differences between each pH unit. Based on this assessment, using a pH meter for both the initial and confirmatory pH tests is scientifically and forensically valid.

The Department believes it is scientifically acceptable to use the same creatinine test for both the initial and confirmatory creatinine tests and to use refractometry to measure specific gravity for both the initial and confirmatory specific gravity tests. For creatinine, the most accepted method to determine the creatinine concentration is the Jaffe' or modified Jaffe' colorimetric procedure. In addition, any endogenous substance that may interfere with the creatinine colorimetric test is going to produce a reading such that the creatinine concentration will appear to be higher rather than lower than the true creatinine concentration. In other words, interfering compounds will increase the creatinine concentration, raising it above 2 mg/dL, and therefore the specimen will not meet the criteria to report it as substituted. As of this time, the Department does not know of any endogenous interfering substance that will lower the apparent reading on the colorimetric creatinine test. Therefore, the Department believes it is acceptable to use the same colorimetric creatinine test for both the initial and confirmatory tests.

With regard to using refractometry for both specific gravity tests, a refractometer, like a pH meter, is considered a reference instrument and its results are scientifically acceptable. Therefore, the Department believes it is acceptable to use refractometry for both specific gravity tests. Moreover, the combination of specific gravity and creatinine serves as two tests employing different scientific principles.

A valid scientific identification is based on the use of two methods used on two separate aliquots obtained from the original urine specimen. The nature of the analytical method is based on the chemical composition of the substance to be tested. Further, the combination of techniques is a function of both the expected prevalence of the substance to be tested and the nature of the analytical technique. This may be illustrated by the following examples:

(1) For drugs, drugs are tested by immunoassay on the first aliquot. Each immunoassay test has variable specificity for a particular drug class. The gas chromatography/mass spectrometry (GC/MS) confirmatory drug test is specific for a particular drug or metabolite. The presence of drugs is not expected in a urine specimen. While the number of drugs to be identified in a urine specimen is limited to those specified by these Guidelines, the number of drugs to be excluded comprises a long list.

(2) For creatinine, creatinine is tested by colorimetric assays using the same assay in each of two aliquots. The presence of creatinine in urine is expected. Its concentration is normally expected to be relatively high and it is among a very small number of waste products found in urine.

(3) For alcohol, although not part of the Federal workplace drug testing program, a breath sample is initially tested on an approved device and, if positive, a confirmatory test is conducted using the same approved device on a second breath sample. The most common of the breath devices utilizes a fuel cell in which the alcohol is consumed resulting in a proportional electronic response. Alcohol is a volatile substance and although not expected to be present in the breath, is among a very short list of possible substances. The concentration of alcohol, when present in the body, is relatively very high.

The three examples constitute valid scientific and forensic identification although there is variation in the analytical parameters and expected prevalence of the substances in biological specimens. Program Documents 35 and 37 issued by HHS in 1998 and 1999 established the framework for reporting a specimen as substituted and adulterated. This framework included an analysis on two aliquots with various qualitative and quantitative procedures. Each laboratory had the flexibility to develop the specific testing requirements, to validate the methods used, and to establish quality control procedures using good laboratory practices. This generally stated scientific approach has been recommended since the inception of this program.

Our on-going review of specimen validity test results and inspection of laboratories has shown analysis to date to be competent and reasonable and to have met satisfactory scientific criteria. Results of these specimen validity tests have also been introduced and effectively been supported in legal proceedings. The Department conducted a special review of SVT in all certified laboratories. This included analysis for adulterants where the same test was used on two different aliquots of the donor's specimen. Based on program experience and availability and development of refined analytical procedures, the Department is establishing specific requirements for analytical procedures to identify the common adulterants. *See* section 2.4(h).

One commenter recommended reporting any specimen with a nitrite concentration between 200 mcg/mL and 500 mcg/mL as an "invalid result.'' The Department agrees with this recommendation and has changed the Guidelines at paragraph 2.4(h)(7)(iii) to include a nitrite range as one of the conditions upon which a specimen must be reported as an "invalid result.'' Although a 500 mcg/mL nitrite concentration is established as the concentration at or above which a specimen is reported adulterated for nitrite, clinical evidence (*see* Urry, F.M. *et al.*, Nitrite Adulteration of Workplace Urine Drug Testing Specimens. 1. Sources and Associated Concentrations of Nitrite in Urine and Distinction Between Natural Sources and Adulteration, "Journal of Analytical Toxicology'' 22: 89–95 (1998)) indicates that any nitrite concentration above 129 mcg/mL is not physiologically possible and is, therefore, an abnormal concentration. The Department also notes that since Program Documents 35 and 37 were issued in 1998 and 1999 and the proposed Changes to the Mandatory Guidelines were published in August 2001, some adulterant products now contain lower amounts of nitrite mixed with other oxidant compounds in an effort to avoid detection.

5. Retesting a Specimen for Adulterants (Section 2.4(k))

One commenter suggested deleting any reference to limit of quantitation (LOQ) when a second laboratory is retesting a specimen for any adulterant other than when retesting for pH or to reconfirm the presence of nitrite. The commenter suggested that the retesting should use the limit of detection (LOD) as is used when retesting a specimen for a drug positive to ensure consistency between the retesting policy for drugs and the policy for retesting adulterants. The Department agrees with the recommendation and has specified using the LOD to reconfirm the presence of an adulterant except when retesting for pH and nitrite. However, the retesting for an adulterant requires the second laboratory to use its confirmatory test for the adulterant that was reported present in the single or Bottle A specimen by the first laboratory. For example, reconfirming a pH that was too low or too high requires the second laboratory to test an aliquot of a single specimen or the split (Bottle B) specimen using its confirmatory pH meter test. Another example, reconfirming the presence of chromium (VI) requires the second laboratory to test an aliquot of a single specimen or the split (Bottle B) specimen using its confirmatory test to determine the presence of chromium (VI) above the LOD. The second laboratory cannot use its initial colorimetric test to reconfirm the presence of chromium (VI).

6. Quality Control Requirements for Validity Tests (Section 2.5(d))

One commenter suggested that the Mandatory Guidelines should specify what the reference method is for each type of validity test. The Department believes that the methods being used for the various validity tests, with the exception of the pH meter, do not meet the classical definition of a reference method (*i.e.*, a method to which other tests are compared). The Department views it as more important that the performance characteristics of the method used for each type of validity test can be documented by the laboratory prior to using the method, as is the case for the drug tests used by the laboratories. Establishing the performance characteristics of a method prior to its use ensures that the method can provide accurate measurements on donor specimens which are verified by simultaneously obtaining results for quality control samples. If the quality control samples results indicate a possible error, then all specimens associated with those quality control samples must be retested until the quality control sample results satisfy the acceptance criteria established by the laboratory.

One commenter suggested that the proposed number of calibrators and controls is excessive for some of the validity tests. The Department believes that the proposed quality control requirements for the validity tests are appropriate and are similar to those required for the initial and confirmatory

drug tests. Since the results of validity tests can lead to the same personnel actions that may occur as if the specimen was reported positive for a drug, it is essential that every effort is made to ensure the accuracy and reliability of every validity test result.

7. Requirements for Measuring Creatinine Concentration (Section 2.5(e))

One commenter suggested that requiring calibrators at 5 mg/dL and 20 mg/dL for a creatinine test requires an unnecessary re-validation of the test and that a control in the normal range (greater than 20 mg/dL) is useful. The Department proposed using calibrators at 5 mg/dL and 20 mg/dL because most creatinine tests are calibrated at 100 mg/dL. Since the decision points for our workplace drug testing program are so much lower than used for most clinical laboratory testing, it is essential that the method be validated and calibrated at 2 mg/dL to ensure the highest degree of accuracy and confidence around the decision point used to determine a substituted specimen. With regard to including a control in the normal range, the commenter overlooked the fact that a control in the normal range was included in the requirements for the initial creatinine test. Given an initial creatinine test result at less than the 2 mg/dL cutoff concentration, there is no need to run another control in the normal range for the confirmatory test. However, controls are needed above and below 2 mg/dL to ensure the highest degree of accuracy and confidence around the cutoff.

8. Requirements for Measuring Specific Gravity (Section 2.5(f))

One commenter stated that the requirement for four quality control samples when determining specific gravity is excessive. The commenter suggested simply including one calibrator at each decision point and one control in the normal range. The Department believes that a decision point must be bracketed whenever possible to ensure the accuracy of a test result rather than using the approach recommended by the commenter. Since the time the proposed policy was published, the Department has re-evaluated the control requirements for measuring specific gravity. The Department believes that each initial and confirmatory specific gravity test should have a calibrator and controls covering the entire range rather than selecting controls based on whether the specimen is being evaluated against the lower decision point (*i.e.*, less than or equal to 1.0010) or the higher decision point (*i.e.*, greater than or equal to 1.0200). Therefore, the Department has combined the controls that are required when conducting either the initial or confirmatory specific gravity tests regardless of which decision point is applicable.

9. Requirements for Measuring pH (Section 2.5(g))

One commenter suggested that, when determining pH levels, a control in the normal range should also be included. The Department agrees with this suggestion and is requiring that either a calibrator or control in the normal range be included in each test batch when conducting either the initial or confirmatory pH test.

One commenter noted that the controls proposed for a colorimetric pH test are inconsistent with the controls required for a pH meter test. The Department believes that this inconsistency cannot be eliminated due to the differences in the way colorimetric pH tests and pH meters are calibrated.

Section 2.5(g) has been revised to require the use of three controls when using a pH screening test (*i.e.*, pH paper, dipsticks, or colorimetric tests that have a narrow dynamic range and do not support the pH cutoffs) to determine if the pH of a specimen is too low or too high. This section also specifies the calibrators and controls that must be used if an initial colorimetric pH test or initial pH meter test is conducted without having used a screening test to determine if the pH of a specimen may be too low or too high. Additionally, the Department believes that when a pH screening test is used and the pH of the specimen is possibly too low or too high, the initial and confirmatory pH meter tests may use calibrators and controls that are focused on either the lower or upper decision point, as appropriate. This is a reasonable approach because pH meter tests are manual rather than automated. However, an exception exists when a colorimetric pH test is used as the initial pH test whether a screening pH test was or was not conducted. The Department believes that most laboratories will use an initial colorimetric pH test to test all specimens received, rather than using screening tests, because it is an automated procedure and would be efficient and cost effective compared to using pH screening tests or a "manual" pH meter test. To avoid having to repeat the colorimetric pH test with focused calibrators and controls only for those specimens that may have a pH that is too low or too high, the entire pH range should be covered with appropriate calibrators and controls.

10. Requirements for Performing Oxidizing Adulterant Tests (Section 2.5(h))

Several commenters expressed concern with the proposed requirements for performing oxidizing adulterant tests. There was a general request for more specific information and a concern that these oxidizing tests fail to meet appropriate scientific standards. The Department agrees that the proposed requirement for performing oxidizing adulterants was unclear. Therefore, the Department has revised the requirements described in section 2.5(h). The Department expects each laboratory to test each specimen for one or more oxidizing adulterants. This can be accomplished by either using a single test that responds to several oxidizing adulterants (*e.g.*, a general oxidant colorimetric test for the initial test for oxidizing adulterants) or one or more initial tests that identify specific oxidizing adulterants (*e.g.*, an initial nitrite colorimetric test, an initial chromium (VI) colorimetric test). Additionally, the Department is permitting the general oxidant colorimetric test to be used with different calibrators or controls to possibly detect different adulterants. For example, the general oxidant colorimetric test can be used to detect nitrite using a calibrator or control with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff or to detect chromium (VI) using a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff. Since individuals attempting to subvert the drug testing program may use a number of different oxidizing adulterants, the testing requirement for oxidizing adulterants is intentionally drafted broadly to permit the flexibility needed to combat such tampering with the testing process. Although these oxidizing adulterant tests are new, the Department expects the laboratories to validate each oxidizing adulterant test before it is used to test donor specimens and to apply the specified quality control requirements to ensure the proper performance of each test on donor specimens.

11. Requirements for Performing "Other" Adulterant Tests (Section 2.5(j))

One commenter suggested that the proposed requirement for the performance of "other" validity tests for adulterants did not permit the flexibility necessary to ensure that as new adulterants are identified, the Mandatory Guidelines would permit

laboratories to test for these new adulterants. The Department agrees with that comment and has revised paragraph 2.5(j)(3) to ensure that newly identified adulterants not included in paragraphs 2.5(j)(1) or (2) or in any other section of the Mandatory Guidelines can be tested for by a laboratory.

One commenter asked if a specimen containing glutaraldehyde could be reported as adulterated based on using the confirmatory test procedure on two separate aliquots. The revision to the Mandatory Guidelines requires that a specimen can only be reported adulterated for glutaraldehyde if the initial and confirmatory glutaraldehyde tests use different methodologies. For glutaraldehyde, the characteristic response on immunoassay drug tests is very well established and may serve as the initial test for determining the presence of glutaraldehyde or by performing a separate initial aldehyde test. The confirmatory test for glutaraldehyde traditionally has been gas chromatography/mass spectrometry.

12. MRO Qualifications and Review of Results (Section 2.6)

One commenter recommended that the Mandatory Guidelines be revised to require an MRO to complete formal training and pass an examination, as required in the DOT Procedures for Transportation Workplace Drug and Alcohol Testing Program (49 CFR Part 40). The Department recognizes that other changes to the Mandatory Guidelines may be needed; however, our intent in the solicitation of comment was to focus only on proposing changes associated with mandating validity testing on specimens collected under the Mandatory Guidelines.

One commenter expressed concern that an MRO may direct a laboratory to send a specimen to another laboratory before determining that the second laboratory has the capability to perform any additional tests. The Department agrees that an MRO should always contact a laboratory to determine its capability before having a specimen transferred for additional validity testing. This policy applies especially to paragraph 2.6(c)(2) when Laboratory A reports an invalid result and the laboratory and MRO agree that further testing may be useful in an attempt to be able to report a positive, adulterated, or substituted result.

13. Laboratory Result Not Reconfirmed by a Second Laboratory (Section 2.6(g))

One commenter interpreted the proposed requirement that the MRO notify the designated HHS regulatory office when a second laboratory was unable to reconfirm the result reported by the original laboratory testing the specimen as meaning that the MRO is not receiving the same notification. The agency's designated representative always receives all results reported by an MRO. This requirement is intended to ensure that the HHS regulatory office is notified of such reports to permit the initiation of an investigation to determine if an error was made by either laboratory.

14. Additional Changes Related to the New SVT Requirements

In addition to the changes discussed above, the Department is revising other sections of the Mandatory Guidelines that are directly affected by the new SVT requirements.

In section 1.2, the original definitions for an "initial test'' and a "confirmatory test'' are being changed to read "initial drug test'' and "confirmatory drug test,'' respectively, to prevent any confusion with the new definitions for "initial validity test'' and "confirmatory validity test.'' The Department is adding the word "drug'' throughout the Mandatory Guidelines when referring to initial drug tests and confirmatory drug tests.

Under section 2.2(f)(4), the collector must direct the donor to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the donor places the items back into his or her pockets and the collection procedure continues. If the donor refuses to show the collector the items in his or her pockets, this is considered a refusal to cooperate in the testing process. The Department believes this requirement is necessary because of the ease with which a donor can conceal a small amount of an adulterant and the availability of numerous adulterants on the Internet and in drug culture magazines. This change also ensures consistency with the collection procedure specified in the DOT drug testing regulations (49 CFR Part 40). The Department believes that every effort must be made to prevent a donor from bringing something to the collection site that could be used to adulterate a specimen and, thereby, preventing it from being properly tested for drugs.

Section 2.4(h)(2) was revised to ensure that each specimen is subject to validity testing to determine that it is a valid urine specimen before a negative result is reported.

Section 2.2(h)(8) was deleted because it only deals with the testing of a split (Bottle B) specimen that failed to reconfirm a positive drug result reported for Bottle A.

In section 2.4(h), the Department included all the reporting requirements to report a specimen adulterated, substituted, diluted, or as an invalid result in paragraphs (4), (5), (6), and (7).

A new section 2.4(h)(12) was included to require a laboratory to report on the Federal CCF and/or computer-generated electronic report the actual numerical value (*e.g.*, concentration) associated with an adulterated specimen (when applicable) and the confirmatory creatinine concentration and the confirmatory specific gravity for a substituted specimen. The Department believes that this requirement will eliminate the need for an MRO to generate a separate written request, thereby reducing the paperwork associated with each adulterated and substituted specimen.

Section 2.4(h)(15) was revised to require each laboratory to provide a statistical summary report every six months rather than monthly to a Federal agency. The format for the report was also changed to include the provision for information on adulterated, substituted, and invalid specimens. The Department believes reducing the frequency of the report to a semi-annual basis is cost effective and avoids requiring laboratories to report a summary for several specimens as opposed to a more reasonable number that would be tested over a six-month period of time. Both of these changes are consistent with the requirements in the DOT drug testing regulations (49 CFR Part 40).

In sections 2.4(i) and 3.9, the requirement to retain positive specimens in long-term storage is expanded to include specimens reported as adulterated, substituted, and invalid. Because administrative and/or legal actions may be taken that relate to specimens with these results, it is imperative that they be retained frozen and available for possible future retesting.

In section 2.4(j), the retesting policy for drugs has been expanded. If a second laboratory fails to reconfirm the presence of a drug when retesting a single specimen or testing a split (Bottle B) specimen, the second laboratory is required to conduct validity tests in an attempt to determine a reason for failing to reconfirm the presence of the drug or metabolite.

Sections 2.5(k)(1) and (3) have been revised to require that an agency blind sample program includes samples that are adulterated or substituted along with negative samples and drug positive samples. This requirement ensures that

a laboratory's procedures are challenged with samples that are adulterated or substituted.

Section 2.6, where appropriate, has been revised to describe how an MRO is expected to review adulterated, substituted, and invalid results as well as drug positive results.

Sections 2.6(g)(1) through (16) give specific requirements on how an MRO reports a result to a Federal agency when Laboratory B fails to reconfirm the test result reported by Laboratory A. The Department believes these requirements are necessary to ensure uniformity among MROs when a failed to reconfirm occurs.

Section 2.6(h) has been revised to describe how an MRO shall report a final test result to a Federal agency.

Section 3.4 has been revised to ensure that each laboratory has the capability to test for the five required classes of drugs as well as to conduct validity tests as specified in these Mandatory Guidelines.

Section 3.5 has been revised to clarify that all drug and validity tests are to be conducted by a certified laboratory at the same facility.

Sections 3.17, 3.18, and 3.19 have been revised to clearly distinguish between performance testing (PT) samples that contain drugs and PT samples that will challenge a laboratory's specimen validity tests. In the proposed changes to the Mandatory Guidelines, a revision was proposed to section 3.2 to indicate that laboratories would be challenged with specimen validity samples in the PT program and inspections would include reviewing validity testing procedures. The Department believes the specific performance requirements for the samples challenging a laboratory's specimen validity tests are comparable to the requirements for the performance testing with samples containing drugs or metabolites.

15. Other Changes

The Department is making several technical changes and/or clarifications to other sections of the Mandatory Guidelines. Several of these changes reflect policies or procedures that have been previously implemented. The Department believes it is appropriate to include these changes in this revision of the Guidelines.

The term "collection site person'' is being replaced with the term "collector'' throughout the Mandatory Guidelines. The Department is making this change because the use of the term "collector'' has become the most common way to refer to the individual involved with collecting a specimen from a donor.

The term "specimen chain of custody form'' is being replaced with the term "Federal drug testing custody and control form'' (or "Federal CCF'') throughout the Mandatory Guidelines. This is the official name given to the form approved by the Office of Management and Budget (OMB) to collect a urine specimen from a Federal employee.

The definition for "chain of custody'' has been revised to clarify that it refers to a "process'' that is used to track the handling and storage of specimens rather than "procedures'' and deleted the sentences that reference the OMB form because the Federal CCF is defined separately.

Section 2.2(g) was revised because the current Federal CCF does not allow a collector to transfer the custody of a specimen to another individual prior to releasing the specimen to an express carrier or courier for shipment to a laboratory. In addition, the first sentence requiring the collector to maintain the specimen bottle within sight is redundant with the requirement in paragraph 2.2(f)(17) as revised and was deleted.

Section 2.4(b)(2) was revised to clearly describe the types of errors that may occasionally occur on a Federal CCF and/or specimen bottle label/seal that are considered to be fatal flaws. These errors require a laboratory to stop the testing process and to report the result as rejected for testing. Paragraph 2.4(b)(3) was added to describe two types of correctable flaws that, if not corrected, would also require the laboratory to report a specimen as rejected for testing. Provisions similar to these were originally implemented by Program Document #9 (October 10, 1991). The Department believes including these provisions in the Guidelines will ensure uniform treatment by laboratories when these types of errors occur. The provisions are also consistent with those contained in the DOT drug testing regulations (49 CFR Part 40).

Section 2.4(f)(1) was revised to allow a laboratory to report a quantitative drug test result three different ways. The Department believes that a laboratory should have the option to report a quantitative result as either "exceeds the linear range of the test,'' "greater than or equal to (specify the upper limit of linearity),'' or as an accurate quantitative result obtained by diluting an aliquot of the specimen before conducting the confirmatory drug test.

Section 2.4(h)(13) and (14) were revised to describe the different ways results can be transmitted from a laboratory to an MRO. A laboratory always completes the test result section on the Federal CCF; however, a copy of the Federal CCF may or may not be sent to the MRO depending on whether the test result is negative or non-negative. For a negative result, an electronic report is sufficient. The Department believes the reporting requirements in these two sections will reduce the paperwork burden and is consistent with the intended use of the five-part Federal CCF.

A new section 2.4(h)(11) was included to require a laboratory to report to an MRO a quantitative value for morphine or codeine that is greater than or equal to 15,000 ng/mL. Section 2.6(d) was also revised regarding the policy that an MRO must follow when verifying a donor specimen as positive for morphine or codeine when the concentration is at or above 15,000 ng/mL. The Department believes that a morphine or codeine concentration at or above 15,000 ng/mL is high enough to prevent falsely accusing an individual of opiate abuse who may have only eaten poppy seeds or falsely accusing an individual who does not exhibit any clinical evidence of opiate abuse and does not provide a legitimate medical explanation. These revisions are also consistent with the laboratory reporting and MRO verification policies in DOT 49 CFR Part 40.

Section 2.4(h)(14) was revised to clarify that a laboratory may report all test results by faxing a completed copy of the Federal CCF, sending a completed copy of the Federal CCF by courier or mail, electronically transmitting a legible image or copy of the completed Federal CCF, and/or may forward a computer-generated electronic report. The Department believes that revising this paragraph clarifies the point that sending a computer-generated electronic report does not prohibit a laboratory from also sending a completed Federal CCF by one of the other ways described. The section also requires that a copy of the completed Federal CCF must be transmitted by one of the ways described for a non-negative result (*i.e.*, a computer-generated electronic report is not sufficient, by itself, when a laboratory reports a non-negative result to the MRO).

Sections 2.5(b) and (c) were revised to modify the general quality control requirements for the initial drug and confirmatory drug tests. The current Guidelines require including "positive control(s) fortified with drug or metabolite'' and "at least one positive control with the drug or metabolite at or near the threshold (cutoff).'' These two requirements can actually be satisfied using a single control, which was not

the intent of the requirements. The use of the original phrase "at or near the threshold (cutoff)'' is too vague and allows different interpretations. The Department believes the revised requirements will ensure consistency by stating that each initial drug test batch shall include a control targeted at 25 percent above the cutoff and a control targeted at 75 percent of the cutoff. The revised requirements in these two sections have been described in other NLCP program documents for several years and placing them in the Mandatory Guidelines eliminates possible misinterpretation.

A new section 2.5(c)(4) was added to require a laboratory to include in each confirmatory drug test batch at least one calibrator or control at or below 40 percent of the cutoff. Prior Department policy required a laboratory to include such a calibrator or control only when the confirmatory drug test batch contained an aliquot of a single specimen or a split (Bottle B) specimen received from a different laboratory for confirmatory drug testing. The Department believes including a calibrator or control at or below 40 percent of the cutoff in each confirmatory drug test batch is appropriate to ensure that the laboratory documents the accuracy of the confirmatory drug test below the cutoff for each confirmatory drug test whether it contains or does not contain such a specimen received from a different laboratory. This has been clarified in other program documents and ensures that a uniform policy exists in all laboratories.

Section 3.20 has been revised to provide that the number of inspectors on an inspection team can be two or more rather than the three previously specified for any inspection. In practice, the number of inspectors on an inspection team has varied depending on the size of the laboratory. This change was implemented several years ago because the consolidation and growth of several laboratories caused a significant increase in their workloads, and these increases made it difficult for inspectors to review a sufficient number of non-negative test results in the time allotted. By changing the number of inspectors for different sized laboratories, the percentage of non-negative test results reviewed by the inspection teams remains somewhat comparable between the different sized laboratories. Currently, there are several very small laboratories, and using two inspectors is clearly sufficient to conduct a thorough review of the laboratory's procedures and test results. Conversely, several very large laboratories have workloads that require more inspectors to conduct a thorough review of both their procedures and test results. The Department believes this change is fair, equitable, and cost effective for all the laboratories.

Other appropriate minor editorial changes are being made for clarity and consistency.

16. List of Adulterants

In accordance with the **Federal Register** notice (66 FR 43876) dated August 21, 2001, the Department will begin including a list of known adulterants in the monthly **Federal Register** notice that lists the laboratories that meet minimum standards to engage in urine drug testing for Federal agencies. The list will be revised as new adulterants are identified.

Executive Order 12866: Economic Impact

In accordance with Executive Order 12866, the agency has submitted the Guidelines for review by the Office of Management and Budget. However, because the Mandatory Guidelines will not have an annual impact of $100 million or more, and will not have a material adverse effect on the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, they are not subject to the detailed analysis requirements of Section 6(a)(3)(C) of Executive Order 12866.

Paperwork Reduction Act of 1995

These guidelines contain information collection provisions which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA)(44 U.S.C. 3507(d)). The title, description and respondent description of the information collections are shown in the following paragraphs with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Description: The Mandatory Guidelines for Federal Workplace Drug Testing Programs establish the scientific and technical guidelines for Federal Workplace drug testing programs and standards for certification of laboratories engaged in urine drug testing for Federal agencies under authority of section 503 of Public Law 100–71, 5 U.S.C. 7301 and Executive Order 12564. These revisions to the Mandatory Guidelines do not change the information collection requirements in them.

The Mandatory Guidelines establish the standards for a National Laboratory Certification Program (NLCP), which include requirements for a laboratory to become certified and to maintain certification. Prior to the initial certification process, each interested laboratory is required to submit an application to the NLCP contractor for review and evaluation.

Certified laboratories are inspected every six months. Prior to each maintenance inspection, the laboratory receives and completes a copy of Sections B and C of the NLCP inspection checklist. The information submitted by the laboratory allows the members of the inspection team to become familiar with a laboratory's procedures before arriving at the laboratory to conduct the inspection, thereby facilitating the completion of the inspection.

The Mandatory Guidelines require certified laboratories to maintain information concerning quality assurance and quality control, security and chain of custody, documentation, to report test results in accordance with the specifications, and to participate in a performance testing and inspection program. In addition, there are procedures that are used to review the suspension or proposed revocation of a certified laboratory.

The Mandatory Guidelines also require using an OMB-approved Federal custody and control form (CCF) to document the integrity and security of a urine specimen from the time it is collected until received by the laboratory.

Description of Respondents: Individuals or Households; Business or other for-profit; Not-for profit institutions.

Response burden estimate: We estimate the total annual response burden imposed by the Mandatory Guidelines to be 1,786,839 hours. This is comprised as follows: (1) A laboratory is estimated to require an average of 3 hours to complete the NLCP Application form. An average of 3 laboratories apply each year, resulting in an annual estimate of 9 hours of response burden. (2) Sections B and C of the NLCP Inspection Checklist, which average 3 hours to complete, must be completed in advance of each of the 2 annual inspections. Based on 50 certified laboratories undergoing 2 maintenance inspections each year, the annual estimated response burden for the NLCP Inspection Checklist is 300 hours. (3) Recordkeeping, reporting and

disclosure burden for each laboratory is estimated at 250 hours per laboratory per year, for an annual total of 12,500 hours for 50 laboratories. This estimate includes the following:

Section	Topic
Recordkeeping	
2.3(a)(4)*	Responsible person at laboratory documents in-service training of personnel.
2.3(a)(5)* and 2.4(q)(1)*	Maintain manual of all procedures used and dates they were in effect.
2.3(a)(6)* and 2.5(a)*	Documentation of quality assurance program.
2.3(f)*	Specifies contents of laboratory personnel files.
2.4(a)(1)*	Requires documentation of laboratory visitor access.
2.4(a)(2)* and (b)(4)*	Requires use of laboratory chain of custody form by personnel conducting tests.
2.4(h)(17)*	Requires specimen records to be maintained for two years.
2.4(p)*	Requires two year retention of documentation of all aspects of testing process.
2.5(k)(6)	Requires documenting retesting when false positive error occurs on blind performance testing sample.
Reporting	
2.2(c), 2.2(f)(8) and 2.2(f)(14)	Require use of Federal CCF by collector and specify things to note on it.
2.4(h); 3.17(f)	Specifies reporting of test results from laboratory to Medical Review Officer (MRO); specifies same reporting method for performance testing samples.
2.4(h)(15)	Specifies contents of periodic laboratory summary statistical report to Federal agency.
2.6(h)(1)	Specifies MRO reporting of final test results to Federal agency using Federal CCF.
3.17(f)	Specifies laboratory reporting of performance test samples.
4.4 and 4.5(a)	Specify contents of laboratory request for official review of suspension/proposed revocation of certification.
4.6	Requires appellant notification to reviewing official at end of abeyance period.
4.7(a)	Specifies contents of appellant review submission.
4.9(a) and (c)	Specify contents of appellant expedited review file.
Disclosure	
3.4	Requires laboratories to notify non-regulated private-sector employers/clients when testing specimens not under Guidelines.

Note: Activities designated by an * are considered to be usual and customary business practices for such laboratories and no additional burden is considered to be imposed by these requirements.

(4) There are an estimated 7,096,000 Federal CCFs completed each year, with an average response burden of 5 minutes for the donor, 4 minutes for the collector, 3 minutes for the laboratory, and 3 minutes for the Medical Review Officer. This results in 1,419,200 hours of burden.

Individuals and organizations may submit comments on these burden estimates or any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to: SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

The information collection provisions in the Mandatory Guidelines have been approved under OMB control number 0930–0158. This approval expires July 31, 2006. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Charles G. Curie,

Administrator, SAMHSA.

Dated: April 2, 2004.

Tommy G. Thompson,

Secretary.

The Mandatory Guidelines as revised are hereby adopted in accordance with section 503 of Public Law 100–71 and Executive Order 12564. For the public's convenience, the full version of the Mandatory Guidelines as revised is provided. It includes the new validity testing requirements as well as the changes to the opiate cutoff concentrations that became effective on December 1, 1998 (63 FR 63483).

Mandatory Guidelines for Federal Workplace Drug Testing Programs

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

Subpart A—General

Section 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) 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.

(c) 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.

(d) These Guidelines do not apply to drug testing conducted under legal authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as arrestees, detainees, probationers, incarcerated persons, or parolees.[1] (e) 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.

(f) Agencies shall purchase drug testing services only from laboratories certified by HHS or an HHS-recognized certification program in accordance with these Guidelines.

Section 1.2 Definitions

For purposes of these Guidelines, the following definitions are adopted:

Aliquot. A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen.

Adulterated Specimen. A urine specimen containing a substance that is not a normal constituent or containing an endogenous substance at a concentration that is not a normal physiological concentration.

Calibrator. A solution of known concentration used to calibrate a measurement procedure or to compare the response obtained with the response of a test specimen/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a calibration curve over a range of interest.

Certifying Scientist. An individual with at least a bachelor's degree in the chemical or biological sciences or medical technology or equivalent who reviews all pertinent data and quality control results. The individual shall have training and experience in the theory and practice of all methods and procedures used in the laboratory, including a thorough understanding of chain of custody procedures, quality control practices, and analytical procedures relevant to the results that the individual certifies. Relevant training and experience shall also include the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial action to be taken in response to test systems being out of control-limits or detecting aberrant test or quality control results.

Chain of Custody. Refers to the process used to document the handling and storage of a specimen.

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.

Collector. 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 collector shall have successfully completed training to carry out this function.

Confirmatory Drug Test. A second analytical procedure to identify the presence of a specific drug or metabolite which is independent of the initial test and which uses a different technique and chemical principle from that of the initial test in order to ensure reliability and accuracy. (At this time, gas chromatography/mass spectrometry (GC/MS) is the only authorized confirmation method for cocaine, marijuana, opiates, amphetamines, and phencyclidine.)

Confirmatory Validity Test. A second test performed on a different aliquot of the original urine specimen to further support a validity test result.

Control. A sample used to monitor the status of an analysis to maintain its performance within desired limits.

Dilute Specimen. A urine specimen with creatinine and specific gravity values that are lower than expected for human urine.

Donor. The individual from whom a urine specimen is collected.

Federal Drug Testing Custody and Control Form (Federal CCF). The OMB-approved form used to document the handling and transfer of a specimen from the time of collection until receipt by the laboratory and used by the certifying scientist to certify the laboratory results.

Initial Drug Test (also known as Screening Test). An immunoassay test to eliminate "negative'' urine specimens from further consideration and to identify the presumptively positive specimens that require confirmation or further testing.

Initial Validity Test. The first test used to determine if a urine specimen is adulterated, dilute, or substituted.

Invalid Result. Refers to the result reported by a laboratory for a urine

[1] Although HHS has no authority to regulate the transportatiion industry, the Department of Transportation (DOT) does have such authority. DOT is required by law to develop requirements for its regualted industry that "incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines * * *'' *See, e.g.,* 49 U.S.C. 20140(c)(2). In carrying out its mandate, DOT requires by regulation that its federally regulated employers use only HHS certified laboratories in the testing of employees, 49 CFR 40.39, and incorporates the scientific and technical aspects of the guidelines in its regulations. The DOT-regulated industry should refer to the DOT regulations at 49 CFR Part 40.

specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic, or has an endogenous substance at an abnormal concentration that prevents the laboratory from completing testing or obtaining a valid drug test result.

Laboratory Chain of Custody Form. The form(s) used by the testing laboratory to document the handling and security of the specimen and all aliquots of the specimens during testing and storage by the laboratory. The form, which may account for an entire laboratory test batch, shall include the names and signatures of all individuals who handled the specimens or aliquots and the date and purpose of the access.

Limit of Detection. The lowest concentration at which an analyte can be reliably shown to be present under defined conditions.

Limit of Quantitation. The lowest concentration at which an analyte can be reliably shown to be present and quantified under defined conditions.

Medical Review Officer (MRO). 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 test result together with his or her medical history and any other relevant biomedical information.

Non-Negative Specimen. A urine specimen that is reported as adulterated, substituted, positive (for a drug or drug metabolite), or invalid.

Oxidizing Adulterant. A substance that acts alone or in combination with other substances to oxidize drugs or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test. Examples of these agents include, but are not limited to, nitrites, pyridinium chlorochromate, chromium (VI), bleach, iodine, halogens, peroxidase, and peroxide.

Quality Control Sample. A sample used to evaluate whether or not the analytical procedure is operating within predefined tolerance limits. Calibrators, controls, negative urine samples, and blind samples are collectively referred to as "quality control samples'' and each as a "sample.''

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

Sample. A representative portion of a urine specimen or quality control sample used for testing.

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

Specimen. The portion of urine that is collected from a donor.

Standard. A reference material of known purity or a solution containing a reference material at a known concentration.

Substituted Specimen. A urine specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human urine.

Section 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

Section 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 urine specimens for marijuana and cocaine;

(2) Federal agency applicant and random drug testing programs may also test urine specimens for opiates, amphetamines, and phencyclidine;

(3) When conducting reasonable suspicion, post accident, or unsafe practice testing, a Federal agency may have a urine specimen tested for any drug listed in Schedule I or II of the CSA; and

(4) Federal agency drug testing programs shall have validity tests performed on urine specimens, as provided under section 2.4(g).

(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, Public Law 100–71, and these Guidelines shall not be used for any other analysis or test unless authorized by an agency's drug-free workplace program.

(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.

Section 2.2 Specimen Collection Procedures

(a) *Designation of Collection Site.* An 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.* A collection site must 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 collecting specimens shall be secured during the time a specimen is collected.

(c) *Chain of Custody.* A Federal CCF shall be properly completed by a collector for each urine specimen collected for a Federal agency to document the collection of the specimen and the transfer of the specimen to the laboratory for testing.

(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.* The procedure for collecting a urine specimen shall allow individual privacy unless there is reason to believe that a particular donor may alter or substitute the specimen to be provided.

(f) *Integrity and Identity of Specimen.* The collector shall take the following minimum precautions to ensure that a urine specimen is correctly documented as being provided by a specific donor and that the donor has not adulterated, substituted, or diluted the specimen:

(1) To deter the dilution of a specimen at the collection site, a toilet bluing

agent shall be placed in a toilet tank 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 a donor arrives at the collection site, the collector shall request the donor to present photo identification. If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor, the coordinator of the drug testing program, or any other agency official who can positively identify the donor. If the donor's identity cannot be established, the collector shall not proceed with the collection.

(3) If the donor fails to arrive at the assigned time or if the donor fails to remain present through the completion of the collection, the collector shall contact the appropriate authority to obtain guidance on the action to be taken.

(4) The collector shall ask the donor 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 donor's urine specimen. The collector shall ensure that all personal belongings such as a purse or briefcase remain with the outer garments. The donor may retain his or her wallet. The collector directs the donor to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate the specimen. If nothing is there that can be used to adulterate a specimen, the donor places the items back into the pockets and the collection procedure continues. If the donor refuses to show the collector the items in his or her pockets, this is considered a "refusal to test.'' If an item is found that appears to have been brought to the collection site with the intent to adulterate the specimen, a direct observation collection procedure is used. If the item appears to be inadvertently brought to the collection site, the collector shall secure the item and continue with the normal collection procedure.

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

(6) After washing hands, the donor shall remain in the presence of the collector 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 collector shall give the donor a clean specimen bottle or specimen collection container. The donor may provide his/her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy.

(8) The collector shall note any unusual behavior or appearance on the Federal CCF.

(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 person of the same gender as the donor shall accompany the donor 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 collector 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 collector shall instruct the donor not to flush the toilet until the specimen is delivered to the collector. After the collector has possession of the specimen, the donor will be instructed to flush the toilet and to participate with the collector in completing the chain of custody procedures.

(10) Upon receiving the specimen from the donor, the collector shall determine the volume of urine in the specimen bottle/container.

(i) If the volume is at least 30 milliliters (mL), the collector will proceed with step (11) below.

(ii) If the volume is less than 30 mL and the temperature is within the acceptable range specified in step (13) below, the specimen is discarded and a second specimen shall be collected. The donor may be given a reasonable amount of liquid to drink for this purpose (*e.g.*, an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 24 ounces). If the donor fails for any reason to provide 30 mL of urine for the second specimen collected, the collector shall contact the appropriate authority to obtain guidance on the action to be taken.

(iii) If the volume is less than 30 mL and the temperature is outside the acceptable range specified in step (13) below, a second specimen shall be collected using the procedure specified in step (13) below.

(11) After the specimen has been provided and submitted to the collector, the donor shall be allowed to wash his or her hands.

(12) Immediately after the specimen is collected, the collector 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 the specimen is outside the range of 32°–38°C/90°–100°F, that is a reason to believe that the donor may have altered or substituted the specimen, and another specimen shall be collected under direct observation of a person of the same gender and both specimens shall be forwarded to the laboratory for testing. The agency shall select the observer if there is no collector of the same gender available. A donor may volunteer to have his or her oral temperature taken to provide evidence to counter the reason to believe the donor 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 collector shall also inspect the specimen to determine if this is any sign indicating that the specimen may not be a valid urine specimen. Any unusual finding shall be noted on the Federal CCF.

(15) A specimen suspected of not being a valid urine specimen shall be forwarded to the laboratory for testing.

(16) When there is any reason to believe that a donor may have altered or substituted the specimen, another specimen shall be obtained as soon as possible under the direct observation of a person of the same gender and both specimens shall be forwarded to the laboratory for testing. The agency shall select the observer if there is no collector of the same gender available.

(17) Both the donor and the collector shall keep the specimen bottle/container in view at all times prior to its being sealed and labeled. If the specimen is transferred from a specimen collection container to a specimen bottle, the collector shall request the donor to observe the transfer of the specimen and the placement of the tamper-evident label/seal on the bottle.

(18) The collector and the donor shall be present at the same time during procedures outlined in paragraphs (19) to (22) of this section.

(19) The collector shall place the tamper-evident label/seal on the specimen bottle. The collector shall record the date of the collection on the tamper-evident label/seal.

(20) The donor shall initial the tamper-evident label/seal on the specimen bottle for the purpose of certifying that it is the specimen collected from him or her.

(21) The collector shall ensure that all the information required on the Federal CCF is provided.

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

(23) Based on a reason to believe that the donor may alter or substitute the specimen to be provided, a higher level supervisor shall review and concur in advance with any decision by a collector to obtain a specimen under direct observation. The person directly observing the specimen collection shall be of the same gender. The agency shall select the observer if there is no collector of the same gender available.

(24) The collector shall sign the Federal CCF.

(25) The urine specimen and Federal CCF 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 Federal CCF be under the control of the collector. If the collector leaves the collection site momentarily, the urine specimen and Federal CCF shall be taken with him or her or shall be secured. After the collector returns to the collection site, the custody process will continue. If the collector is leaving for an extended period of time, the specimen and Federal CCF shall be packaged for shipment to the laboratory before he or she leaves the collection site.

(g) *Collection Control.* If the specimen and Federal CCF are not immediately prepared for transfer to the laboratory, they shall be appropriately safeguarded until the specimen and Federal CCF are prepared for transfer to the laboratory.

(h) *Split Specimens.* An agency may, but is not required to, use a split specimen method of collection. If the urine specimen is split into two specimen bottles (hereinafter referred to as Bottle A and Bottle B) the following procedure shall be used:

(1) The donor shall urinate into either a specimen bottle or specimen collection container. The collector, in the presence of the donor, after determining specimen temperature, pours the urine into two specimen bottles that are labeled Bottle A and Bottle B or, if Bottle A was used to collect the specimen, pours an appropriate amount into Bottle B. A minimum of 45 mL of urine is required when using a split specimen procedure, *i.e.*, 30 mL for Bottle A and 15 mL for Bottle B.

(2) The Bottle A specimen, containing a minimum of 30 mL of urine, is to be used for the drug test. If there is no additional urine available for the second specimen bottle (Bottle B), the first specimen bottle (Bottle A) shall nevertheless be processed for testing.

(3) A minimum of 15 mL of urine shall be poured into the second specimen bottle (Bottle B).

(4) All requirements of this part shall be followed with respect to Bottle A and Bottle B, including the requirements that a copy of the Federal CCF accompany the two bottles processed under split sample procedures.

(5) The collector shall send the split specimens (Bottle A and Bottle B) at the same time to the laboratory that will be testing the Bottle A specimen.

(6) If the test of the primary (Bottle A) specimen is verified positive, adulterated, or substituted by the MRO, the MRO shall report the result to the agency. Only the donor may request through the MRO that the split (Bottle B) specimen be tested by a second certified laboratory to reconfirm the positive, adulterated, or substituted result reported by the primary laboratory. The MRO shall honor the request if it is made within 72 hours after informing the donor that a positive, adulterated, or substituted result was being reported to the agency. The second laboratory shall test the split specimen in accordance with the requirements in section 2.4 pertaining to retesting for drugs, adulterants, or substitution.

(7) Any action taken by a Federal agency as a result of an MRO verified positive, adulterated, or substituted test result (*e.g.,* removing a donor from performing a safety-sensitive function) may proceed whether Bottle B is or is not tested.

(i) *Transportation to Laboratory.* A collector shall arrange to ship the collected specimens to the certified 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. The collector shall ensure that the Federal CCF is enclosed within the container sealed for shipment to the drug testing laboratory. Since specimens are sealed in packages that would indicate any tampering during transit to the laboratory and couriers, express carriers, and postal service personnel do not have access to the Federal CCFs, there is no requirement that such personnel document chain of custody for the package during transit.

Section 2.3 Laboratory Personnel

(a) *Day-to-Day Management.*

(1) The laboratory shall have a responsible person (RP) 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 multi-speciality 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 in-service 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 laboratory personnel, and followed by those personnel. The procedure manual shall be reviewed, signed, and dated by this responsible person 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 paragraph 2.4(q)(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 specimen results are not reported until all corrective actions have been taken and he or she can assure that the results provided are accurate and reliable.

(b) *Certifying Test Results.* The certified laboratory shall have one or more certifying scientists, as defined in section 1.2, who review all pertinent data and quality control results to attest to the validity of the laboratory's test results. A laboratory may designate certifying scientists that only certify results that are reported negative and certifying scientists that certify results that are reported both negative and non-negative.

(c) *Day-to-Day Operations and Supervision of Analysts.* The laboratory's urine drug testing facility shall have an individual(s) 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 technical and nontechnical staff shall have the necessary training and skills for the tasks assigned.

(e) *Training.* The laboratory shall make available continuing education programs to meet the needs of laboratory personnel.

(f) *Files.* Each laboratory personnel file shall include, at a minimum, a resume, any professional certification or license, a job description, and documentation to show that the individual has been properly trained to perform his or her job.

Section 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 or emergency personnel (*e.g.,* firefighters and medical rescue teams), all authorized visitors and maintenance and service personnel shall be escorted at all times. The laboratory shall maintain a record that documents the dates, time of entry and exit, escort and purpose of entry of authorized visitors, maintenance personnel, and service personnel accessing secured areas.

(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 a laboratory 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 appropriate entries on the laboratory chain of custody forms for those specimens or aliquots as they are received.

(b) *Receiving.*

(1) After opening a shipping package and gaining access to a specimen and its accompanying Federal CCF, an accessioner shall compare the information on the specimen bottle label/seal to the information on the accompanying Federal CCF.

(2) The following discrepancies are considered to be fatal flaws and the laboratory must stop the testing process and reject the specimen for testing and indicate the reason for rejecting the specimen on the Federal CCF:

(i) The specimen ID number on the specimen bottle label/seal does not match the ID number on the Federal CCF or the ID number is missing either on the Federal CCF or on the specimen bottle label/seal;

(ii) The specimen bottle label/seal is broken or shows evidence of tampering on the specimen bottle from a single specimen collection or on the primary (Bottle A) specimen from a split specimen collection (and the split specimen cannot be designated as the primary (Bottle A) specimen);

(iii) The collector's printed name and signature are omitted on the Federal CCF; or

(iv) There is an insufficient amount of urine for analysis in the specimen bottle from a single specimen collection or in the primary (Bottle A) specimen from a split specimen collection (unless the split specimen can be designated as the primary (Bottle A) specimen).

(3) The following discrepancies are considered to be correctable flaws:

(i) If a collector failed to sign the Federal CCF, the laboratory must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the laboratory may report the test result for the specimen. If the laboratory cannot recover the collector's signature, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(ii) If a specimen is submitted using a non-Federal form or an expired Federal CCF, the laboratory must test the specimen and also attempt to obtain a memorandum for record explaining why a non-Federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If the laboratory cannot obtain a memorandum for record from the collector, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

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

tests while the original specimen bottles and Federal CCFs remain in secure storage.

(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. A certified laboratory must have the capability to ensure proper storage conditions in the event of a prolonged power failure.

(d) *Specimen Processing.* A laboratory will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly. Every batch shall satisfy the quality control requirements in section 2.5.

(e) *Initial Drug Test.* (1) The initial drug 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 DRUG TEST LEVEL

	(ng/mL)
Marijuana metabolites	50
Cocaine metabolites	300
Opiate metabolites	2,000
Phencyclidine	25
Amphetamines	1,000

(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. The agency requesting the authorization to include other drugs shall submit to the Secretary in writing the agency's proposed initial drug test methods, testing levels, and proposed performance test program.

(3) A negative specimen shall be discarded or may be pooled for use in the laboratory's internal quality control program unless validity test results indicate that the specimen may not be a valid specimen.

(4) Multiple initial drug tests (also known as rescreening) for the same drug or drug class may be performed provided that all tests meet all Guideline cutoffs and quality control requirements (see section 2.5(b)). Examples: a test is performed by immunoassay technique "A'' for all drugs using the HHS cutoff levels, but presumptive positive amphetamines are forwarded for immunoassay technique "B'' to eliminate any possible presumptive positives due to structural analogues; a valid analytical result cannot be obtained using immunoassay technique "A'' and immunoassay technique "B'' is used in an attempt to obtain a valid analytical result.

(f) *Confirmatory Drug Test.*

(1) A specimen identified as positive on an initial drug test shall be confirmed for the class(es) of drugs screened positive on the initial drug test using gas chromatography/mass spectrometry (GC/MS) at the cutoff values listed in this paragraph. Each confirmatory drug test shall provide a quantitative result. When the concentration of a drug or metabolite exceeds the linear range of the standard curve, the certified laboratory may record the result as "exceeds the linear range of the test'' or as "greater than or equal to (insert the value for the upper limit of the linear range),'' or may dilute an aliquot of the specimen to obtain an accurate quantitative result when the concentration is above the upper limit of the linear range.

CONFIRMATORY DRUG TEST LEVEL

	(ng/mL)
Marijuana metabolite [1]	15
Cocaine metabolite [2]	150
Opiates	
Morphine	2,000
Codeine	2,000
6-Acetylmorphine [3]	10
Phencyclidine	25
Amphetamines	
Amphetamine	500
Methamphetamine [4]	500

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

[2] Benzoylecgonine.

[3] Test for 6-AM when the morphine concentration is greater than or equal to 2,000 ng/mL.

[4] Specimen must also contain amphetamine at a concentration greater than or equal to 200 ng/mL.

(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. The agency requesting the authorization to include other drugs shall submit to the Secretary in writing the agency's proposed confirmatory test methods, testing levels, and proposed performance test program.

(3) A specimen that tests negative on confirmatory drug tests shall be discarded or may be pooled for use in the laboratory's internal quality control program unless validity test results indicate that the specimen may not be a valid specimen.

(g) *Validity Testing.* A certified laboratory shall:

(1) Determine the creatinine concentration on every specimen;

(2) Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL;

(3) Determine the pH on every specimen;

(4) Perform one or more validity tests for oxidizing adulterants on every specimen; and

(5) Perform additional validity tests when the following conditions are observed:

(i) Abnormal physical characteristics;

(ii) Reactions or responses characteristic of an adulterant obtained during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standards, unusual response); or

(iii) Possible unidentified interfering substance or adulterant.

The choice of additional validity tests is dependent on the observed indicators or characteristics as described in (i), (ii), and (iii) of this section.

(h) *Reporting Results.*

(1) The laboratory shall report a test result directly to the agency's MRO within an average of 5 working days after receipt of the specimen by the laboratory using the Federal CCF and/or an electronic report. Before any test result is reported, it must be certified as correct by a certifying scientist.

(2) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each specimen validity test result indicates that the specimen is a valid urine specimen.

(3) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive.

(4) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported adulterated when:

(i) The pH is less than 3 or greater than or equal to 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(ii) The nitrite concentration is greater than or equal to 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-

wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(iii) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration greater than or equal to 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration greater than or equal to the LOD of the confirmatory test on the second aliquot;

(iv) The presence of halogen (*e.g.,* bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff or a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration greater than or equal to the LOD) for the initial test on the first aliquot and a different confirmatory test (*e.g.*, multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration greater than or equal to the LOD of the confirmatory test on the second aliquot;

(v) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and GC/MS for the confirmatory test with the glutaraldehyde concentration greater than or equal to the LOD of the analysis on the second aliquot;

(vi) The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff or a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration greater than or equal to 50 mcg/mL) for the initial test on the first aliquot and GC/MS for the confirmatory test with the pyridine concentration greater than or equal to the LOD of the analysis on the second aliquot;

(vii) The presence of a surfactant is verified by using a surfactant colorimetric test with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry) with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(viii) The presence of any other adulterant not specified in 4(iii) through 4(vii) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(5) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported substituted when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or greater than or equal to 1.0200 on both the initial and confirmatory creatinine tests (*i.e.,* the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (*i.e.,* a refractometer is used to test both aliquots) on two separate aliquots.

(6) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported dilute when the creatinine concentration is greater than or equal to 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(7) A urine specimen from a single specimen collection or the primary (Bottle A) specimen from a split specimen collection is reported as an invalid result when:

(i) Inconsistent creatinine concentration and specific gravity results are obtained (*i.e.,* the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is greater than or equal to 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(ii) The pH is greater than or equal to 3 and less than 4.5 or greater than or equal to 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(iii) The nitrite concentration is greater than or equal to 200 mcg/mL using a nitrite colorimetric test or greater than or equal to the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial test and the confirmatory test or using either initial test and the nitrite concentration is greater than or equal to 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (*e.g.,* multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(iv) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff greater than or equal to 50 mcg/mL chromium (VI) for both the initial test and the confirmatory test on two separate aliquots;

(v) The possible presence of a halogen (*e.g.*, bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff greater than or equal to the LOD for both the initial test and the confirmatory test on two separate aliquots or relying on the odor of the specimen as the initial test;

(vi) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial test and the confirmatory test on two separate aliquots;

(vii) The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with a greater than or equal to 200 mcg/mL nitrite-equivalent cutoff, a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff, or a halogen concentration is greater than or equal to the LOD) for both the initial test and the confirmatory test on two separate aliquots;

(viii) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with a greater than or equal to 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial test and the confirmatory test on two separate aliquots or a foam/shake test for the initial test;

(ix) Interference occurs on the immunoassay drug tests on two separate aliquots (*i.e.*, valid immunoassay drug test results cannot be obtained);

(x) Interference with the GC/MS drug confirmation assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

(xi) The physical appearance of the specimen is such that testing the system may damage the laboratory's instruments; or

(xii) If the physical appearances of Bottles A and B (when a split specimen collection is used) are clearly different,

the test result for Bottle A is one of the reasons stated in (i) through (xi) of this section and/or was screened negative for drugs.

(8) The laboratory shall reject a specimen for testing when a fatal flaw occurs as described in paragraph 2.4(b)(2) or when a correctable flaw as described in paragraph 2.4(b)(3) is not recovered. The laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(9) The laboratory must report all non-negative test results for a specimen. For example, a specimen can be positive for a specific drug and adulterated.

(10) For a specimen that is tested positive for a drug, the laboratory shall report the specimen as positive and specify the drug for which the specimen is positive. The concentration of the drug shall be provided to the MRO only when the MRO requests such information. The MRO's request may either be a general request covering all such results or be on a case by case basis. When the concentration of an analyte exceeds the linear range of the standard curve, the laboratory may report to the MRO that the quantitative value "exceeds the linear range of the test,'' that the quantitative value is "greater than or equal to (insert the value for the upper limit of the linear range),'' or may report an accurate quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen. The MRO shall not disclose the concentration of the drug to the agency.

(11) The laboratory shall provide quantitative values for confirmed opiate results for morphine or codeine that are greater than or equal to 15,000 ng/mL, even if the MRO has not requested quantitative values for the test result.

(12) For a specimen that is found to be adulterated or substituted, the laboratory shall report the specimen as adulterated or substituted and shall provide the numerical values that support the adulterated (when applicable) or substituted result. For a specimen that has an invalid result for one of the reasons stated in paragraphs 2.4(h)(7)(iv) to (xii), the laboratory shall contact the MRO and both will decide if testing by another certified laboratory would be useful in being able to report a positive or adulterated result. If no further testing is necessary, the laboratory then reports the invalid result to the MRO.

(13) The laboratory may transmit results to the MRO 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.

(14) For all test results, a laboratory may fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF, and/or forward a computer-generated electronic report. However, for non-negative results, the laboratory must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

(15) The laboratory shall provide to the agency official responsible for coordination of the drug-free workplace program a semi-annual statistical summary report of urinalysis testing of Federal employees and shall not include in the summary any personal identifying information. In order to avoid sending data from which it is likely that information about a donor's test result can be readily inferred, the laboratory must not send a summary report if the agency has fewer than five specimen test results in a six-month period. When that situation occurs, the laboratory must send the agency a report indicating that not enough specimens were tested to permit providing a summary report. The summary report shall include test results that are reported within the six-month period. Normally, the summary report is sent within 14 calendar days after the end of the six-month period covered by the report. The summary report shall contain the following information:

Reporting Period: (inclusive dates)
Laboratory Name and Address
Federal Agency Name
(i) Specimen Results Reported (total number)
By Type of Test
(a) Pre-employment (number)
(b) Post-Accident (number)
(c) Random (number)
(d) Reasonable Suspicion/Cause (number)
(e) Return-to-Duty (number)
(f) Follow-up (number)
(g) Type of Test Not Noted on CCF (number)
(ii) Specimens Reported
(a) Negative (number)
(b) Negative and Dilute (number)
(iii) Specimens Reported as Rejected for Testing (total number)
By Reason
(a) Fatal flaw (number)
(b) Uncorrected Flaw (number)
(iv) Specimens Reported as Positive (total number)
By Drug
(a) Marijuana Metabolite (number)
(b) Cocaine Metabolite (number)
(c) Opiates (number)
(1) Codeine (number)
(2) Morphine (number)
(3) 6-AM (number)
(d) Phencyclidine (number)
(e) Amphetamines (number)
(1) Amphetamine (number)
(2) Methamphetamine (number)
(v) Adulterated (number)
(vi) Substituted (number)
(vii) Invalid Result (number)

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

(17) 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.

(i) *Long-Term Storage.* Long-term frozen storage (−20°C or less) ensures that positive, adulterated, substituted, and invalid urine specimens will be available for any necessary retest. 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 reported positive, adulterated, substituted, or invalid. Within this 1-year period, an agency may request the laboratory to retain the specimen for an additional period of time. If no such request is received from the agency, the laboratory may discard the specimen at the end of this 1-year period.

(j) *Retesting a Specimen for Drugs.*

(1) A second laboratory shall use its confirmatory drug test when retesting an aliquot of a single specimen or testing a split (Bottle B) specimen for the drug or drug metabolite that was reported positive in the single specimen or the primary (Bottle A) specimen by the first laboratory.

(2) Because some drugs or drug metabolites may deteriorate during storage, the retest of an aliquot of a single specimen or the test of a split (Bottle B) specimen is not subject to a specific drug cutoff requirement, but must provide data sufficient to confirm the presence of the drug or metabolite.

(3) If the second laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first laboratory, the second laboratory shall attempt to determine the reason for not reconfirming the presence of the drug or drug metabolite by conducting specimen validity tests. The second laboratory shall conduct the same

specimen validity tests it would conduct on a single specimen or a primary (Bottle A) specimen. The second laboratory reports all test results to the MRO.

(k) *Retesting a Specimen for Adulterants.*

(1) A second laboratory shall use the required confirmatory validity test specified in paragraph 2.4(h)(4) and the same confirmatory criterion specified in paragraph 2.4(h)(4) to reconfirm an adulterant result when retesting an aliquot from a single specimen collection or when testing a split (Bottle B) specimen.

(2) The second laboratory may only retest an aliquot from a single specimen collection or test a split (Bottle B) specimen for the adulterant reported by the first laboratory.

(l) *Retesting a Specimen for Substitution.*

(1) A second laboratory shall use its confirmatory creatinine test and confirmatory specific gravity test, when retesting an aliquot of a single specimen or testing a split (Bottle B) specimen, to reconfirm that the creatinine concentration was less than 2 mg/dL and the specific gravity was less than or equal to 1.0010 or greater than or equal to 1.0200.

(2) The second laboratory may only retest an aliquot from a single specimen collection or test a split (Bottle B) specimen to reconfirm the substituted result reported by the first laboratory.

(m) *Subcontracting.* Drug testing laboratories shall not subcontract and shall perform all work with their own personnel and equipment unless otherwise authorized by the Secretary.

(n) *Laboratory Facilities.*

(1) Laboratory facilities shall comply with applicable provisions of any State licensor 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 the five classes of drugs (marijuana, cocaine, opiates, phencyclidine, and amphetamines) and performing the validity tests specified in these Guidelines.

(o) *Inspections.* The Secretary, a Federal agency, or any organization performing laboratory certification on behalf of the Secretary may inspect the laboratory at any time. Federal 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 may carry out pre-award inspections and evaluation of the procedural aspects of the laboratory's drug testing operation.

(p) *Documentation.* The drug testing laboratories shall maintain and make documents of all aspects of the testing process available for at least 2 years. This 2-year period may be extended upon written notification by HHS 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; Federal CCFs and laboratory chain of custody forms; 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 method validation data and any documents for any specimen under legal challenge for an indefinite period.

(q) *Additional Requirements for Certified Laboratories.*

(1) 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, corrective 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) Laboratory calibrators and controls shall be prepared using pure drug reference materials, stock standard solutions obtained from other laboratories, or standard solutions obtained from commercial manufacturers. The calibrators and controls shall be properly labeled as to content and concentration. The standards (*e.g.*, pure reference materials, stock standard solutions, purchased standards) shall be labeled with the following dates: when received (if applicable); when prepared or opened; when placed in service; and expiration date.

(3) 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. 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 troubleshooting and repair. Records shall be available on preventive maintenance.

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

(5) A laboratory shall make available a qualified individual to testify in an administrative or disciplinary proceeding against a Federal employee when that proceeding is based on a non-negative result reported by the laboratory.

(6) The laboratory shall not enter into any relationship with an agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having an agency use a specific MRO.

Section 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 accessioning, chain of custody, security and reporting of results, initial and confirmatory testing, certification of calibrators and controls, and validation of analytical procedures. The performance characteristics (*e.g.*, accuracy, precision, limit of detection (LOD), limit of quantitation (LOQ), specificity) shall be documented for each test as appropriate. Validation of procedures shall document that carryover does not affect the donor's specimen results. Periodic re-verification of analytical procedures is required. Quality assurance procedures shall be designed, implemented, and reviewed to monitor the conduct of each step of the testing process.

(b) *Laboratory Quality Control Requirements for Initial Drug Tests.*

Each analytical run of specimens to be screened shall include:

(1) Sample(s) certified to contain no drug (*i.e.*, negative urine samples);

(2) At least one control fortified with drug or metabolite targeted at 25 percent above the cutoff;

(3) At least one control fortified with drug or metabolite targeted at 75 percent of the cutoff;

(4) A sufficient number of calibrators 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 calibrators, those values will be used to calculate sample data;

(5) A minimum of 10 percent of the total specimens and quality control samples in each analytical run shall be quality control samples; and

(6) One percent of each run, with a minimum of at least one sample, shall be the laboratory's blind quality control samples to appear as routine specimens to the laboratory analysts.

(c) *Laboratory Quality Control Requirements for Confirmatory Drug Tests.*

Each analytical run of specimens to be confirmed shall include:

(1) Sample(s) certified to contain no drug (*i.e.*, negative urine samples);

(2) Positive calibrator(s) and control(s) fortified with drug or metabolite;

(3) At least one control with drug or metabolite targeted at 25 percent above the cutoff; and

(4) At least one calibrator or control that is targeted at or below 40 percent of the cutoff.

(d) *Laboratory Quality Control Requirements for Specimen Validity Tests.*

(1) Each validity test result shall be based on performing an initial validity test on one aliquot and a confirmatory validity test on a second aliquot; and

(2) Each analytical run of specimens for which an initial or confirmatory validity test is being performed shall include the appropriate calibrators and controls.

(e) *Requirements for performing creatinine tests.*

(1) The creatinine concentration shall be measured to one decimal place on both the initial creatinine test and the confirmatory creatinine test.

(2) The initial creatinine test shall have a calibrator at 2 mg/dL.

(3) The initial creatinine test shall have a control in the range of 1.0 mg/dL to 1.5 mg/dL, a control in the range of 3 mg/dL to 20 mg/dL, and a control in the range of 21 mg/dL to 25 mg/dL.

(4) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) shall have a calibrator at 2 mg/dL, a control in the range of 1.0 mg/dL to 1.5 mg/dL, and a control in the range of 3 mg/dL to 4 mg/dL.

(f) *Requirements for performing specific gravity tests.*

(1) The refractometer shall report and display the specific gravity to four decimal places. The refractometer shall be interfaced with a laboratory information management system (LIMS), computer, and/or generate a hard copy of the digital electronic display to document the numerical result.

(2) The initial and confirmatory specific gravity tests shall have a calibrator or control at 1.0000.

(3) The initial and confirmatory specific gravity tests shall have the following controls:

(i) One control targeted at 1.0020;

(ii) One control in the range of 1.0040 to 1.0180; and

(iii) One control greater than or equal to 1.0200 but not greater than 1.0250.

(g) *Requirements for performing pH tests.*

(1) Colorimetric pH tests that have the dynamic range of 2 to 12 to support the 3 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Colorimetric pH tests, dipsticks, and pH paper that have a narrow dynamic range and do not support the cutoffs may be used only to determine if an initial pH validity test must be performed.

(2) pH screening tests shall have, at a minimum, the following controls:

(i) One control below the lower decision point in use;

(ii) One control between the decision points in use; and

(iii) One control above the upper decision point in use.

(3) An initial colorimetric pH test shall have the following calibrators and controls:

(i) One calibrator at 3;

(ii) One calibrator at 11;

(iii) One control in the range of 2 to 2.8;

(iv) One control in the range 3.2 to 4;

(v) One control in the range of 4.5 to 9;

(vi) One control in the range of 10 to 10.8;

(vii) One control in the range of 11.2 to 12.

(4) An initial pH meter test, if a pH screening test is not used, shall have the following calibrators and controls:

(i) One calibrator at 4;

(ii) One calibrator at 7;

(iii) One calibrator at 10;

(iv) One control in the range of 2 to 2.8;

(v) One control in the range 3.2 to 4;

(vi) One control in the range of 10 to 10.8; and

(vii) One control in the range of 11.2 to 12.

(5) An initial or confirmatory pH meter test, if a pH screening test is used, shall have the following calibrators and controls when the screening result indicates that the pH is below the lower decision point in use:

(i) One calibrator at 4;

(ii) One calibrator at 7;

(iii) One control in the range of 2 to 2.8; and

(iv) One control in the range 3.2 to 4.

(6) An initial or confirmatory pH meter test, if a pH screening test is used, shall have the following calibrators and controls when the screening result indicates that the pH is above the upper decision point in use:

(i) One calibrator at 7;

(ii) One calibrator at 10;

(iii) One control in the range of 10 to 10.8; and

(iv) One control in the range of 11.2 to 12.

(h) *Requirements for performing oxidizing adulterant tests.*

(1) The initial test shall include an appropriate calibrator at a cutoff specified in sections 2.4(h)(4) and (7) for the compound of interest, a control without the compound of interest (*i.e.*, a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration.

(2) A confirmatory test for a specific oxidizing adulterant shall use a different analytical method than that used for the initial test. Each confirmatory test batch shall include an appropriate calibrator, a control without the compound of interest (*i.e.*, a certified negative control), and a control with the compound of interest at a measurable concentration.

(i) *Requirements for performing nitrite tests.* The initial and confirmatory nitrite tests shall have a calibrator at the cutoff concentration, a control without nitrite (*i.e.*, certified negative urine), one control in the range of 200 mcg/mL to 400 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL.

(j) *Requirements for performing "other'' adulterant tests.*

(1) The initial and confirmatory tests for any "other'' adulterant that may be identified in the future shall satisfy the requirements in section 2.5(d).

(2) The confirmatory test for "other'' adulterants shall use a different analytical principle or chemical reaction than that used for the initial test.

(3) The initial and confirmatory tests for adulterants in this section shall include an appropriate calibrator, a control without the compound of interest (*i.e.*, a certified negative control), and a control with the compound of interest at a measurable concentration.

(k) *Agency Blind Sample Program.*

(1) Agencies shall only use blind quality control samples that have been certified by the supplier to be negative (*i.e.*, certified by immunoassay and GC/MS to contain no drug), drug positive (*i.e.*, certified by immunoassay and GC/MS to contain a drug(s)/metabolite(s) between 1.5 and 2 times the initial drug test cutoff concentration), adulterated (*i.e.*, certified to be adulterated with a specific adulterant using an appropriate confirmatory validity test(s)), or substituted (*i.e.*, the creatinine concentration and specific gravity satisfy the criteria for a substituted specimen using confirmatory creatinine and specific gravity tests, respectively). The supplier shall also provide the expiration date for each quality control sample to ensure that each quality control sample will give the expected result when it is submitted and correctly tested by a laboratory before the expiration date.

(2) During the initial 90-day period of any new drug testing program, each agency shall submit blind performance test samples to each laboratory it contracts with in the amount of at least 20 percent of the total number of specimens submitted (up to a maximum of 200 blind samples) and thereafter a minimum of 3 percent blind samples (up to a maximum of 100 blind samples) submitted per quarter.

(3) Approximately 75 percent of the blind quality control samples shall be negative (*i.e.*, certified to contain no drug), approximately 15 percent shall be positive for one or more drugs, and approximately 10 percent shall be either adulterated or substituted. The positive samples shall be spiked only with those drugs for which the agency is testing.

(4) The agency shall investigate any unsatisfactory blind performance test sample results and submit its findings to the Secretary. The Secretary shall continue the investigation to ensure that the laboratory has corrected the cause of the unsatisfactory performance test result. A report of the Secretary's investigative findings and the corrective action taken by the laboratory shall be sent to the agency contracting officer. 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 sample 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 sample and the error is determined to be a technical or methodological error, the laboratory shall submit all 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 Responsible Person. The Secretary may require an on-site review of the laboratory which may be conducted unannounced during any hours of operation of the laboratory. The Secretary has the option of revoking (section 3.13) or suspending (section 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.

Section 2.6 Reporting and Review of Results

(a) *MRO Qualifications.*

(1) An MRO shall be a licensed physician (Doctor of Medicine or Osteopathy).

(2) An MRO shall have knowledge about and clinical experience in controlled substance abuse disorders, detailed knowledge of alternative medical explanations for laboratory positive drug test results, knowledge about issues relating to adulterated and substituted specimens, and knowledge about possible medical causes for specimens that may be reported as having an invalid result.

(3) An MRO may be an employee of the agency or a contractor for the agency; however, an MRO shall not be an employee or agent of or have any financial interest in the laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific drug testing laboratory or have any agreement with the laboratory that may be construed as a potential conflict of interest.

(b) *MRO Review of Results.* An essential part of the drug testing program is the final review of each test result reported by a laboratory. A positive drug test result does not automatically identify a donor as an illegal drug user nor does an adulterated, substituted, or invalid test result automatically indicate that a donor has tampered with a specimen. The review of a non-negative test result shall be performed by the MRO before the result is transmitted to the agency's designated representative. Staff under the direct, personal supervision of the MRO may review and report a negative test result to the agency's designated representative.

(c) *MRO Review of Positive, Adulterated, Substituted, or Invalid Test Results.*

(1) Prior to making a final decision on a specimen that was reported positive, adulterated, substituted, or an invalid test result by the laboratory, the MRO shall interview the donor to determine if the donor has a valid medical explanation for the test result. This action could include a review of the donor's medical history and a review of any other biomedical factors. The MRO shall review medical records made available by the donor when a result could have resulted from taking a legally prescribed medication. After making a determination, the MRO reports the verified result to the agency's designated representative.

(2) When a laboratory reports an invalid result because of one of the reasons specified in paragraphs 2.4(h)(7)(iv) to (xii), the MRO and the laboratory shall determine if additional testing by another HHS-certified laboratory may be useful in resolving the reason for the invalid result and possibly being able to report a positive or adulterated result. If the MRO and the laboratory agree that no further testing would be useful, the MRO shall report the invalid result as "Test Cancelled—Invalid Result (specify reason for the invalid result)'' to the agency and indicate one of the following actions:

(i) An immediate direct observed collection is not required because the explanation provided by the donor for the invalid result is acceptable with no further action required unless a negative test result is required (*i.e,* pre-employment, return-to-duty, or follow-up test); or

(ii) An immediate direct observed collection is required because the explanation provided by the donor for the invalid result is not acceptable.

(d) *Verification for Opiates; Review for Prescription Medication.* Before the MRO verifies a confirmed positive result for opiates, he or she shall determine that there is clinical evidence—in addition to the urine test result—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 laboratory confirms the presence of 6-acetylmorphine (*i.e.*, the presence of this metabolite is proof of heroin use) or the morphine or codeine concentration is greater than or equal to 15,000 ng/mL and the donor does not present a legitimate medical explanation for the presence of morphine or codeine at or above this concentration. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(e) *Donor Request to MRO for Retest.*

(1) For a positive, adulterated, or substituted result reported on a single specimen or a primary (Bottle A) specimen, a donor may request through the MRO that an aliquot from the single specimen or the split (Bottle B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory. For a single specimen or primary (Bottle A) specimen reported as an invalid result, a donor may not request that an aliquot from the single specimen or the split (Bottle B) specimen be tested by a second HHS-certified laboratory.

(2) The donor has 72 hours (from the time the MRO notified the donor that his or her specimen was reported positive, adulterated, or substituted) to request a retest of an aliquot from the single specimen or to test the split (Bottle B) specimen.

(3) If the single specimen or split (Bottle B) specimen cannot be tested by a second laboratory (*e.g.*, insufficient volume, lost in transit, split (Bottle B) not available), the MRO shall direct the agency to immediately collect another specimen under direct observation.

(4) If a donor chooses not have an aliquot from the single specimen or the split (Bottle B) specimen tested by a second HHS-certified laboratory, a Federal agency may have a single or split specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result.

(f) *Result Consistent with Legal Drug Use.* If the MRO determines there is a legitimate medical explanation for the positive drug test result, he or she shall normally take no further action and report the test result as negative.

(g) *Laboratory Result Not Reconfirmed by a Second Laboratory.* After a second laboratory tests an aliquot of the single specimen or the split (Bottle B) specimen, the MRO shall take the following actions when the second laboratory reports the following results:

(1) *Failed to reconfirm a single or all drug positive results and adulterated.* If the donor provides a legitimate medical explanation for the adulteration result, the MRO reports a failed to reconfirm (specify drug(s)) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm (specify drug(s)) and a refusal to test to the agency and indicates the adulterant that is present in the urine specimen. The MRO gives the donor 72 hours to request that Laboratory A retests the single or Bottle A specimen for the adulterant. If Laboratory A reconfirms the adulterant, the MRO reports refusal to test and indicates the adulterant present. If Laboratory A fails to reconfirm the adulterant, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(2) *Failed to reconfirm a single or all drug positive results and substituted.* If the donor provides a legitimate medical explanation for the substituted result, the MRO reports a failed to reconfirm (specify drug(s)) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm (specify drug(s)) and a refusal to test (substituted) to the agency. The MRO gives the donor 72 hours to request Laboratory A to review the creatinine and specific gravity results for the single or Bottle A specimen. If the original creatinine and specific gravity results confirm that the specimen was substituted, the MRO reports a refusal to test (substituted) to the agency. If the original creatinine and specific gravity results from Laboratory A fail to confirm that the specimen was substituted, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the appropriate regulatory office about the failed to reconfirm and cancelled test.

(3) *Failed to reconfirm a single or all drug positive results and not adulterated or substituted.* The MRO reports to the agency a failed to reconfirm result (specify drug(s)), cancels both tests, and notifies the appropriate regulatory office.

(4) *Failed to reconfirm a single or all drug positive results and invalid result.* The MRO reports to the agency a failed to reconfirm result (specify drug(s) and gives the reason for the invalid result), cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure, and notifies the appropriate regulatory office.

(5) Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and adulterated. The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was adulterated. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(6) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and substituted.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was substituted. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(7) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and not adulterated or substituted.* The MRO reports a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(8) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and invalid result.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(9) *Failed to reconfirm substitution or adulteration.* The MRO reports to the agency a failed to reconfirm result (specify adulterant or not substituted) and cancels both tests. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(10) *Failed to reconfirm a single or all drug positive results and reconfirmed an adulterated or substituted result.* The MRO reports to the agency a reconfirmed result (adulterated or substituted) and a failed to reconfirm result (specify drug(s)). The MRO tells

the agency that it may take action based on the reconfirmed result (adulterated or substituted) although Laboratory B failed to reconfirm the drug(s) result.

(11) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterated or substituted result.* The MRO reports to the agency a failed to reconfirm result (specify drug(s) and specify adulterant or substituted) and cancels both tests. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(12) *Failed to reconfirm at least one drug and reconfirmed the adulterated result.* The MRO reports to the agency a reconfirmed result (specify drug(s) and adulterated) and a failed to reconfirm result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) and the adulterated result although Laboratory B failed to reconfirm one or more drugs.

(13) *Failed to reconfirm at least one drug and failed to reconfirm the adulterated result.* The MRO reports to the agency a reconfirmed result (specify drug(s)) and a failed to reconfirm result (specify drug(s) and specify adulterant). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterated result.

(14) *Failed to reconfirm an adulterated result and failed to reconfirm a substituted result.* The MRO reports to the agency a failed to reconfirm result ((specify adulterant) and not substituted) and cancels both tests. The MRO shall notify the appropriate regulatory office regarding the test results for the specimen.

(15) *Failed to reconfirm an adulterated result and reconfirmed a substituted result.* The MRO reports to the agency a reconfirmed result (substituted) and a failed to reconfirm result (specify adulterant). The MRO tells the agency that it may take action based on the substituted result although Laboratory B failed to reconfirm the adulterated result.

(16) *Failed to reconfirm a substituted result and reconfirmed an adulterated result.* The MRO reports to the agency a reconfirmed result (adulterated) and a failed to reconfirm result (not substituted). The MRO tells the agency that it may take action based on the adulterated result although Laboratory B failed to reconfirm the substituted result.

(h) *Reporting Final Results.* The MRO shall report the final results of the tests in writing and in a manner designed to ensure confidentiality of the information. When reporting the result for a single specimen or primary (Bottle A) specimen to the agency, the MRO shall report whether the specimen was negative, dilute, positive (specify drug), refusal to test (adulterated or substituted), or test cancelled (state reason). When reporting the result for a retest of an aliquot of a single specimen or the test of a split (Bottle B) specimen to the agency, the MRO shall report reconfirmed, failed to reconfirm (state reason), refusal to test (adulterated or substituted), or cancel both test results as described in section 2.6(g). The MRO shall not disclose any numerical values to the agency.

Section 2.7 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. 522a. In addition, laboratory contracts shall require compliance with patient access and confidentiality provisions of sec. 503 of Public Law 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 the agency's records of employee urinalysis results. The contract and the Privacy Act System of Records shall specifically require that employee records be maintained and used with the highest regard for employee privacy.

Section 2.8 Individual Access to Test and Laboratory Certification Results

In accordance with sec. 503 of Public Law 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

Section 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.

Section 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, drug metabolites, adulterants, or substituted specimens according to sections 2.4(e), 2.4(f), and 2.4(g) to protect the rights of the Federal employees being tested.

(b) *Need to Set Standards; Inspections.* The ability to accurately determine the presence or absence of specific drugs/metabolites or to accurately determine the validity of a urine specimen is critical to achieving the goals of the testing program and to protect the rights of the Federal employees being tested. Standards have been set which laboratories engaged in Federal employee urine drug testing shall meet to achieve the required accuracy of test results. These laboratories will be evaluated by the Secretary or the Secretary's designee as defined in section 1.2 in accordance with these Guidelines. Applicant laboratories shall test three cycles of performance testing samples that challenge the laboratory's ability to correctly test for drugs and to correctly perform specimen validity tests. Applicant laboratories shall undergo an initial inspection and upon certification are also required to undergo a second inspection within 3 months after being certified. Certified laboratories are required to analyze quarterly performance testing samples that challenge the laboratories to correctly test for drugs and to correctly perform validity tests and are required to undergo periodic inspections.

(c) *Urine Drug Testing Applies Analytical Forensic Toxicology.* The possible impact of a non-negative 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, proper documentation of all records, storage of non-negative specimens for later or independent testing, presentation of evidence in court, and expert witness testimony.

Section 3.3 General Certification Requirements

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

Section 3.4 Capability to Test for Five Classes of Drugs and to Conduct Validity Tests

To be certified, a laboratory must be capable of testing for marijuana, cocaine, opiates, amphetamines, and phencyclidine using the initial immunoassay and confirmatory GC/MS methods and conducting the specimen validity tests as specified in these Guidelines. The certification program will be limited to these five classes of drugs and specimen validity tests in accordance with the methods specified in these Guidelines (sections 2.4(e), (f), and (g)). The laboratory will be inspected and performance tested for these drugs and validity tests. Certified laboratories must clearly inform all non-regulated, private-sector employers/clients when their specimens are being tested using procedures that are different from those for which the laboratory is certified (*i.e.*, testing specimens not under the Guidelines).

Section 3.5 Initial and Confirmatory Capability at Same Site

Certified laboratories shall have the capability to perform initial and confirmatory drug tests and initial and confirmatory validity tests at the same laboratory site.

Section 3.6 Personnel

Laboratory personnel shall meet the requirements specified in section 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.

Section 3.7 Quality Assurance and Quality Control

Certified laboratories shall have a quality assurance program which encompasses all aspects of the testing process, including but not limited to specimen accessioning, chain of custody, security and reporting of results, initial and confirmatory testing, and validation of analytical procedures. As specified in these Guidelines, quality control procedures shall be designed, implemented, and reviewed to monitor testing.

Section 3.8 Security and Chain of Custody

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

Section 3.9 One-Year Storage for Positive, Adulterated, Substituted, and Invalid Specimens

All positive, adulterated, substituted, and invalid specimens shall be retained in accordance with the provisions of section 2.4(i) of these Guidelines.

Section 3.10 Documentation

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

Section 3.11 Reports

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

Section 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 any laboratory that is certified by an HHS-recognized certification program in accordance with these Guidelines.

(b) *Criteria.* In determining whether to certify a laboratory or to accept the certification of an HHS-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 or validity tests and reporting done by the laboratory.

(c) *Corrective Action by Certified Laboratories.* A laboratory must meet all the pertinent provisions of these Guidelines in order to qualify for and maintain certification. The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug and validity testing and reporting, to resolve problems related to drug and validity testing, and to enforce all standards set forth in these Guidelines. The Secretary shall have the authority to issue directives to any laboratory suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; order any laboratory to undertake corrective actions to respond to material deficiencies identified by an inspection or through proficiency testing; order any laboratory to send aliquots of urine specimens to another laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; order the review of results for specimens tested under the Guidelines for private-sector employers/clients to the extent necessary to ensure the full reliability of drug and validity testing for Federal agencies; and order any other action necessary to address deficiencies in drug or validity testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

Section 3.13 Revocation

(a) *General.* The Secretary shall revoke certification of any laboratory certified under these provisions or accept revocation by an HHS-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 and validity 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 and validity 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 and validity 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 and validity testing of Federal employees.

Section 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 and validity testing for Federal agencies. The Secretary may also accept suspension of certification by an HHS-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 and validity testing of Federal employees.

Section 3.15 Notice

(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 facsimile mail, 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 the laboratory received the notice, or if expedited review is requested, within 3 days of the date the laboratory received the notice. Subpart D contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

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

(e) *Public Notice.* The Secretary will publish in the **Federal Register** the name, address, and telephone number of any laboratory that has its certification suspended or revoked under section 3.13 or section 3.14, respectively, and the name of any laboratory which has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory that has its certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of subpart D.

Section 3.16 Recertification

Following revocation, a laboratory may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under section 3.13(a) or the reviewing official's decision under section 4.9(e) or 4.14(a), a laboratory which has had its certification revoked may reapply for certification as an applicant laboratory.

Section 3.17 Performance Testing (PT) Requirement for Certification

(a) *An Initial and Continuing Requirement.* The PT program is a part of the initial evaluation of a laboratory seeking certification (both PT 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 PT cycles of testing shall be required before a laboratory is eligible to be considered for certification.

(c) *Four Cycles Per Year.* After certification, laboratories shall be challenged with at least 10 PT samples on a quarterly cycle.

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

(e) *Agency PT Samples.* Any certified laboratory shall be subject to receiving and testing PT samples (see section 2.5(k)) submitted by a Federal agency. A certified laboratory is expected to correctly test and report each agency submitted PT sample (that is, report a negative sample as negative, a drug positive sample as positive, an adulterated sample as adulterated, or a substituted sample as substituted).

(f) *Reporting PT Sample Results.* The laboratory shall report results of PT program samples to the certifying organization in the same manner as specified in section 2.4(h) for routine specimens.

Section 3.18 PT Program Samples

(a) *Drug PT Samples.* Each PT cycle shall have samples that contain the drugs and drug metabolites listed in sections 2.4(e) and (f). For some samples, the composition will consist of the parent drug as well as metabolites. Also, more than one drug class may be included in one sample, but generally no more than two drugs will be present in any one sample. For any particular PT cycle, the samples in each set of samples going to the laboratories may vary but, within any annual period, all laboratories participating in the PT program will have analyzed the same total set of samples.

(b) *Composition of the Drug PT Samples.* PT program samples shall satisfy, but are not limited to, one of the following criteria:

(1) A drug or drug metabolite concentration will be at least 20 percent above the cutoff for either the initial drug test or the confirmatory drug test depending on which is to be evaluated;

(2) For retest samples, the drug or drug metabolite concentration may be as low as 40 percent of the cutoff;

(3) For routine samples, the drug or drug metabolite concentration may be below the cutoff for special purposes;

(4) A negative sample shall contain no target drug analyte at a concentration greater than 10 percent of the confirmatory cutoff;

(5) Samples may be fortified with interfering substances.

(c) *Specimen Validity Testing PT Samples.* Each PT cycle shall contain samples that challenge a laboratory's ability to identify substituted and adulterated specimens. For any particular PT cycle, the samples in each set of samples going to the laboratories may vary but, within any annual period,

all laboratories participating in the PT program will have analyzed the same total set of specimen validity testing PT samples.

(d) *Composition of the Specimen Validity Testing PT Samples.* Specimen validity testing PT samples shall satisfy, but are not limited to, one of the following criteria:

(1) The nitrite concentration will be at least 20 percent above the cutoff;

(2) The pH will be less than 2.75 or greater than 11.25;

(3) The concentration of an oxidant will be at a level sufficient to challenge a laboratory's ability to identify and confirm the oxidant;

(4) The creatinine concentration will be between 0 and 20 mg/dL;

(5) The specific gravity will be less than or equal to 1.0050 or between 1.0170 and 1.0230.

Section 3.19 Evaluation of PT Sample Results

(a) *Initial Certification of Applicant Laboratories.*

(1) An applicant laboratory shall not report any false positive drug test result on any PT sample during the initial certification process. A false positive drug result will automatically disqualify a laboratory from further consideration.

(2) An applicant laboratory shall maintain an overall grade of 90 percent for the three cycles of PT samples that challenge the laboratory's ability to conduct drug tests (*i.e.*, it must correctly identify and confirm 90 percent of the total drug challenges). A laboratory which achieves a score on any one cycle of the initial certification process such that it can no longer achieve a grade of 90 percent over three consecutive PT cycles will be immediately disqualified from further consideration.

(3) An applicant laboratory shall obtain quantitative values over the three initial PT cycles that are within ±20 percent or ±2 standard deviations of the calculated reference group mean (whichever range is larger) for at least 80 percent of the total drug challenges. Failure to satisfy this requirement for the total drug challenges will result in disqualification.

(4) An applicant laboratory shall not obtain any quantitative value on a drug challenge sample that differs by more than 50 percent from the calculated reference group mean. An applicant laboratory that obtains a quantitative value that differs by more than 50 percent on any drug challenge sample will result in disqualification.

(5) 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 challenges for each drug. An applicant laboratory that fails to successfully quantitate at least 50 percent of the challenges for each drug will result in disqualification.

(6) An applicant laboratory shall maintain an overall grade of 80 percent for the three cycles of PT samples that challenge the laboratory's ability to conduct specimen validity tests (*i.e.*, to correctly identify and confirm 80 percent of the total specimen validity testing challenges). An applicant laboratory that achieves a score on any one of the initial PT cycles such that it can no longer achieve a total grade of 80 percent over the three consecutive PT cycles for the specimen validity testing samples will result in disqualification.

(7) For quantitative specimen validity tests, an applicant laboratory shall obtain quantitative values for at least 80 percent of the total challenges that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are within ±20 percent or ±2 standard deviations of the calculated reference group mean;

(ii) pH values are within ±0.3 pH units of the calculated reference group mean; and

(iii) Specific gravity values are within ±0.0003 specific gravity units of the calculated reference group mean.

An applicant laboratory that achieves a score on any one initial PT cycle such that it cannot achieve a total grade of 80 percent over three consecutive PT cycles for the specimen validity testing samples will be disqualified.

(8) An applicant laboratory shall not obtain any quantitative value on a specimen validity testing sample that differs by more than ±50 percent for nitrite and creatinine concentrations, ±0.8 units for pH measurements, or ±0.0006 units for specific gravity from the calculated reference group means. An applicant laboratory that reports such an error for an initial certification PT sample will be disqualified.

(9) For qualitative specimen validity tests, an applicant laboratory shall correctly report at least 80 percent of the challenges for each qualitative specimen validity test over the three initial PT cycles. Failure to correctly report at least 80 percent for each qualitative specimen validity test will result in disqualification.

(10) An applicant laboratory shall not report any sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the calculated group reference mean is within the acceptable pH range, or substituted when the calculated group means for both creatinine and specific gravity are within the acceptable range. An applicant laboratory reporting any such error will be disqualified.

(b) *Evaluation of Certified Laboratories.*

(1) *Requirement for No False Positives.* A certified laboratory that reports a false positive drug result for a PT sample may be subject to suspension or revocation of its certification. The most serious false positive is by drug class, such as reporting THCA in a negative PT sample or reporting cocaine metabolite in a PT sample containing only opiates. An identification or reporting error within a class (*e.g.*, reporting codeine for morphine) is unacceptable, but is less serious than a misidentification of a class.

(2) *Requirement to Identify and Confirm 90 Percent of Total Drug Challenges.* Failure of a certified laboratory to maintain a grade of 90 percent over two consecutive PT cycles (*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 the laboratory's certification.

(3) *Requirement to Quantitate 80 Percent of Total Drug Challenges Within ±20 Percent or ±2 Standard Deviations.* Quantitative values reported by a certified laboratory over two consecutive PT cycles must be within ±20 percent or ±2 standard deviations of the calculated reference group mean (whichever is larger) for at least 80 percent of the total drug challenges. A certified laboratory that fails to achieve the 80 percent requirement may have its certification suspended or revoked.

(4) *Requirement to Quantitate within 50 Percent of Calculated Reference Group Mean.* A certified laboratory shall not obtain any quantitative value on a drug challenge that differs by more than ±50 percent from the calculated reference group mean. More than one error of this type for the same drug class over two consecutive PT cycles may result in suspension or revocation of the laboratory's certification.

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

(6) *No False Adulterated or Substituted Specimen Validity Testing Sample Result.* A certified laboratory shall not report any sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the calculated group reference mean is within the acceptable

pH range, or substituted when the calculated group means for both creatinine and specific gravity are within the acceptable range. A certified laboratory that reports this type of error may have its certification suspended or revoked.

(7) *Requirement to Identify and Confirm 80 Percent of the Total Specimen Validity Testing Challenges.* A certified laboratory shall maintain an overall grade of 80 percent over two consecutive PT cycles that challenge the laboratory's ability to conduct specimen validity tests (*i.e.*, to correctly identify and confirm 80 percent of the total specimen validity testing challenges). A certified laboratory that fails to maintain a grade of 80 percent over two consecutive PT cycles may have its certification suspended or revoked.

(8) *Requirement to Correctly Quantitate 80 Percent of the Total Challenges for Quantitative Specimen Validity Tests.* For quantitative specimen validity tests, a certified laboratory shall obtain quantitative values for at least 80 percent of the total challenges that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are within ±20 percent or ±2 standard deviations of the calculated reference group mean;

(ii) pH values are within ±0.3 pH units of the calculated reference group mean; and

(iii) Specific gravity values are within ±0.0003 specific gravity units of the calculated reference group mean.

A certified laboratory that fails to achieve 80 percent over two consecutive PT cycles may have its certification suspended or revoked.

(9) *Requirement to Report No More than One Quantitative Error for a Quantitative Specimen Validity Test.* A certified laboratory shall not obtain any quantitative value on a specimen validity testing sample that differs by more than ±50 percent for nitrite and creatinine concentrations, ±0.8 unit for pH measurements, or ±0.0006 units for specific gravity from the calculated reference group means. More than one error of this type for the same adulterant, for creatinine, for pH, or for specific gravity over two consecutive PT cycles may result in suspension or revocation of a laboratory's certification.

(10) *Requirement for Each Qualitative Specimen Validity Test.* For each qualitative specimen validity test, a certified laboratory shall correctly report at least 80 percent of the challenges for each qualitative specimen validity test over two consecutive PT cycles. A certified laboratory that fails to correctly report at least 80 percent of the challenges may have its certification suspended or revoked.

(11) *Procedures When Requirements in Paragraphs (b)(1)—(b)(10) of this Section Are Not Met.* 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 to develop and submit a plan for implementing corrective actions to address the source of the error within 30 days. 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) *Eighty Percent of Participating Laboratories Must Detect Drug or Specimen Validity Testing Challenge.* A laboratory's performance shall be evaluated for all drug and specimen validity testing challenges unless the overall response from participating laboratories indicates that less than 80 percent of them were able to correctly report the drug or specimen validity testing challenge.

(d) *Participation Required.* Failure to participate in a PT cycle or to participate satisfactorily may result in the suspension or revocation of a laboratory's certification.

Section 3.20 Inspections

(a) *Frequency.* Prior to laboratory certification under these Guidelines and at least twice a year after certification, a team of two or more qualified and trained inspectors shall conduct an on-site inspection of laboratory premises. Inspections shall document the overall ability of the laboratory to satisfy the certification requirements specified in these Guidelines.

(b) *Inspectors.* The Secretary shall establish criteria for the selection of inspectors to ensure high quality, unbiased, and thorough inspections. The inspectors shall perform inspections consistent with the guidance in section 3.12(b).

(c) *Inspection Performance.* Inspectors shall assess the overall compliance of the certified or applicant laboratory to these Guidelines. The laboratory's operation shall be consistent with good forensic laboratory practice and shall be in compliance with these Guidelines. It is the laboratory's responsibility to correct deficiencies identified during the inspection consistent with these Guidelines and with good forensic laboratory practice. In accordance with sections 3.13 and 3.14, deficiencies identified at inspections may be the basis for suspending or revoking a laboratory's certification.

Section 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 sections 3.13 and 3.14 of these Guidelines.

Section 3.22 Listing of Certified Laboratories

A **Federal Register** listing of laboratories certified by HHS will be updated and published periodically. Laboratories which are in the applicant stage of HHS certification are not to be considered as meeting the minimum requirements in these Guidelines. A laboratory is not certified until HHS has sent the laboratory an HHS letter of certification.

Subpart D—Procedures for Review of Suspension or Proposed Revocation of a Certified Laboratory

Section 4.1 Applicability

These procedures apply when:

(a) The Secretary has notified a laboratory in writing that its certification to perform urine drug testing under these Mandatory Guidelines for Federal Workplace Drug Testing Programs has been suspended or that the Secretary proposes to revoke such certification.

(b) The laboratory has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

Section 4.2 Definitions

Appellant. Means the laboratory which has been notified of its suspension or proposed revocation of its certification to perform urine drug and/or validity testing and has requested an informal review thereof.

Respondent. Means the person or persons designated by the Secretary in implementing these Guidelines (currently the National Laboratory Certification Program is located in the

Division of Workplace Programs, Substance Abuse and Mental Health Services Administration).

Reviewing Official. Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of his or her employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Section 4.3 Limitation on Issues Subject to Review

The scope of review shall be limited to the facts relevant to any suspension or proposed revocation, the necessary interpretations of those facts, the Mandatory Guidelines for Federal Workplace Drug Testing Programs, and other relevant law. The legal validity of the Mandatory Guidelines shall not be subject to review under these procedures.

Section 4.4 Specifying Who Represents the Parties

The appellant's request for review shall specify the name, address, and phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

Section 4.5 The Request for Informal Review and the Reviewing Official's Response

Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

Section 4.6 Abeyance Agreement

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory attempts to regain compliance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

Section 4.7 Preparation of the Review File and Written Argument

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) *Appellant's Documents and Brief.* Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) *Respondent's Documents and Brief.* Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform urine drug and/or validity testing, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) *Reply Briefs.* Within 5 days after receiving the opposing party's submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) *Cooperative Efforts.* Whenever feasible, the parties should attempt to develop a joint review file.

(e) *Excessive Documentation.* The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

Section 4.8 Opportunity for Oral Presentation

(a) *Electing Oral Presentation.* If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) *Presiding Official.* The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) *Preliminary Conference.* The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at his or her discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place

determined by the presiding official following consultation with the parties.

(e) *Conduct of the Oral Presentation.*

(1) *General.* The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of his or her employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

(2) *Burden of Proof/Standard of Proof.* In all cases, the respondent bears the burden of proving by a preponderance of the evidence that its decision to suspend or propose revocation is appropriate. The appellant, however, has a responsibility to respond to the respondent's allegations with evidence and argument to show that the respondent is wrong.

(3) *Admission of Evidence.* The rules of evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) *Motions.* The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) *Transcripts.* The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) *Obstruction of Justice or Making of False Statements.* Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under 18 U.S.C. 1505 or 1001.

(g) *Post-hearing Procedures.* At his or her discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

Section 4.9 Expedited Procedures for Review of Immediate Suspension

(a) *Applicability.* When the Secretary notifies a laboratory in writing that its certification to perform urine drug and/or validity testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the laboratory received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) *Reviewing Official's Response.* As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) *Review File and Briefs.* Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following: (1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically, and (2) a written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) *Oral Presentation.* If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7–10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a pre-hearing conference in accordance with section 4.8(c) and will conduct the oral presentation in accordance with the procedures of sections 4.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7–10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in section 4.14 will apply.

(f) *Transmission of Written Communications.* Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile or overnight mail.

Section 4.10 Ex Parte Communications

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

Section 4.11 Transmission of Written Communications by Reviewing Official and Calculation of Deadlines

Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing. In counting days, include Saturdays, Sundays, and holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

Section 4.12 Authority and Responsibilities of Reviewing Official

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in

accordance with the objectives of these procedures.

Section 4.13 Administrative Record

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

Section 4.14 Written Decision

(a) *Issuance of Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefor in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

(b) *Date of Decision.* The reviewing official will attempt to issue his or her decision within 15 days of the date of the oral presentation, the date on which the transcript is received, or the date of the last submission by either party, whichever is later. If there is no oral presentation, the decision will normally be issued within 15 days of the date of receipt of the last reply brief. Once issued, the reviewing official will immediately communicate the decision to each party.

(c) *Public Notice.* If the suspension and proposed revocation are upheld, the revocation will become effective immediately and the public will be notified by publication of a notice in the **Federal Register**. If the suspension and proposed revocation are denied, the revocation will not take effect and the suspension will be lifted immediately. Public notice will be given by publication in the **Federal Register**.

Section 4.15 Court Review of Final Administrative Action; Exhaustion of Administrative Remedies

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under section 4.9(e) or 4.14(a), constitutes final agency action and is ripe for judicial review as of the date of the decision.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of proposed revisions to mandatory guidelines.

SUMMARY: The Department of Health and Human Services ("HHS'' or "Department'') is proposing to establish scientific and technical guidelines for the testing of hair, sweat, and oral fluid specimens in addition to urine specimens; scientific and technical guidelines for using on-site tests to test urine and oral fluid at the collection site; requirements for the certification of instrumented initial test facilities; and added standards for collectors, on-site testers, and medical review officers.

DATES: Submit comments on or before July 12, 2004.

ADDRESSES: You may submit comments, identified by (insert docket number and/or RIN number), by any of the following methods:

- E-mail: *wvogl@samhsa.gov.* Include docket number and/or RIN number in the subject line of the message.
- Fax: 301–443–3031
- Mail: 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857.
- Hand Delivery/Courier: 5515 Security Lane, Suite 815, Rockville, Maryland 20852.
- Information Collection Requirements: Submit comments to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street, NW., Washington, DC 20502, Attn: Desk Officer for SAMHSA. Because of delays in receipt of mail, comments may also be sent to 202–395–6974 (fax).

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this rulemaking. All comments will be available for public review at 5515 Security Lane, Suite 815, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Walter F. Vogl, Ph.D., Drug Testing Section, Division of Workplace Programs, CSAP, 5600 Fishers Lane, Rockwall II, Suite 815, Rockville, Maryland 20857, 301–443–6014 (voice), 301–443–3031 (fax), *wvogl@samhsa.gov* (e-mail).

SUPPLEMENTARY INFORMATION:

Background

The Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and have since been revised in the **Federal Register** on June 9, 1994 (59 FR 29908), and on September 30, 1997 (62 FR 51118). The Guidelines establish the scientific and technical guidelines for Federal workplace drug testing programs and establish standards for certification of laboratories engaged in urine drug testing for Federal agencies under authority of Pub. L. 100–71, 5 U.S.C. section 7301 note, and E.O. 12564.

In developing and organizing the proposed revisions to the Guidelines, there are a number of issues presented in this preamble, that include the rationale for the order and manner of presentation of what is proposed and why. These issues are first presented by general topic area, and later presented in summary, as they appear in the text of the proposed Guidelines.

History of the HHS Certification Program for Federal Employee Drug Testing Programs, and Related Knowledge

Since the beginning of the program in 1988, many challenges have been overcome and lessons learned from the specific and rigorous HHS certification of laboratories to perform forensic workplace testing for job applicants and Executive Branch Federal employees.

The initial Guidelines were published for a 60-day public comment period, and were first published as a final notice in the **Federal Register** in April of 1988. Originally, it was believed that fewer than 10 laboratories would apply for HHS certification under the Guidelines to conduct Federal employee drug testing, and that the Department would not require even that many to test the urine specimens from all Federal agencies.

This situation changed very quickly when the Department of Transportation (DOT) published a final drug testing rule (54 FR 49854) in December 1989 for its regulated transportation industries. DOT required its regulated industries to use drug testing laboratories that were certified by HHS. This requirement began a close relationship between HHS and DOT. Additionally, the Nuclear Regulatory Commission (NRC) in its Fitness for Duty program contained in 10 CFR Part 26 requires its licensees to use drug testing laboratories certified by HHS.