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Part III

Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines and Proposed Revisions to Mandatory Guidelines for Federal Workplace Drug Testing Programs; Notices

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

Subpart A—General

Subpart B—Scientific and Technical Requirements

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

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.

[FR Doc. 04–7985 Filed 4–6–04; 12:39 pm]

BILLING CODE 4162–20–P

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.

As the Guidelines received both public and judicial support, the private sector chose to incorporate the requirement to use only a laboratory that has HHS certification under the Guidelines, for employee drug testing. Between July 1988 and early 1990, 50 laboratories had received HHS certification under the Guidelines, while another 100 laboratories were awaiting certification.

In developing the preamble for the proposed expansion and revision of the Guidelines, it has been very helpful to keep in sight important areas of consideration that have remained visible as the program matured over the ensuing fifteen years. These include, but are not limited to, custody and control that ensures donor specimen identity and integrity, specimen collection procedures, analytical testing methods, quality control and quality assurance, reporting results, the role of the medical review officer (MRO), and HHS certification issues that include testing site inspections and performance testing (PT) samples.

The Department has remained committed to maintaining the integrity of the entire Drug-Free Federal Workplace Program by identifying and using the most accurate, reliable drug testing technology available. To accomplish that goal, the Department collaborates with the DOT, NRC, Federal regulators, researchers, the testing industry, and both public and private sector employers on an on-going basis on scientific and program matters. As the number and types of commercial workplace drug testing products and testing options have increased over the past decade, the Department, through SAMHSA's Drug Testing Advisory Board (DTAB), has expressed increasing interest in assessing these new products and procedures for possible use in Federal agency employee testing programs.

Laboratory-based testing using automated screening tests at instrumented initial test facilities (IITFs) was proposed by the same group of individuals that developed the Guidelines as an area of interest immediately after the Guidelines were first published in 1988. At that time, the industries regulated by the NRC began using this approach as part of their Fitness for Duty programs to allow job applicants access to nuclear power plants. A study of 10 sites (including both NRC licensee and other private sector sites) was conducted where such an IITF was used. Point of collection test (POCT) devices were also being developed, but with non-instrumented, visually read end-points. By 1997, the Department began, as discussed below, a dedicated assessment of drug testing using alternative specimens and drug testing technologies, including head hair, oral fluid (saliva), and sweat, for possible application in Federal workplace drug testing programs.

The Added Specimens—Major Change

The Department proposes to expand the kinds of specimens that may be tested under Federal agency workplace drug testing programs. The proposed addition of head hair, oral fluid, and sweat specimens are the result of a directed Department process that began with a 3-day scientific meeting of the DTAB held in April 1997 to discuss drug testing of alternative specimens and using new testing technologies as they apply to workplace drug testing programs. The entire meeting was open to the public. The first two days consisted of presentations on the principles and criteria of workplace drug testing program requirements and industry representatives discussing alternative specimens (hair, oral fluid, sweat as well as urine) and technologies (non-instrument based on-site tests). The presentations focused on the following areas for each specimen/technology: specimen collection and chain of custody, initial test reagents and procedures, confirmatory test procedures, internal quality control program, reporting test results, interpreting test results, and external quality assurance program. Industry coordinators selected the presenters for the alternative specimens and technologies to ensure a thoroughly unbiased review based on the science available. On the third day, the public was given an opportunity to make official statements or comments.

Following this meeting, the DTAB members continued reviewing the large amount of information presented at the meeting. Their efforts resulted in the identification of specific requirements necessary for the scientific, administrative, and procedural integrity of a comprehensive workplace drug testing program, which includes alternative specimens and technologies. They developed a chart summarizing workplace drug testing program requirements, reviewed the technical materials submitted to them, and identified the necessary workplace drug testing requirements for each alternative specimen/testing technology.

The DTAB has continued its evaluation of the information submitted by the industry representatives on alternative specimens and technologies since September 1997. The first working draft of the new Guidelines was presented at the June 2000 DTAB meeting. The initial, work-in-progress draft Guidelines were placed on our web site and the public was invited to submit supplemental information and informal comments to help improve our knowledge base. Twenty-eight separate commenters submitted comments on the first working draft. The comments were summarized and presented at the next DTAB meeting held in September 2000. At the September 2000 DTAB meeting, the second working draft of the Guidelines was presented and, again, comments were requested from all interested parties. At the December 2000 DTAB meeting, the public comments submitted were used to prepare the third working draft of the Guidelines.

As the DTAB continued to work on the Guidelines, the Department initiated a voluntary pilot PT program. PT samples were developed and produced at government expense. The PT samples were sent to several laboratories for testing at the laboratories' own expense, using the procedures that they routinely use to test head hair, oral fluid, and sweat specimens. This pilot PT program began in April 2000 and was necessary for two reasons. First, it was necessary to determine if it was possible to prepare stable and accurate PT samples for the different types of specimens that would be needed as part of a laboratory certification program. Second, the results reported by the laboratories would indicate if the PT program could establish credibility, precision, accuracy, and reliability in drug testing with alternative specimens. Based on the information obtained from four rounds of PT samples, it appears that valid PT samples can be prepared, although some further refinement is needed, and that over time some laboratories testing alternative specimens have been able to achieve performance levels approaching those levels applied to urine testing laboratories. The criteria for laboratory-based hair, oral fluid, and sweat testing, and for POCT urine and oral fluid tests have been developed and proposed by the industry-lead working groups.

Although performance in the pilot PT program has been encouraging, with individual laboratory and group performance improving over time, there are still three serious concerns. First, the data from the pilot PT program to date show that not all participants have developed the capability to test for all required drug classes, nor to perform such tests with acceptable accuracy. Second, some drug classes are more difficult to detect than others, for any given type of specimen. Third, the specific drug classes that are difficult to

detect varies by the type of specimen. That means that special awareness will be required to select the most appropriate type of specimen to be collected from a specific donor, when use of a specific drug is suspected. This public comment period is intended to provide an opportunity for all interested parties to review the testing criteria and associated specimen-specific procedures, to be sure that required performance is achievable and sustainable when implemented.

Alternative Specimens

The use of specimens other than urine in workplace drug testing programs have become a frequent topic in scientific meetings worldwide. This includes organizations such as the Society of Forensic Toxicologists, The International Association of Forensic Toxicologists, the Society of Hair Testing, and the American Academy of Forensic Sciences. The most frequently discussed specimens are hair, oral fluid, and sweat. Until recently it was considered too soon for the forensic community to apply these alternative specimens to workplace drug testing. Current scientific literature provides much of the information that was not previously available in peer reviewed literature. Addition of these specimens to the Federal Workplace Drug Testing Program would complement urine drug testing and aid in combating the threat from industries devoted to suborning drug testing through adulteration, substitution, and dilution.

The preamble provides a list of scientific studies that were used in making the policy decisions. The Department asks whether commenters are aware of any other studies or data that would cast more light on the appropriateness of using any of the alternative specimens or on limitations on how the specimens should be used.

Hair

The Department is proposing that hair testing be included in the Federal Workplace Drug Testing Program. Hair testing increases the time period over which drug use can be detected as compared to urine, sweat, or oral fluid. Hair is easily collected, transported and stored, is less likely to transmit bio-organisms than urine or oral fluid, and is more difficult to adulterate than urine. As separation techniques and detection sensitivity and specificity have improved, scientists are now able to detect and quantify drugs and/or metabolites in hair at picogram levels. Like other drug testing specimens, drugs in hair are initially detected using an immunoassay technique and results are confirmed with a more sophisticated technique, most frequently by gas chromatography/mass spectrometry (GC/MS). Tandem mass spectrometry (MS/MS) using GC or liquid chromatography (LC) separation has emerged in recent years as the testing method of choice in order to increase sensitivity and selectivity and to analyze polar compounds without derivitization.[10,15,16]

Hair consists of a hair follicle and hair shaft. At the base of the follicle (bulb) are highly vascularized matrix cells. As matrix cells in the dermis of the skin move outward during growth, they form layers of a hair shaft that include the outer protectant cuticle, central cortex and inner medulla. Hair grows in three stages: about 85 percent of hair follicles are in active growth (anagen), while the others are in a transition phase (catagen) before the resting phase (telogen). At the vertex region of the scalp, the average growth rate of hair is about 0.4 millimeters per day or approximately 1 centimeter per month.[1] The Department is proposing to permit agencies as part of their Federal workplace program to test hair with lengths of about 1.5 inches long, representing a time period of 90 days, and to use these specimens for pre-employment, random, return-to-duty, or follow-up testing.

Analytes for the regulated drugs tested in hair are marijuana metabolite (delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA)), cocaine (parent drug and metabolites (benzoylecgonine, norcocaine, and cocaethylene)), phencyclidine (parent drug (PCP)), opiates (codeine, morphine, and heroin metabolite (6-acetylmorphine (6-AM)), and amphetamines (amphetamine, methamphetamine, methylenedioxymethamphetamine (MDMA), methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA)).

Drugs and drug metabolites may be incorporated into hair by several different pathways.[1,3-7] As drugs and their metabolites travel through the body in blood, they passively diffuse from the bloodstream into the base of the hair follicle. Drugs and/or metabolites are embedded into the hair as bands during the growth process. The amount of drug in the hair band is proportional to the concentration in the blood when the hair was formed. The distance of the drug bands from the skin can estimate the time of drug use. Drugs and/or metabolites may also be incorporated into hair via secretions of the apocrine sweat glands and sebaceous glands, which are in close contact with hair as it develops in and emerges from the skin. Sweat and sebum can deposit drugs and/or metabolites on the hair shaft that in turn are absorbed into the hair shaft during and after its formation. Sweat can be responsible for drug incorporation at distal segments of hair which does not correspond to the time of drug ingestion.

There are a number of factors that may influence the amount of drug incorporated into hair (*e.g.*, drug dose, length of exposure, drug chemical structure, charge). Of particular concern are environmental contamination and the role of hair color.

Concern has been raised about environmental contamination where a person may claim, for example, that the drug is present because the individual was in a room where others were using marijuana or cocaine. While washing the hair sample may remove some of the contamination, ultimately we can differentiate environmental contamination from actual use because of the presence of the metabolite, which is not present when environmental contamination is the source of the drug.

The role of hair color is also a major concern. Melanin, which is responsible for pigmentation in hair, is produced in the hair bulb and incorporated into the cells that form the cortex and medulla during growth of the hair shaft. Melanin is a polyanionic polymer of two types: eumelanin and pheomelanin, the quantity of each determine hair color. Eumelanin concentration is highest in black hair and lowest in red hair while pheomelanin concentration is highest in red hair and lowest in black hair.[2] Melanin is absent in white hair.

Animal studies have shown that hair color influences drug incorporation with black hair containing the most and yellow (non-pigmented) hair the least.[7] In vitro studies in which black, brown, and blond hair from drug-free human subjects were placed in a solution of benzoylecgonine showed the highest concentration of the drug in black hair and the least in blond.[8] Although there have been a limited number of human clinical controlled studies, data show that higher concentrations of some drugs are found in dark hair when compared to blond or red hair (*e.g.*, codeine[2], cocaine[9], amphetamine[10]). The limited population studies published in peer reviewed literature at this time do not indicate a significant association between hair color or race and drug analyte.[11 13] In one study, 1852 people that classified themselves as ''black'' or ''white'' showed no evidence of a group adversely affected by hair testing, compared to urine

testing, for cocaine and marijuana testing.[11] The examination of 500 positive hair samples for each of three drugs (cannabinoids, cocaine, and amphetamine) revealed little statistical evidence of selective binding of drugs to hair of a particular color.[12] Statistical examination of 2791 data points that include heroin and its metabolites, cocaine and its metabolites, MDMA and its analogs, and amphetamine and methamphetamine failed to detect a significant hair color effect.[13]

Despite these suspected limitations, the Department still proposes to go forward with incorporation of this new technology as an alternative to urine for Federal agencies who may find it useful in certain missions and tasks that only individual Federal agencies can identify. Though there continues to be some question about the effect of hair color on the amount of a drug or its metabolite present in hair, there is no question about the fact that the drug or metabolite is present. The purpose of the Federal Workplace Drug Testing Program is to ensure the safety of the workplace which it does in two ways. First, it identifies individuals in security or safety sensitive positions who have been using drugs, and second, it acts as a deterrent for people who might otherwise use drugs lest they be detected. Hair testing can improve the success of the program because it increases the time period over which drug use can be detected as compared to urine; it is easily collected, transported and stored; it is less likely to transmit bio-organisms than urine; and is more difficult to adulterate.

Oral Fluid

Testing methods for drugs in oral fluid have been developed in recent years and have been extensively used in some tested populations (*e.g.,* therapeutic drug monitoring, risk assessment in the insurance industry, and non-Federal workplace testing).[17-19] Many studies support the use of oral fluid as a specimen for forensic drug testing.[20,21]

Oral fluid offers some advantages over other types of specimens.[22] Oral fluid is readily accessible and its collection is perceived as less invasive than a urine specimen collection. Oral fluid collections can easily be observed and, therefore, the specimen is less susceptible to adulteration or substitution by the donor. Drugs can be detected in oral fluids within one hour of use making oral fluids useful in detecting very recent drug use.[27]

Substitution can be identified by measuring an endogenous component (IgG) in the specimen. Although the specimen volumes and amount of drug are lower in oral fluid than in urine specimens, current analytical methods (*e.g.,* immunoassay, GC/MS, GC/MS/MS, LC/MS/MS) have the required sensitivity to be used for oral fluid specimen testing.[23-26]

As with the other relatively new test specimens for drugs of abuse testing, less is known about the pharmacokinetics and disposition of drugs into oral fluid as compared to urine.[3,28-30] Science shows that opiates, PCP, amphetamines and cocaine and most drugs including prescription medications enter oral fluid through passive diffusion of the drug from the blood stream into the oral fluid. However, the active component of marijuana (delta-9-tetrahydrocannabinol (THC)) does not diffuse into oral fluid.[26,31,32] The only way to detect marijuana use is through the presence of the parent drug (THC) in the oral fluid because the parent drug was present in the oral cavity. Unfortunately, further scientific study is needed to be able to differentiate between whether the parent drug was present in the oral cavity due to drug use or environmental contamination, *i.e.* the individual was present in a room when others smoked marijuana, for example.

In order to protect Federal workers from incorrect test results for marijuana, the Department proposes that a second biological specimen, a urine specimen, will need to be collected under the current Guidelines at the same time the oral fluid specimen is obtained, primarily for the purpose of testing for marijuana when the oral fluid specimen is positive for marijuana. The Department will revise the Guidelines when the science is available to differentiate between actual use and environmental contamination.

Analytes for the regulated drugs tested in oral fluid are marijuana (parent drug (THC)), cocaine (parent drug or metabolite benzoylecgonine), PCP (parent drug), opiates (codeine, morphine, and 6–AM), and amphetamines (amphetamine, methamphetamine, MDMA, MDA, MDEA).

The pH of oral fluid can affect incorporation of some drugs.[33-35] Salivary pH ranges from about 6.2 to 7.4. Increased saliva flow rate raises the pH up to a maximum of 8.0 due to higher bicarbonate levels. Oral fluid collection devices cause some stimulation of saliva flow. Studies have found that concentrations of drugs (*e.g.,* cocaine and its metabolites) in non-stimulated oral fluid specimens were greater than the concentrations of specimens collected using other methods.[34] Mechanical saliva stimulation (*i.e.,* chewing gum) can also lower drug concentrations in oral fluid.[33] To avoid saliva stimulation some recommend spitting into a cup, but some donors may be opposed to spitting, especially when observed, and may experience dry mouth.

The Department finds that the collection difficulties associated with oral fluid collection procedures are not functionally different than other specimen collection difficulties currently encountered with urine. Therefore, despite these known limitations, the Department proposes to incorporate this new technology as an optional selection for Federal agencies because oral fluid testing may be useful in certain missions and tasks that only individual Federal agencies can identify.

Sweat

The incorporation of drugs into sweat is poorly understood but possible mechanisms appear to be passive diffusion of drugs from blood into sweat gland and transdermal migration of drugs to the skin surface, where it is dissolved in sweat.[3,36,37] The time interval between drug consumption and detection in sweat depends on the nature of the particular drug or drug metabolite and the sensitivity of analytical method used.[3,36,38]

Sweat may be collected as liquid perspiration,[38] on sweat wipes,[20,39] or with a sweat patch.[40-44] Sweat collection is a non-invasive procedure [37,38] and privacy during collection does not appear to be a concern.[38] Commercially available sweat patches may be worn for an extended period of time, are waterproof, and are generally accepted by patients.[39] Currently, there are a limited number of commercially available collection devices,[20,39] only one of which is FDA-cleared. Attempts to remove or tamper with the FDA-cleared sweat patch are usually visible to personnel trained to remove them.[3,37] Sweat patch contamination issues continue to be a concern.[3,39,45] For example, one study suggests that sweat patches are susceptible to contamination by a drug that is on the skin before the sweat patch is applied and by absorption into the patch through the surface of the protecting membrane.[39] Other studies indicate that the polyurethane (outer) layer is impermeable to molecules larger than dimer water.[45] Based on that information, the Department believes that external absorption of any drugs through the outer layer is not possible under normal circumstances. With regard to contamination from a drug

present on the skin before applying the sweat patch, the Department proposes that the skin area be washed with soap and cool water or with a disposable towelette. Then the collector must thoroughly clean the skin area where the patches will be worn with alcohol wipes prior to application. However, the Department encourages researchers to conduct further research in this area.

The Department knows from direct experience both at the National Institute on Drug Abuse and the Substance Abuse and Mental Health Services Administration that some individuals may not be able to wear the sweat patch for the optimal period of time. Skin sensitivity and rash are factors that can only be known after the patch is applied for the first time.

The Department also knows from direct experience that if the patch is applied in a normally visible area of the body, such as the upper arm, that there could be a stigmatizing effect on the wearer.

Despite these known limitations, the Department proposes to incorporate this new technology as an optional selection for Federal agencies because sweat testing may be useful in certain missions and tasks that only individual Federal agencies can identify.

Unlike urine, head hair, or oral fluid, the use of a sweat patch detects drug use that occurred shortly before the patch is applied and while the device remains applied to the skin.[3,20,37,46] The window of detection for the sweat patch is for as long as the patch remains on the skin and is a cumulative measure of drug ingestion.[3,37]

Unlike urine, primarily the parent drug is found in sweat; however, some drug metabolites may also be detected.[3,20,36,37,47] Some drugs and drug metabolites that have been detected in sweat are THC,[51] amphetamine, methamphetamine,[20,48] codeine, morphine, 6–AM, heroin,[40,43,45,47,49,50] PCP,[72] and cocaine, benzoylecgonine, ecgonine methylester.[20,44,47,52] Investigations to compare the detection of drugs in sweat to other specimens are ongoing.[38-41,47,48,51,53,54]

Analytes for the regulated drugs tested in sweat are marijuana (parent drug (THC)), cocaine (parent drug or metabolite benzoylecgonine), PCP (parent drug), opiates (codeine, morphine, and 6–AM), and amphetamines (amphetamine, methamphetamine, MDMA, MDA, and MDEA).

The amount of sweat excreted is variable for each person and between individuals and is dependent upon their daily activities, emotional state, and environment.[39] The amount of sweat collected for testing is small and the drug concentration low. Therefore, the analytical procedures used for measurement of drugs and/or their metabolites in sweat must be very sensitive. Confirmation of drug analytes in sweat are routinely confirmed by GC/MS [54] and sometimes with LC/MS/MS.[38]

Currently, sweat testing is used in the private sector for monitoring drug use during substance abuse treatment [37] and is also used in the criminal justice system.[17] Sweat also appears to be well suited for return-to-duty and follow-up testing for workplace testing.[3,20]

The Added Types of Testing Options and Locations—Major Change

Instrumented Initial Test Facility (IITF)

The Department proposes to include IITF options in the Guidelines. An IITF is basically the screening part of a screening and confirmatory laboratory, but established in locations to potentially more quickly and economically meet special local testing needs. The Department has learned a great deal from the experience of the NRC, where such urine-based facilities were permitted beginning in 1990. These IITFs were intended to support the periodic large testing needs of nuclear-fueled electrical power generating facilities, whenever facility maintenance and fuel rod replacements were needed, at which time hundreds of maintenance workers needed to be allowed timely access into the secured areas of the nuclear power plant.

The numbers and fixed locations of IITFs make them more ''like'' laboratories. Presently there are fewer than 60 laboratories HHS-certified to perform workplace urine drug testing for Federal agencies. With the rigorous certification, performance testing, and inspection requirements proposed for the IITF, it is unlikely that the total number of laboratory and laboratory ''like'' facilities will increase very much, or even double to 120 in total. Thus, the IITF could be certified in much the same fashion as a laboratory with inspections and PT, with the focus exclusively on initial drug and validity testing.

The Department proposes that IITFs should: (1) Be at a permanent location, (2) meet program forensic standards, (3) participate in open and blind proficiency testing, (4) have a rigorous quality assurance program, (5) be subject to site inspections, (6) use instrumented immunoassay tests for drugs which meet FDA requirements for commercial distribution, (7) conduct required specimen validity tests, (8) use HHS cutoffs, and (9) submit all non-negative specimens to a full service HHS-certified laboratory for required additional testing. In meeting these criteria, the IITF will meet Guideline requirements of the initial test section of an HHS-certified laboratory.

POCT for Drugs

POCT devices for drugs of abuse were first available in the early 1990s. POCTs include non-instrumented devices with visually read endpoints as well as semi-automated or automated instrumented testing devices with machine read endpoints. Drug tests conducted with these devices utilize competitive binding immunoassays, the same scientific principle as the initial tests conducted in certified laboratories.

The development and commercial availability of POCT products has evolved to include both urine and oral fluid specimens at this time, with more specimens likely to be added in the future. The Department has learned a great deal from collaboration with the National Institute on Drug Abuse, the Administrative Office of the U.S. Courts, the Federal Probation and Parole Office, and the Department of Defense (DoD) Armed Forces drug testing program office. Collectively, these collaborations and the results of actual product assessments [58] have provided the experience and knowledge to propose procedures in the Guidelines to more uniformly assess the on-going performance of these devices in Federal drug testing applications.

Non-instrumented POCT for urine testing have been subjected to evaluations by investigators independent of the manufacturers and found to perform similar to that of the instrumented immunoassay tests in certified laboratories.[55-58] These tests were conducted on both spiked and donor specimens with and without drug analytes. Little difference in the performance of these devices was observed between tests conducted by laboratory technicians and laymen who had been trained in the proper procedures for conducting and reading the tests.[55,56]

Non-instrumented POCTs for oral fluid have been characterized by only one group of independent investigators.[59] Their study was performed on spiked oral fluid at concentrations consistent with the proposed cutoffs. This study found device variability and difficulty in detecting cannabinoids, but suggests the rapid evolution of the technology should overcome current problems relating to targeted analyte and

manufacturer's cutoff and provide an assay consistent with proposed HHS cutoffs. The investigators felt that "there is every reason to be optimistic about the future for drug testing using oral fluid matrix.'' [59] Presently, there are no POCT devices that have received FDA clearance for drugs of abuse in hair or sweat.

POCTs could potentially be employed almost anywhere, with hundreds, if not thousands of testing sites possible. The value and utility of the POCT is that it provides quick, negative drug results and validity test results and has the added benefit of not requiring a fixed facility, expensive test equipment, and highly trained testing personnel; moreover, POCTs could be run in low numbers, infrequently, and at any given location, as needed. These factors make it very difficult, if not impossible to use a laboratory "like'' inspection and quality assurance process. The use of highly trained laboratory personnel provides no specific or added value to any oversight process, beyond the actual testing of sample POCT devices. Further, the sheer potential number and diverse locations of sites where POCT devices might be used by choice, make large-scale, routine, or scheduled on-site inspections a logistic and budgeting nightmare.

In order to provide an equivalent program of on-going quality assurance for POCT devices, the Department proposes a certification process under which POCT device manufacturers would provide tests for evaluation to be placed on the list of SAMHSA-certified devices published by the Secretary. This would be followed by periodic additional testing as new lots of manufactured tests become available as well as PT sample requirements, training of POCT testers, and on-going quality assurance requirements. This is a complex area that will benefit from public comments now, and from lessons learned over time.

Advantages of POCTs

POCT products could potentially be employed almost anywhere. The value and utility of the FDA-cleared and SAMHSA-certified POCT is that it will provide quick, negative drug and specimen validity test results. Those specimens that test presumptively positive for drugs or indicate that additional specimen validity testing is necessary would then be referred for confirmatory testing.

POCT testing of urine is most suited for situations that require quick, negative drug and specimen validity test results such as in emergency/crisis management. It may be least suited for pre-employment, return to duty and follow-up testing.

POCT testing of oral fluid is most suited for situations that require quick, negative results such as in emergency/crisis management. It is most suited for reasonable suspicion/cause and post-accident. It may be least suited for random testing. Oral fluid is not suited for return to duty, follow-up testing and pre-employment. In order to protect Federal workers from incorrect test results for marijuana, a second biological specimen, a urine specimen, will need to be collected at the same time the oral fluid specimen is obtained.

POCT for Specimen Validity Testing

Specimen validity POCT devices for the detection of substitution and the presence of adulterants have become more widely used in the past three years. Specimen validity POCTs include non-instrumented devices with visually read endpoints as well as semi-automated or automated instrumented testing devices with machine read end points. Specimen validity tests conducted with these devices utilize colorimetric assays, the same scientific principle as the initial tests conducted in certified laboratories.

Non-instrumented specimen validity POCT for urine testing have been subjected to evaluations by independent investigators and were able to detect abnormal urine specimens.[60-62] These tests were conducted on spiked specimens with drug analytes. Results from these preliminary studies are variable; however, they demonstrate the ability of the devices to detect adulterants and creatinine. This is why the Department will incorporate the evaluation of the accuracy and reliability of specimen validity testing as part of the POCT device evaluation process.

Urine Specimen Validity Testing

On August 21, 2001, HHS published a notice in the **Federal Register** (66 FR 43876), proposing that the Mandatory Guidelines be revised to include specific standards for determining the validity of urine specimens collected by Federal agencies under the Federal Workplace Drug Testing Program. The Department has issued a final revision with comments to the Mandatory Guidelines as they currently exist implementing the urine specimen validity testing requirements. These requirements have been incorporated in this revision.

Manner of Presentation and the Use of Plain Language—Major Change

Although the order of presentation in the proposed revisions to the Guidelines has been retained, the manner of presentation has been totally revised. This "improved'' process has been based on the experience and very positive public feedback that other Federal agencies have had when they used a similar process. The goal of the HHS process was to revise the manner of presentation to use "plain language,'' and address complex issues by using simple questions to identify each specific topic. Unfortunately, these Guidelines are scientifically based and the answers are often complex.

Wherever possible, the questions and answers have been organized as a group for a specific specimen, testing option, or related topic. The Department understands that such organization may produce some repetition, for example when reading about head hair, oral fluid, or sweat, and seeing identical information presented for collection site, donor identification, or confidentiality, as repeated text. Because this change in format is significantly different than the current Guidelines, major changes from the current Guidelines will be noted in the discussion of each subpart.

Organization of Draft Guidelines—No Major Change

Within the text for the proposed revisions to the Guidelines, the order of presentation of topics follows the existing Guidelines, with expanded details to address the added specimens (head hair, oral fluid, sweat), testing options (IITF and POCT), and related issues. This seems to be the most appropriate way to permit those already familiar with the existing Guidelines to do a detailed comparison with what is being proposed. For those relatively few first-time readers of the Guidelines, they may wish to first review the current Guidelines so as to understand the current proposal. Where there are no changes to specific sections in the proposed revisions to the Guidelines, that has been stated in the preamble.

HHS Contractor—No Major Change

In accordance with current practice, the HHS contractor performs certain functions on behalf of the Department. These functions include maintaining a laboratory inspection program and a PT program that satisfy the requirements described in the Guidelines. These activities include, but are not limited to, reviewing inspection reports submitted by inspectors, reviewing PT results

submitted by laboratories, preparing inspection and PT result reports, and making recommendations to the Secretary regarding certification, continued certification, or suspension/revocation of laboratories' certification. It is important to note that while the contractor gathers and evaluates information provided to it by inspectors or laboratories, all final decisions regarding laboratory certification, suspension or revocation of certification status is retained within the Department.

In addition, the contractor has historically collected certain fees from the laboratories for services related to the certification process, specifically for laboratory application and inspection and PT activities for laboratories applying to become HHS-certified, and in the process of maintaining HHS-certification. All fees that are collected by the contractor are applied to its costs under the contract.

This same process, which has been used since the inception of the laboratory certification program, will also be used by the HHS contractor to collect similar fees from laboratories that seek, achieve, and continue HHS-certification for testing additional types of specimens (*e.g.,* hair, oral fluid, sweat), and from IITFs that seek, achieve, and continue HHS-certification to test hair, oral fluid, sweat, or urine.

The Department also contributes funds to this contract for purposes not directly related to laboratory certification activities, such as evaluating the technologies and instruments and providing an assessment of their potential applicability to workplace drug testing programs.

Subpart A—Applicability

Sections 1.1, 1.2, 1.3, and 1.4 contain the same policies as described in the current Guidelines with regard to who is covered by the Guidelines, who is responsible for the development and implementation of the Guidelines, how a Federal agency requests a change from these Guidelines, and how these Guidelines are revised.

In section 1.5, where terms are defined, the Department proposes to add or revise several of the definitions contained in the Guidelines. These include, for example, new or revised definitions for adulterated specimen, certifying scientist, collector, confirmatory validity test, dilute specimen, failed to reconfirm, follow-up test, initial validity test, IITF, invalid result, non-negative specimen, oxidizing adulterant, POCT facility, post-accident test, pre-employment, random test, reasonable suspicion/cause test, reconfirmed, rejected for testing, responsible person, responsible technician, return to duty test, specimen, split specimen, substituted specimen, and standard. Every effort has been made to define terms such that they would apply to each type of specimen collected, as appropriate.

Section 1.6 specifies what an agency is required to do to protect employee records. It is the same policy as described in the current Guidelines except it has been amended to include records at IITFs, POCT sites, specimen collection sites, and records produced and maintained by medical review officers.

Subpart B—Specimens—Major Change

In section 2.1, the Department proposes to expand the urine drug testing program for Federal agencies to permit testing head hair, oral fluid, and sweat specimens. The Department wants to make it very clear to agencies that there is no requirement that they use hair, saliva or sweat as part of their drug testing program, but rather that agencies may use those specimens. If they choose to use these alternative specimens then agencies are required to follow these Guidelines.

In section 2.2, in order to guide Federal agencies, the Department has added to the Guidelines a chart indicating in what circumstances each specimen can be collected.

Urine

Laboratory based urine testing has traditionally been used for pre-employment, random, reasonable suspicion/cause, post-accident, return-to-duty, and follow-up testing.

Drug ingestion for a 3–5 day interval preceding the specimen collection can usually be identified in urine. Based on the detection window, urine is most suited for random, return to duty and follow-up testing.

Because of the increasingly evident potential that Federal agency workplace urine-based drug testing has the potential for being seriously compromised by clandestine products and procedures intended to mask current drug use, especially when given sufficient time to obtain these products, urine drug testing may be least suited for pre-employment.

Oral Fluid

Drug detection times for the regulated analytes in oral fluid range from less than one to approximately 24 hours. Drugs may be detected in urine longer after drug use than in oral fluid. This makes oral fluid useful in detecting very recent drug use. Based on the detection window, oral fluid is most suited for reasonable suspicion/cause and post-accident. It may be least suited for random testing if prior notice (greater than 24 hours) is given. Because of the short detection window, oral fluid is not suited for return to duty, and follow-up testing. In order to protect Federal workers from incorrect test results for marijuana, a second biological specimen, a urine specimen, will need to be collected at the same time the oral fluid specimen is obtained.

Hair

Hair is useful for detecting drug use for longer time intervals, *i.e.,* weeks (>7–10 days) to months. Based on the detection window, hair is most suited for pre-employment and random testing. The window of detection is much longer than that of urine. Hair may be used for return to duty and follow-up testing depending on the time of last known drug use. Hair is not suited for reasonable suspicion/cause and post-accident because it takes 7–10 days for drug or drug metabolites to appear in hair.

Sweat Patch

The window of detection for the sweat patch is for as long as the patch remains on the skin and is a cumulative measure of drug ingestion. The sweat patch may not be useful for pre-employment, random, reasonable suspicion/cause and post accident drug testing because it must be worn for days after its application. The sweat patch is best used for return to duty and follow-up testing.

The Department is specifically requesting public comment on the appropriateness of the reasons for defining and limiting the selection of specimens for the different types of testing proposed in this notice. Commenters are requested to submit supporting documentation if recommending that other reasons for testing would be appropriate for some of the types of specimens being collected.

In section 2.3, the Department proposes to prohibit routinely collecting more than one type of specimen from a donor at the same time except when an oral fluid specimen is collected. This restriction is appropriate because it prevents Federal agencies from expecting an individual to provide multiple specimens each time he or she is selected for a drug test and then attempting to compare results from different types of specimens. It is expected that different results would be obtained for the different types of specimens because the windows of

detection are different, as explained above. If a problem occurs during the collection of one type of specimen (*e.g.,* shy bladder for a urine specimen, insufficient specimen available), permission can be obtained from the Federal agency to collect an alternative specimen.

In section 2.4, the Department proposes to establish the requirement for all specimens to be collected as split specimens, and in section 2.5 to establish a minimum quantity that must be collected for each type of specimen. For hair, 100 mg of head hair was the quantity recommended by the hair testing industry. For oral fluid, the Department is proposing that 2 mL be collected in a collection tube rather than allowing oral fluid to be collected directly into a collection device that does not provide an accurate measurement of the volume of oral fluid collected. This approach allows establishing specific cutoffs for oral fluid testing. For sweat, since the "sweat patch'' is the only FDA-cleared device currently available, the quantity of sweat collected is determined by the length of time the patch is worn. Requiring that the patch be worn at least 3 days but no more than 7 days ensures that a sufficient amount of sweat is collected that could possibly contain a measurable amount of drugs or drug metabolites. For urine, the Department is proposing to eliminate the single specimen collection procedure and to require each Federal agency to use the split specimen collection procedure. The 45 mL requirement ensures that each Federal employee is offered the same opportunity to have the split specimen tested by a second laboratory.

Subpart C—Drug and Validity Tests—Major Change

Section 3.1 contains the same policy that is in the current Guidelines regarding which tests must be performed on a specimen. A Federal agency is required to test each specimen for marijuana and cocaine, and is authorized to also test for opiates, amphetamines, and phencyclidine. The Department realizes that most Federal agencies already test for all five drug classes authorized by the existing Guidelines, but has not made this a mandatory requirement. The Department will continue to rely on the individual agencies and departments to determine their testing needs above the minimum. The one new requirement is that each Federal agency is required to ensure that each specimen is tested to determine if it is a valid specimen.

The policy in section 3.2 remains unchanged. Any Federal agency that wishes to routinely test its specimens for any drug not included in the Guidelines must obtain approval from the Department before expanding its program. A specimen may be tested for any drug listed in Schedule I or II of the Controlled Substances Act when there is reasonable suspicion/cause to believe that a donor may have used a drug not included in these Guidelines. When reasonable suspicion/cause exists to test for another drug, the Department is proposing that a Federal agency must document the possibility that the use of another drug exists, attach the documentation to the original Federal drug testing custody and control form (Federal CCF), and ensure that the HHS-certified laboratory has the capability to test for the additional drug. The HHS-certified laboratory is expected to validate the test methods for this additional drug and to use the same quality control criteria that are used for the other drug analyses described in the Guidelines. The Department believes this proposed policy is sufficient to ensure that this testing for an additional drug would be forensically and scientifically supportable.

Section 3.3 restates the policy in the current Guidelines that specimens may not be used for any unauthorized purposes.

Sections 3.4, 3.5, 3.6, and 3.7 list the proposed cutoff concentrations for each type of specimen collected. As previously stated in this preamble, the Department is proposing to adopt the cutoff concentrations that were recommended by the industry working groups. Based on the results from the PT testing program, it appears that some industry proposed cutoff concentrations for the alternative specimens are currently set at what appears to be approaching a limit of quantitation that reflect the analytical capabilities of one or two laboratories to detect extremely low drug concentrations. The Department believes that each laboratory testing a specific type of specimen for a particular drug must be able to accurately determine the concentration for a drug or drug metabolite that is less than the cutoff concentration, as well as concentrations equal to or greater than the cutoff. The Department is specifically requesting comments on the appropriateness of these cutoff concentrations and the ability of laboratories to meet this requirement.

Since the late 1980's, a number of recommendations have been made that additional drugs be considered for inclusion in workplace drug testing. Over the past decade, MDMA and its analogues have become increasingly prevalent in the workplace. The 2002 National Survey on Drug Use and Health (NSDUH)) (available on the Internet at *http://www.samhsa.gov/oas/nhsda.htm* [63]) indicates that the estimated number of people using ecstasy, the generic name for MDMA, within the past year and within the month before the survey was taken, exceeded that found for heroin, crack cocaine, LSD, and PCP. This is further supported by Drug Abuse Warning Network (DAWN) data [64] which finds that MDMA was on the list of the top 10 drugs mentioned in emergency room visits, just below methamphetamine and was one of the top ten of drugs seized and sent to Federal, State and municipal crime laboratories, as noted in the National Forensic Laboratory Information System (NFLIS) 2002 Annual Report.[65] In 2000, the prevalence of MDMA found in active duty Army personnel exceeded that of methamphetamine.[66] Thus, Federal agencies may elect to test for additional drugs including MDMA, under section 3.2(a) of the Mandatory Guidelines.

The Department is specifically interested in obtaining information on the ability of the various immunoassay test kits to detect MDMA, within the amphetamine class of drugs. The Department is aware that DoD drug tests members of the uniformed services for MDMA using an additional initial test focused on that drug. Based on this experience from DoD, if drug testing is proposed at the cutoffs in this document, the Department believes that the only sensitive and specific manner to perform the initial test for methamphetamine, amphetamine, and MDMA is to use two separate initial tests, one for methamphetamine and amphetamine and a second initial test for MDMA. Recommendations on using a single amphetamine test kit or the need to use separate test kits are requested.

The Department periodically reviews the cutoff for all drugs authorized for workplace drug testing and revises those cutoffs as necessary to maximize the deterrent effect of the program. As a result of this review, the initial test cutoff for marijuana was lowered in 1994 and both the initial test and confirmatory test cutoff for opiates was raised in 1998. These changes were instituted after review of the science supporting the change, the technical capabilities of the certified laboratories and the effect of the change on the deterrent intent of workplace drug testing.

The Department proposes to lower the cutoff concentration for cocaine and amphetamine analytes. Reductions in

initial and confirmatory cutoffs for most drugs in urine will increase the time period in which those drugs will be found.[67] The proposed lower cutoffs will produce an increase in the number of urine specimens that are identified as containing cocaine metabolites and amphetamines.[68-70] The cutoff reductions proposed in this revision are estimated to identify 10–20 percent more urine specimens containing cocaine metabolites [68,69] and 5–24 percent more urine specimens containing amphetamines.[70] Data provided by currently certified laboratories are consistent with these estimates and will increase the deterrent effect of the program and allow early identification of substance use by individuals. The lowering of these cutoffs should not result in increased claims of passive exposure.[71]

The capability of HHS-certified laboratories to respond to these changes has been evaluated. Since the beginning of this program, laboratories certified by HHS have exhibited significantly less quantitative variability when analyzing PT samples than applicant laboratories. Evaluations of their performance since 1990 have also shown that the quantitative variability of the certified laboratory population has continued to decrease for all drugs. Evaluations of performance for the testing of cocaine and amphetamines have found that certified laboratories have demonstrated the precision and accuracy necessary for the proposed cutoff revisions. Certified laboratories demonstrated their ability to meet current Guideline requirements through the testing of quarterly PT samples containing amphetamine, methamphetamine, and benzoylecgonine. Documentation of their capabilities with method validations has demonstrated the precision and accuracy of the method down to 40 percent of the current cutoffs. In addition, laboratories have been challenged quarterly with PT samples which contained drug concentrations at 40 percent of the current cutoff and higher.

For urine, the Department proposes to lower the initial test cutoff concentration for cocaine metabolites from 300 ng/mL to 150 ng/mL with a corresponding decrease of the confirmatory test cutoff concentration from 150 ng/mL to 100 ng/mL. Additionally, the initial test cutoff concentration for amphetamines would be decreased from 1000 ng/mL to 500 ng/mL and the confirmatory test cutoff concentration decreased from 500 ng/mL to 250 ng/mL. The Department continues to require the presence of amphetamine at a concentration below cutoff in order to report a specimen positive for methamphetamine. This "methamphetamine reporting rule'' is retained because of concerns and experience that extremely high concentrations of pseudoephedrine and/or ephedrine in a urine specimen can still lead to inappropriate reporting of a methamphetamine positive result when in fact there is no methamphetamine present at a concentration above the cutoff. Additionally, this requirement to confirm the presence of amphetamine at a concentration below the cutoff is included for reporting a hair, oral fluid, or sweat patch methamphetamine positive result. The confirmatory testing for amphetamines would be expanded to test for MDMA, MDA, and MDEA. The Department believes that the certified laboratories have the capability to accurately test urine specimens using these revised cutoff concentrations. Additionally, the revised cutoff concentrations will increase the windows of detection for these drugs, thereby, increasing the number of specimens that may be reported positive.

In sections 3.8, 3.9, and 3.10, the Department is proposing which validity tests must be conducted on head hair, oral fluids and sweat patches. In section 3.11, the Department then reiterates which validity tests must be conducted on a urine specimen. The Department believes these policies are necessary to identify those individuals who are attempting to suborn a drug test. There are many products marketed on the Internet and in highly publicized market-focused publications that offer different approaches to suborn drug tests. At this time, many products are focused on defeating the well-established, mature urine drug testing program. The Department believes as alternative specimens become increasingly used, attempts to suborn alternative specimen drug tests will increase. The Department also recognizes that validity testing proposed for alternative specimens is not as robust as for urine, but is confident that this testing will be refined over time.

In sections 3.12, 3.13, 3.14, and 3.15, the Department reiterates the criteria that a laboratory will use to report a urine specimen as adulterated and proposes the criteria that a laboratory will use to report a head hair, oral fluid, and sweat patch, respectively, as adulterated.

Section 3.16 describes the proposed requirements to report an oral fluid specimen as substituted. The Department also reiterates the current requirements with regard to a urine specimen being reported as substituted.

Section 3.18 reiterates the criteria to report a urine specimen as dilute.

Sections 3.19, 3.20, 3.21, and 3.22 reiterate the criteria that will be used to report a urine specimen as an invalid result and propose the criteria that will be used to report a head hair, oral fluid, and sweat patch, respectively, as an invalid result. The Department believes these proposed criteria for each type of specimen collected are appropriate to ensure that each specimen is a valid specimen.

Subpart D—Collectors—Major Change

In section 4.1, the Department is proposing to expand the requirements for donor confidentiality for collectors.

Section 4.2 describes what specific training requirements individuals are required to have before they may serve as a collector.

Section 4.3 proposes that another person, such as another employee of the organization or company responsible for providing collection site services, must provide the training for an individual to become a collector and specifies the qualifications for this individual to be a trainer.

In section 4.4, the Department proposes what an organization must do before it allows an individual to serve as a collector. The Department believes these proposed expanded requirements are necessary to ensure that a collector knows the entire collection procedure, how to interact with the donor, how to maintain chain of custody, how to complete the Federal CCF, and how to transfer the specimen for testing.

Subpart E—Collection Sites

The collection site requirements in this subpart are essentially the same as those described in the current Guidelines, with variations for specimen collection that would vary around privacy issues required for the collection of a urine specimen, that would not be required for head hair, oral fluid, or sweat specimens, based on the experience and input from participating industry-led working groups for each type of specimen.

In sections 5.5, 5.6, 5.7, and 5.8, the Department is proposing specific privacy requirements when collecting head hair, oral fluid, sweat patch, and urine specimens, respectively. The privacy requirements for urine are the same as those described in the current Guidelines.

For hair, the Department proposes that head hair is the only type of hair to collect for a hair sample. The Department believes this is appropriate because collecting hair only from the

head is the least invasive area to collect a hair sample and affords the donor the most privacy. If head hair is not available, the Department believes it is more appropriate to conduct a drug test using a different specimen rather than attempting to collect hair from another body site.

For sweat, the Department proposes that the sweat patch may only be applied to the donor's upper arm, or back. The primary site for a sweat patch is the upper arm; however, applying a patch to a donor's chest or back is reasonable if the donor prefers to use these alternative sites to conceal the fact that they are wearing a sweat patch.

For oral fluid, the Department proposes that the donor provide an oral fluid specimen directly into an appropriate container. This approach will ensure that a minimum amount of oral fluid is collected and can then be split for on-site testing or sent to a laboratory for both initial and confirmatory testing.

For each type of specimen collected, the collector and the donor are the only individuals present while the specimen is being collected, except when a direct observed collection is used to collect a urine specimen and the observer is present with the donor.

Subpart F—Federal Drug Testing Custody and Control Forms

The requirement to collect a Federal agency specimen using an OMB-approved form is the same as in the current Guidelines. An OMB-approved Federal CCF must be used for each type of specimen collected. The form for each type of specimen will be developed with the assistance of each industry working group and Federal agencies and approval will be requested from OMB and comment sought from the public prior to these Guidelines being implemented. The Department seeks comments on whether it would be preferable, and practical, to have a single Federal CCF that could be used for all the various specimens, rather than a multiplicity of forms. The Department also seeks comment on whether it would be useful to add a requirement that employees and others could not alter the Federal CCF in any way, *e.g.,* could not write comments on it.

Subpart G—Collection Device

Section 7.1 describes what is considered to be the collection device that is used to collect each type of specimen.

In section 7.2, the Department describes the proposed policy on which devices may be used to collect a specimen. If the FDA has cleared a collection device, it has been determined that the device does not affect the specimen collected. If the FDA has not cleared a collection device, the Federal agency must only use a collection device that does not affect the specimen collected. This requirement arises from incidents in the past where specimen containers themselves, or liners in the lids of specimen containers were found to absorb drugs present in a urine specimen. This means that the actual drug concentration in the specimen was reduced simply by its presence in that particular type of specimen container. Since the Department is proposing drug testing using alternative specimens and technologies, it is reasonable to believe that new and different specimen collection devices will be used to collect Federal employee drug test specimens. The Department requests specific comments on this requirement.

Subpart H—Specimen Collection Procedure—Major Change

In section 8.1, the Department is proposing to establish the basic requirements that would apply to collecting any type of specimen. This includes a requirement for the collector to provide identification to the donor if the donor asks, explain the basic collection procedures to the donor, request that the donor read the instructions on the back of the Federal CCF, and answer any reasonable and appropriate questions the donor may have regarding the collection procedure.

In sections 8.2, 8.3, 8.4, and 8.5, the Department is proposing the collection procedure to be used to collect each type of specimen. The collection procedure for urine is essentially the same as that described in the current Guidelines. The major change is that a split specimen collection would be required for all specimen collections, including urine.

In section 8.6, the Department is proposing to require that a Federal agency conduct an annual inspection of each collection site that is used for its workplace drug testing program. If several Federal agencies are using the same collection site, then only one Federal agency is required to conduct an inspection. The Department believes this requirement will ensure that collectors and collection sites satisfy all the collection requirements in these Guidelines for each type of specimen collected. For the Department to directly carry out this responsibility for a Federal agency, the Department would incur substantial financial and administrative costs. However, to the extent that Federal agencies lack the clinical or technical expertise required to fulfill their requirements under this proposal, they are free to enter into Economy Act transfers with the Department.

Subpart I—HHS Certification of Laboratories and IITFs—Major Change

Section 9.1 reaffirms the goals and objectives of the certification program that are the same as those described in the current Guidelines.

Section 9.2 describes who has the authority to certify laboratories or IITFs to conduct testing for Federal agencies. This is the same policy as in the current Guidelines.

Section 9.3 describes the process that a laboratory or IITF must follow to become certified to conduct testing for a Federal agency. The Department believes that including a description of the certification process will be extremely helpful to those laboratories or IITFs that are interested in applying for certification. It is also important to understand that a laboratory or IITF needs to be certified for each sample type it wants to test (*e.g.,* hair, oral fluid, sweat, urine) since the testing procedures are different for each.

Section 9.5 describes the specifications for the PT samples. The requirements in this section are the same as in the current Guidelines.

Sections 9.6, 9.7, 9.8, and 9.9 describe the proposed PT requirements for an applicant laboratory to conduct testing for each type of specimen. The performance testing requirements for the urine testing program are the same as those in the current Guidelines and the Department is proposing that similar requirements apply to the other types of specimens.

Sections 9.10, 9.11, 9.12, and 9.13 describe the proposed PT requirements that apply to a certified laboratory for each type of specimen. The PT requirements for the urine testing program are the same as those in the current Guidelines and the Department is proposing that similar requirements apply to the other types of specimens.

Sections 9.14, 9.15, 9.16, and 9.17 describe the proposed PT requirements for an applicant IITF to become certified for each type of specimen tested. The Department is including requirements for an IITF in this section because of the similarity of an IITF to the part of a laboratory that performs initial testing. Thus, the same requirements will apply to an IITF as to that portion of a laboratory which performs initial testing.

Sections 9.18, 9.19, 9.20, and 9.21 describe the proposed PT requirements

for an HHS-certified IITF to remain certified to test each type of specimen.

Section 9.22 describes the inspection requirements for an applicant laboratory or IITF to become certified. As noted above, the Department is including requirements for an IITF in this section because of the similarity of an IITF to the part of a laboratory that performs initial testing. Thus, the same requirements will apply to an IITF as to that portion of a laboratory which performs initial testing.

Section 9.23 describes the inspection requirements for an HHS-certified laboratory or IITF to remain certified. The Department proposes to change the requirement that a certified laboratory or IITF be inspected by a team of three inspectors to a requirement that a certified laboratory or IITF be inspected by at least one inspector. The number of inspectors used for maintenance inspections would vary depending on the size of the laboratory. The Department believes that one trained inspector may be sufficient to conduct a thorough inspection of extremely small laboratories.

In section 9.24, the Department is proposing the requirements for an individual to serve as an inspector for the HHS-certification program. The proposed requirements have been used for the past several years and are being incorporated into the Guidelines. An individual may serve as an inspector for the Secretary if he or she has experience and an educational background similar to that required for either the responsible person or the certifying scientist as described in subpart K for a laboratory, or as a responsible technician as described in subpart M, has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance consistent with these Guidelines provided by the Secretary, submits a resume and documentation of qualifications to HHS, attends approved training, and submits an acceptable inspection report and performs acceptably as a trainee inspector on an inspection.

Section 9.25 describes what happens when an applicant laboratory or IITF fails to satisfy the PT requirements or the inspection requirements. The consequences are the same as currently apply to laboratories in the current Guidelines.

Sections 9.27, 9.28, and 9.29 apply the same requirements that are in the current Guidelines regarding the factors used to revoke the certification of a laboratory or an IITF, directing a laboratory or IITF to immediately suspend testing, and the issuance of a notice regarding these actions. It is possible for a laboratory or IITF to lose certification for one sample type while retaining certification to test another type. This is because the kinds of testing procedures used to test one type of sample can be very different from procedures and equipment used to test another sample type.

Section 9.31 restates the policy in the current Guidelines that a list of HHS-certified laboratories and IITFs will be published monthly in the **Federal Register.** The list will also indicate the types of specimens for which each laboratory or IITF is certified to test.

Subpart J—Blind Samples Submitted by an Agency

Section 10.1 continues to require the supplier of a blind sample to ensure that the contents have been validated and are stable until the expiration date. Additionally, the Department proposes that drug positive blind samples must have concentrations sufficiently above the cutoff concentrations used to give a positive result. This requirement ensures that sample degradation will not affect the blind sample and the laboratory will always report a positive result. The Department also proposes that blind samples for the urine testing program contain adulterants or satisfy substitution criteria to challenge a laboratory's capability to identify adulterated or substituted specimens. The specific requirement for urine specimens is based on the donor privacy issue associated with providing a urine specimen, where direct observation is not used, and the potential exists for an adulterant to be added to the collected specimen before it is turned over to the collector. There are no similar donor privacy issues associated with the collection of head hair, oral fluid, or sweat.

The Department seeks comment on whether the proposed reduction of the blind sample rate to one percent will be sufficient to achieve the objectives of sending blind samples to laboratories especially with respect to the newer specimens with which laboratories, collectors and others are less familiar at this time.

In section 10.2, the Department is proposing to reduce the 20 percent requirement for blind samples, for each type of specimen to be tested (*i.e.,* urine, head hair, oral fluid, or sweat) to 3 percent during the initial 90-day period of a new Federal agency program because the 20 percent requirement is excessive and redundant. Since the beginning of the urine testing program, there has never been any evidence to suggest that each Federal agency needs to challenge each laboratory with 20 percent blind samples to determine if a laboratory is making either administrative or technical errors in the testing of specimens.

In section 10.3, the Department is proposing how a blind sample is to be submitted to a laboratory. This section provides more detail on how to complete the Federal CCF and ensure proper submission of the blind samples to the laboratory or IITF.

In section 10.4, the Department is proposing the procedure to be used to investigate errors associated with blind samples. This proposed procedure provides direction and detail on how to evaluate information on what led to an inconsistent result.

Subpart K—Laboratory—Major Change

This subpart has basically the same requirements that are contained in the current Guidelines with the following changes.

Section 11.4 describes a new policy for when the responsible person (RP) leaves a certified laboratory. As stated in the current Guidelines, the RP assumes professional, organizational, educational, and administrative responsibility for the laboratory's drug testing facility. The Department believes it is essential to ensure that drug testing is routinely performed under the direction and supervision of an individual with such qualifications. In this section, the Department proposes requirements to ensure this takes place. Additionally, the Secretary will begin the process of suspension or revocation in accordance with the Guidelines if the RP leaves and no RP is approved within 180 days. This requirement is essential to protect the interests of the United States and its employees to ensure that an HHS-certified laboratory has an individual that can fully attest to the forensic and scientific supportability of the laboratory's testing program.

Section 11.9 requires that a laboratory must be HHS-certified separately for each type of specimen that it wants to test for a Federal agency. The separate certification is necessary because of the differences among urine, head hair, oral fluid, and sweat specimens in all phases of collection, testing, reporting and on-going inspection and performance testing. An HHS certification for a laboratory performing urine tests would provide no quality assurance about that laboratory performing testing on other specimens.

In section 11.15, the Department proposes to allow the use of additional analytical procedures for the confirmatory drug tests. For some of the types of specimens, the confirmatory

drug tests may be performed by LC/MS, GC/MS/MS, and LC/MS/MS in addition to the GC/MS that has been traditionally used to test urine specimens. The Department believes these additional confirmatory methods are scientifically valid, based on on-going reviews of the scientific and forensic literature, and the assessment of a DTAB working group that has studied these newer instruments and technologies. These additional confirmatory methods are the methods and instruments that have been identified by the industry-led working groups that must be used to successfully detect and report the cutoff concentrations proposed in subpart C.

In sections 11.18, 11.19, 11.20, and 11.21, the Department is proposing to use the same analytical and quality control requirements for conducting validity tests for each type of specimen collected. The Department has intentionally proposed to use the same requirements for each type of specimen based on the established requirements for a urine specimen; however, information may become available during the public comment period to suggest that the requirements for each type of specimen should be different.

In sections 11.22, 11.23, 11.24, and 11.25, the Department reiterates the specific analytical requirements to conduct each validity test for a urine specimen and proposes the specific analytical requirements to conduct each validity test for head hair, oral fluid, and sweat patch specimen collected. The Department believes these requirements will ensure that the validity test results reported by a laboratory are scientifically supportable.

Sections 11.26, 11.27, 11.28, and 11.29 describe in detail how a certified laboratory is required to report test results to MROs for each type of specimen collected. These sections include the details of urine specimen validity testing, and also propose that laboratories report drug and/or metabolite concentrations to the MROs on all specimens reported as positive. The Department understands that the data exist, and can be reported electronically as part of the normal workflow, and no longer pose a barrier or significant burden to laboratories. In fact, the Department believes that requiring MROs to request concentrations by exception would create an extra burden to the MRO and the laboratory, and slow the reporting of the final test result by the MRO to the Federal agency. The Department encourages public comment on the appropriateness of this proposed requirement.

In section 11.33, the Department has revised the summary report that a laboratory must provide to a Federal agency to include validity test results. Additionally, the frequency of the report has been significantly reduced from monthly to semiannually. The Department believes that a semiannual report is sufficient to track the effectiveness of an agency's program.

In section 11.34, the Department is proposing a more detailed description of what information a donor is entitled to receive upon request through the MRO and the Federal agency. The Department believes access to the proposed information is appropriate and sufficient.

Section 11.35 describes the information a certified laboratory must provide to its private sector clients when it is using procedures to test its specimens that are different than those used to test Federal agency specimens.

Subpart L—Point of Collection Test (POCT)—Major Change

Employees of Federal agencies are in some cases located in remote areas of the country if they are serving with the Department of Interior, or overseas if they are serving with the Department of State. They are often in locations with few employees as is often the case when they are serving on American Indian reservations or in embassies in small foreign countries. It is often unrealistic to expect that a drug testing program in such places would operate in the same fashion as one that serves employees in the Washington, DC, area. It is in these circumstances and in cases where it is critical to receive an immediate test result that POCT tests play an important role.

Yet a POCT offers a particular challenge to the Federal drug testing program because the device that is used to produce a negative test result is really equivalent to a laboratory test to which the normal laboratory procedures and requirements cannot readily apply. Thus, while the sections of the Guidelines related to specimens, collection procedures, collections sites, chain of custody, drug and validity testing and others do apply, it is necessary to establish requirements particular to POCTs. In addition, it presents logistical problems on how to ensure compliance with the requirements of these Guidelines and thus ensure the integrity of the program when any one agency choosing to use POCT may have many remote sites all over the United States and in many cases all over the world.

To address the logistical problem, the Department considered several options including establishing a new organization to oversee compliance, to do inspections, and to maintain the PT requirements. As we did so, however, logistical challenges developed that could not be readily overcome.

Instead, the Department is adopting a principle that if a Federal agency chooses to use POCTs, then it accepts some of the same responsibilities for ensuring compliance within their agency as the Department currently maintains for the laboratory-based Federal drug testing program. The specifics of these requirements are addressed below.

Section 12.2 establishes criteria for the Secretary to certify a POCT for use in the Federal drug testing program. The device must be FDA-cleared for the purposes of detecting drugs of abuse and it must be determined by the Secretary that it effectively determines the presence or absence of drugs and the validity of a specimen, either as an integral function of the POCT device or as a set of compatible devices or procedures. The second standard is applied because FDA's premarket notification clearance process ensures that a device is substantially equivalent to a legally marketed device, but does not ensure that the device will satisfy minimum performance requirements that are necessary for its use in the Federal drug testing program.

Section 12.4 identifies the two types of POCTs currently available, both of which could be considered for Secretarial certification: non-instrumented devices where end results are determined visually or instrumented devices where results are obtained by instrumental evaluation.

Section 12.5 provides manufacturers a list of what they must provide the Secretary in order to have their device or devices included on the list of SAMHSA-certified devices. Among the requirements, the manufacturer must provide 100 POCT devices and related testing procedures so that the Secretary may analyze the devices for effectiveness when testing for drugs and specimen validity.

Section 12.7 indicates that to remain on the list of SAMHSA-certified devices, the manufacturer must agree to provide to the Secretary any design changes or alterations that have been made to the device so that the Secretary may determine if additional testing is necessary to ensure effectiveness and 50 POCTs as outlined so that the Secretary can ensure the continued quality of the device.

Section 12.8 is critical to the use of POCTs within the Federal drug testing program. This section lays out the

responsibilities of the Federal agency in order for it to use POCT.

If a Federal agency chooses to use POCT, then it must use only POCTs that are on the list of SAMHSA-certified devices, ensure that only trained testers are used and provide them with a standard operating procedures manual, ensure that the requirements of the regulation are fulfilled, accomplish the inspection of the POCT test sites, accomplish proficiency testing, maintain records on the trainers as well as inspections, investigate failures, make available all Federal agency records for the POCT-related activities for periodic inspection by the Secretary, and other responsibilities. For the Department to directly carry out this responsibility for the Federal agency, the Department would incur substantial administrative and financial costs. However, to the extent that Federal agencies lack the clinical or technical expertise required to fulfill their requirements under this proposal, they are free to enter into Economy Act transfers within the Department.

With regard to performance testing, the Federal agency will provide sets of HHS-contractor prepared PT samples periodically to the POCT testing sites to ensure reliability and integrity of the system. The results of the proficiency tests will be forwarded to the Federal agency. Where errors have occurred the Federal agency must act to investigate the cause of the error and determine whether it was an error in procedure or a failure of the device. If the error was a procedural one, the Federal agency must assess the reason for error and take corrective action to ensure compliance with the Guidelines in the future.

If the error is with the device, the Federal agency must immediately notify the Secretary who may suspend the use of the device within the agency. The Department, after considering the information, may suspend the use of the device throughout the Federal drug testing program by informing the agencies through the **Federal Register** and notifying the manufacturer of the problem. The manufacturer then has 30 days to provide information for the Secretary's consideration at which time the Secretary will decide what action needs to be taken. Additionally, the Secretary will notify the FDA of any error with a device so that the FDA can evaluate whether an action under the Food, Drug, and Cosmetic Act is necessary.

The Secretary is also authorized to remove a device from the list of SAMHSA-certified devices in the absence of a suspension. A manufacturer may resubmit the device for approval but in so doing must provide a statement to the Secretary describing what has been done to address the problem that led to the device's removal.

To further ensure the integrity of the system, the Guidelines require that one of every 10 negative samples must be sent to an HHS-certified laboratory for confirmation. The results of this process will be given to the Federal agency.

To date, POCT tests have only been developed for oral fluid and urine. If, in the future, POCTs are developed for hair and/or sweat and the POCTs are cleared by the FDA, the Department will review the devices to evaluate, among other things, whether they use the cutoff identified by these Guidelines, what their performance is around that cutoff, and whether the observed lot to lot variability is appropriate for the program's needs. Section 12.11 identifies the responsibility of the Secretary to inspect a Federal agency using POCT. These responsibilities include, but are not limited to, conducting a semiannual inspection of each Federal agency that uses POCT. These inspections will include a review of the Federal agency's records, standard operating procedure manual, POCT tester training records, POCT device quarterly PT results, and POCT quality assurance data maintained by each POCT tester and site.

Section 12.16 presents the requirements that a POCT tester must meet. It should be kept in mind that the individual is not just a collector but in some capacity functions as a technician in so far as the individual must perform the POCT test, determine specimen validity, perform analysis on periodic PT challenges, interpret and document test results, and when required, forward the specimens with non-negative test results to an HHS-certified laboratory for confirmatory testing. Thus the training and experience requirements reflect this additional responsibility.

To ensure that the process is carried out appropriately the Department has in section 12.18 outlined how a POCT should be conducted step by step. These procedures should be part of the Federal agency standard operating procedure manual. Again the process pays special attention to the integrity of the test results and the specimen, chain of custody, collection procedures, recordkeeping, and reporting.

The Guidelines for a POCT mirror the provision in subparts K and M in that they discuss how a negative result should be reported as well as what must happen to a specimen with non-negative results. The Guidelines further discuss reporting requirements, what information is available to the donor, and what type of relationship is prohibited between a manufacturer of a POCT device or a POCT site operation and a Medical Review Officer. Also, what type of relationship can exist between a manufacturer of a POCT device or a POCT site operation and an HHS-certified laboratory is discussed.

Subpart M—Instrumented Initial Test Facility (IITF)—Major Change

In this subpart, the Department proposes the requirements for a new type of facility. It is being called an instrumented initial test facility (IITF). An IITF is essentially a laboratory that only conducts initial tests for drugs and validity tests. The facility is at a permanent location and uses instrumented initial tests. An IITF must satisfy most of the same requirements as if it were the section of a laboratory that performs only initial drug and validity testing and was located in an HHS-certified laboratory. An IITF is certified under the same provisions as a laboratory as indicated above in subpart I. One significant difference is that the IITF is managed by a responsible technician (RT) whose qualifications are described in section 13.6, and differ slightly from those of a responsible person as required for laboratories.

An IITF may be certified to test head hair, oral fluid, sweat, and/or urine specimens as stated in section 13.2. It is also important to understand that an IITF needs to be certified for each sample type it wants to test (*e.g.*, hair, oral fluid, sweat, urine), since the testing procedures are different for each.

An IITF must test specimens using the same drug cutoff concentrations as used for the initial tests conducted by the HHS-certified laboratories as stated in section 13.3. The Department is including these requirements for an IITF in this section because of the similarity of an IITF to the part of a laboratory that performs initial testing. Thus, the same requirements will apply to an IITF as that portion of laboratory.

Section 13.8 describes a new policy for when the responsible technician (RT) leaves a certified laboratory. The RT assumes professional, organizational, educational, and administrative responsibility for the IITF drug testing. The Department believes it is essential to ensure that drug testing is routinely performed under the direction and supervision of an individual with such qualifications. In this section, the Department proposes requirements to ensure this takes place. Additionally, the Secretary will begin the process of suspension or revocation in accordance with the Guidelines if the

RT leaves and no RT is approved within 180 days. This requirement is essential to protect the interests of the United States and its employees to ensure that an HHS-certified IITF has an individual that can fully attest to the forensic and scientific supportability of the IITF testing program.

The Department proposes in section 13.16 that an IITF be required to retain records for a period of 2 years, which is the same period required for laboratories.

The Department proposes in section 13.17 that an IITF submit a semiannual report on the numbers of specimens tested for Federal agencies, again the same requirement as for laboratories.

In section 13.18, the Department proposes what information would be available to a donor from an IITF, again the same requirement as for laboratories.

In sections 13.19 and 13.20, the Department proposes to prohibit and permit the same types of relationships between the IITF and the MRO as between the laboratory and the MRO.

The Department proposes in section 13.21 that an IITF report a negative result to an MRO within 3 working days of receipt of the specimen and that negative results may be reported electronically. Reporting a negative result electronically is the same requirement as for a specimen that is determined to be negative on an initial test conducted by a certified laboratory.

In section 13.22, the Department proposes how a specimen that is presumptive drug positive, adulterated, substituted, or invalid must be shipped to an HHS-certified laboratory for confirmatory testing.

Subpart N—Medical Review Officer (MRO)—Major Change

In Section 14.1, the Department establishes who may serve as an MRO, including the requirement that the individual successfully complete an examination administered by a nationally recognized entity that certifies MROs or subspecialty board for physicians performing a review of Federal employee drug test results, which has been approved by the Secretary. This section also establishes the requirements for nationally recognized entities that seek approval by the Secretary to certify MROs or for subspecialty boards for physicians performing a review of Federal employee drug test results to submit their qualifications and sample examination. Based on an annual objective review of the qualifications and content of the examination, the Secretary shall annually publish a list in the **Federal Register** of those entities and boards that have been approved.

In section 14.2, the Department is proposing the specific training requirements before a physician may serve as an MRO for Federal agencies. This training should occur before the physician takes the required examination.

In section 14.3, the Department proposes that an individual who works under the direct supervision of an MRO may conduct the review and report of a negative result. However, the MRO must review 5 percent of the negative results reported by staff to ensure that the staff are properly performing the review process.

In sections 14.4, 14.5, 14.6, and 14.7, the Department proposes the procedure an MRO must follow to review the results reported for each type of specimen. For specimens reported as invalid by the laboratory, the Department proposes to allow the MRO to direct the agency to have another specimen collected. The Department requests comments on whether the same type of specimen or one of the other types of specimens should be collected when this occurs.

Section 14.8 describes how the donor may request the testing of a split specimen.

Section 14.9 describes how the MRO reports a primary specimen test result to a Federal agency.

Section 14.10 describes the relationship that is prohibited between an MRO and a laboratory, POCT tester, or IITF.

Subpart O—Split Specimen Tests—Major Change

Section 15.1 amends the current Guidelines by giving the donor the right to have a split specimen tested when a primary specimen was reported substituted or adulterated. This section also proposes to give a Federal agency the option to have a split specimen tested as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result if a donor chooses not have the split specimen tested.

In section 15.2, the Department is proposing the policy on how a second laboratory tests each type of split specimen when the primary specimen was reported positive for a drug(s).

In sections 15.3, 15.4, 15.5, and 15.6, the Department is proposing the policies on how a second laboratory will test each type of split specimen when the primary specimen was reported adulterated. Similarly, sections 15.7 and 15.8 describe the proposed policies on how a second laboratory will test a split oral fluid or urine specimen when the primary specimen was reported substituted. It should be noted that a head hair or sweat patch sample cannot be reported as substituted.

In sections 15.10, 15.11, 15.12, and 15.13, the Department is proposing the actions an MRO must take after receiving the split specimen result from the second laboratory for each type of specimen.

Section 15.14 describes how an MRO reports the split specimen result to a Federal agency. It is the same procedure that is used to report the result on the primary specimen.

In section 15.15, the Department proposes to require that the certified laboratory retain a split specimen for the same length of time that the primary specimen is retained.

Subpart P—Criteria for Rejecting a Specimen for Testing—Major Change

The Department proposes to include this subpart to describe how laboratories, IITFs, or MROs are to handle errors or discrepancies that arise with the use of the Federal CCF. They were not contained in the current Guidelines; however, most of the policies were previously established in guidance documents. The Department believes there is a need to establish specific guidance on how a laboratory, IITF, or MRO must handle discrepancies. Since the forms used to transfer the custody of a specimen from the collector to the POCT tester have not yet been developed, the Department cannot propose a specific list of possible errors or discrepancies that would need to be corrected and included in this section. The Department, however, fully expects to include this list when the final Guidelines are developed.

In section 16.1, the Department proposes those discrepancies that are considered to be fatal flaws, that is, the laboratory or IITF must not test a specimen when one of the fatal flaws occurs. The Department is specifically requesting comments on any additional fatal flaws that may apply to the collection of head hair, sweat, and oral fluid or fatal flaws that may occur when the collector transfers the specimen to a POCT tester (if the POCT tester is not the collector).

Section 16.2 identifies only two errors that the Department believes must be corrected (recovered) by obtaining a memorandum for record (MFR) from the collector before the laboratory or IITF can report a test result to the MRO. The Department is specifically requesting comments on any additional correctable errors that may apply to the collection of head hair, sweat, and oral fluid or

correctable errors that may occur when the collector transfers the specimen to a POCT tester (if the POCT tester is not the collector).

Section 16.3 describes the types of omissions and discrepancies that occasionally occur on the Federal CCF. When an omission or discrepancy occurs that is considered to be insignificant, the laboratory or IITF may proceed with testing the specimen and reporting a result without taking any action to recover or correct the error, omission, or discrepancy. Although each of these errors, omissions, or discrepancies are considered insignificant, the Department believes that requiring collectors to be trained and certified will significantly reduce the occurrence of such errors, omissions, or discrepancies. However, when a collector, laboratory, or IITF makes an error, omission, or discrepancy more than once a month, the Department is proposing that the MRO contacts the collector, laboratory, or IITF and directs the collector or laboratory to take immediate action to prevent the recurrence of the error, omission, or discrepancy. The Department is requesting specific comments on the proposal to have the MRO track these types of problems as well as identifying other insignificant omissions or discrepancies that have not been included for the Federal CCF. Public comments are requested for possible omissions or discrepancies that may occur when completing a Federal CCF to document collecting head hair, sweat, and oral fluid specimens or insignificant types of discrepancies that may occur when the collector transfers the specimen to a POCT tester (if the POCT tester is not the collector).

In section 16.4, the Department proposes to identify those discrepancies that must be corrected before an MRO can report a test to the Federal agency. If one of these errors occurs and it is not corrected by obtaining an MFR from the collector, IITF, or laboratory, the MRO is required to cancel the test. The Department is requesting specific comments on any other errors that must be corrected before the MRO can report a test result or discrepancies that may occur and must be corrected when the collector transfers the specimen to a POCT tester (if the POCT tester is not the collector).

Subpart Q—Laboratory/IITF Suspension/Revocation Procedures

In this subpart, the Department is retaining the procedures that were described in the current Guidelines to suspend or revoke the HHS-certification of laboratories and simply expanding them to include IITFs.

Electronic Technology Applications

The Department is aware that there has been a great deal of discussion in recent years concerning the application of electronic technology to the operation of drug testing programs. Electronic signatures on documents, electronic storage and transmission of records, and appropriate security precautions for confidential information are all issues of substantial interest as applied to Federal testing programs. The Department seeks comment on the extent to which this discussion should be reflected in the new version of the guidelines, and on whether specific provisions concerning electronic technology applications to Federal drug testing programs should be included.

Impact of These Guidelines on Government Regulated Industries

The Department is well aware that these proposed changes to the Guidelines may impact the DOT and NRC regulated industries depending on their decisions to incorporate the final Guidelines into their programs under their own authorities.

Issues of Special Interest

The Department requests public comment on all aspects of this notice. However, the Department is providing the following list of issues or areas for which specific comments are requested.

In the preamble discussion on alternative specimen issues, there are conflicting studies that hair color affects the amount of drug deposited into the hair. In other words, some studies purport that a drug user with dark hair is more likely to test positive because a drug is more likely to be deposited in black hair as compared to blond hair while other studies refute these findings. The Department is requesting specific comments on this hair color bias issue as it applies to the testing of individuals in a workplace environment.

With regard to testing oral fluid specimens for marijuana, there is scientific evidence that the parent marijuana compound (THC) in oral fluid is not from plasma, but is residual THC present either from smoking a marijuana cigarette or from oral contamination. To ensure that a THC result on an oral fluid specimen is from active exposure, the Department is proposing to always collect a urine specimen with an oral fluid specimen that would be available if the oral fluid specimen was positive for THC. The Department is requesting comments on this proposed policy.

Again with regard to oral fluids, the preamble mentions a possibility of an individual having a "dry mouth.'' The Department would appreciate any comments on whether the Department should adopt a specific procedure for "dry mouth'' as it has for "shy bladder'' under urine.

With regard to proper cleansing of the skin prior to the application of a sweat patch, the Department is requesting comment on the proposal that the skin area be washed with soap and cool water or with a disposable towelette followed by a thorough cleaning of the skin area where the patches will be worn with alcohol wipes.

The Department defines in section 1.5 both "confirmatory validity test'' and "confirmatory drug test.'' The confirmatory validity test means putting a different aliquot of the specimen through the same analytical method. A confirmatory drug test involves a second analytical procedure performed on a different aliquot. The Department requests comments on whether the utilization of these procedures is sufficient.

In section 2.2, the Department is proposing to limit the use of alternative specimens for only those reasons listed. The Department is requesting comments on the appropriateness of the reasons listed and supporting documentation if recommending changes.

In section 2.5, the Department requires that a sweat patch should be worn at least three days and no more than 7 days. While the Department believes that this is an adequate time period, the Department seeks comments and additional science on whether the permitted time period should be longer or shorter, and what time frame should be used in specific circumstances.

Sections 3.4, 3.5, 3.6, and 3.7 list the proposed cutoff concentrations for each type of specimen collected. The Department is specifically requesting comments on the appropriateness of these proposed cutoffs and the changes in the cutoffs for urine. Additionally, the Department is interested in obtaining information on the ability of the various immunoassay test kits to detect MDMA within the amphetamine class of drugs.

In section 7.2, the Department is requiring a Federal agency to only use a collection device that does not affect the specimen collected. The Department is requesting specific comments on this requirement.

In section 11.13, the Department establishes criteria for laboratories validating an initial drug test. These criteria are significantly different from those that are currently in the

Guidelines and thus the Department specifically seeks comments on this change.

In sections 11.18, 11.19, 11.20, and 11.21, the Department is proposing to use the same analytical and quality control requirements for conducting validity tests for each type of specimen collected. The Department is requesting specific comments on this proposed policy.

Sections 11.26, 11.27, 11.28, and 11.29 propose to allow a laboratory to report quantitative values for non-negative specimens rather than waiting for the MRO to request the information. The Department is requesting comments on this change in reporting test results.

In sections 14.4, 14.5, 14.6, and 14.7, the Department is proposing to allow the MRO to direct the agency to have another specimen collected when an invalid test result is reported. The Department is requesting comments on whether the same type of specimen or another type of specimen should be collected.

In sections 16.1, 16.2, and 16.3, the Department is requesting specific comments on any additional fatal flaws, correctable errors, omissions or discrepancies that may apply to the collection of head hair, sweat, and oral fluid or that may occur when the collector transfers a specimen to a point of collection test (POCT) tester. Additionally, the Department is requesting comments on the requirement that MROs track these types of problems.

In section 16.4, the Department is requesting specific comment on any other errors that must be corrected before an MRO can report a test.

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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 proposed revised Mandatory Guidelines contain information collections 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, disclosure and recordkeeping 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: Proposed Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Description: The Mandatory Guidelines establish the scientific and technical guidelines for Federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for Federal agencies under authority of Public Law 100–71, 5 U.S.C. 7301 *note*, and Executive Order 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions. The program has depended on urine testing since 1988; the reporting, recordkeeping and disclosure requirements associated with urine testing are approved under OMB control number 0930–0158. Since 1988 several products have appeared on the market making it easier for individuals to adulterate the urine sample. The proposed changes to the Guidelines address this concern. Also, scientific advances in the use of head hair, sweat,

and oral fluid in detecting drugs have made it possible for these specimens to be used in Federal programs with the same level of confidence that has been applied to the use of urine. The proposed changes establish when these alternative specimens may be used, the procedures that must be used in collecting a sample, and the certification process for approving a laboratory to test these alternative specimens.

In an effort to shorten the time for negative results to be reported to the Federal agency, the proposed changes also establish criteria for an IITF that will only perform initial tests and not confirmatory tests, and POCTs or on-site testing kits, as well as POCT testers.

Description of Respondents: Individuals or households; Businesses or other for-profit; Not-for-profit institutions.

The burden estimates in the tables below are based on the following number of respondents: 38,000 donors who apply for employment in testing designated positions, 100 collectors, 50 urine testing laboratories, 10 hair testing laboratories,10 oral fluid testing laboratories, 2 sweat testing laboratories, 25 IITFs, 30 POCT manufacturers, 50 POCT testers, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

Section	Purpose	No. of respondents	Responses/respondent	Hours/response	Total hours
9.3(c), 9.4(a) and (b)	Laboratory or IITF 9.4(a) and (b) required to submit application for certification	50	1	3	150
9.24(b)(3)	Materials to submit to become an HHS inspector	200	1	2	400
11.4(a)	Laboratory submits qualifications of alternate RP to HHS	50	1	2	100
11.4(d)	Laboratory submit information to HHS on new RP	25	1	2	50
11.32(a)	Specifications for laboratory semi-annual statistical report of test results to each Federal agency	72	5	0.5	180
12.5	Specifies what a POCT manufacturer must submit to HHS to be approved	30	1	1	30
12.7(a)	Specifies what a POCT manufacturer must submit to HHS to remain on approved list	30	1	0.5	15
12.14(b)	Requirements for POCT manufacturer statement of action to overcome problems that cause a device to be removed from the approved list	1	1	3	3
13.8(a)	Information an IITF must submit to HHS for an RT	25	1	2	50
13.8(d)	Information an IITF must submit to HHS for a new RT candidate	25	1	2	50
13.17(a)	Specifies contents of IITF semi-annual statistical report to Federal agencies served	25	5	0.5	63
13.22(d)	Specifies how IITF reports test results for specimen that is presumptive drug positive, adulterated, substituted or invalid	25	100	0.05 (3 min)	125
15.14	Specifies that MRO must report all verified split specimen test results to the Federal agency	100	5	0.05 (3 min)	25
17.1(b); 17.5(a)	Specifies content of request for informal review of suspension/proposed revocation of certification	1	1	3	3
17.4	Specifies information appellant provides in first written submission when laboratory or IITF suspension/revocation is proposed	1	1	0.5	0.5
17.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period	1	1	0.5	0.5
17.7(a)	Specifies contents of appellant submission for review	1	1	50	50
17.9(a)	Specifies content of appellant request for expedited review of suspension or proposed revocation	1	1	3	3
17.9(c)	Specifies contents of review file and briefs	1	1	50	50
Total		456			1,358

The following reporting requirements are also in the proposed Guidelines, but have not been addressed in the above reporting burden table: collector must report any unusual donor behavior or appearance on the Federal CCF (sections 8.5(a)(8) and (14)); collector annotates the Federal CCF when a sample is a blind sample (section 10.3(a)); and MRO notifies the Federal agency and HHS when an error occurs on a blind sample (section 10.4(c)). SAMHSA has not calculated a separate reporting burden for these requirements because they are included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to Federal agencies.

ESTIMATE OF ANNUAL DISCLOSURE BURDEN

Section	Purpose	No. of respondents	Responses/respondent	Hours/response	Total hours
4.4(c)	Collector is given name and phone of Federal agency point of contact	100	1	0.05 (3 min)	5
11.33(b)	Information on drug test that laboratory must provide to donor through MRo	50	10	3	1,500

ESTIMATE OF ANNUAL DISCLOSURE BURDEN—Continued

Section	Purpose	No. of respondents	Responses/respondent	Hours/response	Total hours
12.24	Information related to drug test that POCT tester must provide to donor through MRO	50	10	1	500
13.18	Information related to drug test that IITF must provide to donor through MRO	25	10	2	500
14.8(b)	MRO must inform donor of right to request split specimen test when non-negative result is reported	100	5	3	1,500
Total		325			4,005

The following disclosure requirements are also included in the proposed Guidelines, but have not been addressed in the above disclosure burden table: the collector must explain the basic collection procedure to the donor and answer any questions (section 8.1(b) and (d)); and a laboratory must tell private sector clients when the laboratory is not testing their specimen under the Guidelines (section 11.35). SAMHSA believes having the collector explain the collection procedure to the donor and to answer any questions is a standard business practice and not a disclosure burden. With regard to requiring a laboratory to inform a private sector client that its specimens are not being tested under the Guidelines, this is also a standard business practice and not considered an additional burden because it ensures that a private sector client is not being mislead into believing that its specimens are being tested under the Guidelines.

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

Section	Purpose	No. of respondents	Responses/respondent	Hours/response	Total hours
8.2–8.5	Collector completes Federal CCF for each type of specimen collected	100	380	0.07 (4 min)	2,660
11.8(a)	Laboratory completes Federal CCF upon receipt of specimen and before reporting result	50	760	0.05 (3 min)	1,900
12.18(c)	POCT tester completes Federal CCF for primary specimen and documents chain of custody	50	100	0.05 (3 min)	250
13.12(a)	IITF completes Federal CCF upon receipt of specimen and before reporting result	25	1520	0.05 (3 min)	1,900
14.3(a)(4)	MRO completes the Federal CCF before reporting the result	100	380	0.05 (3 min)	1,900
15.1(b)	Donor must request the split to be tested in writing	300	1	0.05 (3 min)	15
Total		625			8,625

The proposed Guidelines contain a number of recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector (section 4.3(a)) and that the documentation be maintained in the collector's training file (section 4.4(b)). SAMHSA believes this training documentation is common practice and is not considered an additional burden. In subpart F, if a collector uses an incorrect form to collect a Federal agency specimen, the collector is required to provide a statement (section 6.2(b)) explaining why an incorrect form was used to document collecting the specimen. SAMHSA believes this is an extremely infrequent occurrence and does not create a significant additional recordkeeping burden. Subpart H (sections 8.5(a)(8) and (14)) requires collectors to enter any information on the Federal CCF of any unusual findings during the urine specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries is included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subparts K and M describe a number of recordkeeping requirements for laboratories and instrumented initial test facilities (IITFs) associated with their testing procedures, maintaining chain of custody, and keeping records (*i.e.,* sections 11.1(a), 11.1(d), 11.2(b), 11.2(c), 11.2(d), 11.7(c), 11.8(b), 11.8(c), 11.8(e), 11.13(b), 11.14(c), 11.16, 11.17(c), 11.17(d), 11.31(a), 13.4(a), 13.4(d), 13.5, 13.7(b), 13.7(c), 13.7(d), 13.10(c), 13.11(c), 13.12(b), 13.12(c), 13.12(e), 13.13, and 13.16(a)). These recordkeeping requirements are necessary for any laboratory or IITF to conduct forensic drug testing and to ensure the scientific supportability of the test results. Therefore, they are considered to be standard business practice and are not considered a burden for this analysis. This same opinion applies to the recordkeeping requirements for POCT testers in section 12.23, for IITFs in section 13.16(a), and for MROs in section 14.3(a)(5).

Thus the total annual response burden associated with the testing of these alternative specimens by the new laboratories and Instrumented Initial Test Facilities (IITFs) and Point of Collection Test sites is estimated to be 13,888 hours (that is, the sum of the total hours from the above tables). This is in addition to the 1,788,089 hours currently approved by OMB under control number 0930–0158 for urine testing under the existing Mandatory Guidelines.

As required by section 3507(d) of the PRA, the Secretary has submitted a copy of these proposed revised Mandatory Guidelines to OMB for its review.

Comments on the information collection requirements are specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

OMB is required to make a decision concerning the collection of information contained in these proposed Guidelines between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication. This does not affect the deadline for the public to comment to HHS on the proposed Guidelines.

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB. (address above).

Charles G. Curie,

Administrator, SAMHSA.

Dated: April 2, 2004.

Tommy G. Thompson,

Secretary.

For the reasons set forth in the preamble, the Department proposes to revise the Mandatory Guidelines for Federal Workplace Drug Testing Programs to read as follows:

Mandatory Guidelines for Federal Workplace Drug Testing Programs

Subpart A—Applicability

Sec.

Subpart B—Specimens

Subpart C—Drug and Validity Tests

Subpart D—Collectors

Subpart E—Collection Sites

Subpart F—Federal Drug Testing Custody and Control Forms

Subpart G—Collection Device

Subpart H—Specimen Collection Procedure

Subpart I—HHS Certification of Laboratories and IITFs

Authority: E.O. 12564 and sec. 503 of Pub. L. 110–71.

Subpart A—Applicability

Section 1.1 Whom Do These Guidelines Cover?

(a) These 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) 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; and

(4) The Intelligence Community, as defined by E.O. 12333, are subject to these Guidelines only to the extent agreed to by the head of the affected Agency; and

(5) Laboratories, instrumented initial test facilities, and point of collection tests that provide drug testing services to the Federal agencies.

(b) The Guidelines do not apply to drug testing under 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]

[1] Although HHS has no authority to regulate the transportation industry, the Department of Transportation (DOT) does have such authority. DOT is required by law to develop requirements for its regulated industry that "incorporate the Department of Health and Human Services

Section 1.2 Who Is Responsible For Developing and Implementing These Guidelines?

(a) Executive Order 12564 and Public Law 100–71 require the Department of Health and Human Services (HHS) to establish scientific and technical guidelines for Federal workplace drug testing programs.

(b) The Secretary has the responsibility to implement these Guidelines.

Section 1.3 How Does a Federal Agency Request a Change From These Guidelines?

(a) Each Federal agency must ensure that its workplace drug testing program complies with the provisions of these Guidelines unless a waiver has been obtained from the Secretary.

(b) To obtain a waiver, a Federal agency must submit a written request to the Secretary that describes the specific change for which a waiver is sought and a detailed justification for the change.

Section 1.4 How Are These Guidelines Revised?

(a) In order to ensure the full reliability and accuracy of drug and validity tests, 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.

(b) The changes will be published in final as a notice in the **Federal Register**.

Section 1.5 What Do the Terms Used in These Guidelines Mean?

The following definitions are adopted:

Accessioner. The individual who receives the specimens at the laboratory or IITF and signs the Federal drug testing custody and control form.

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

Adulterated. A specimen containing either a substance that is not a normal constituent for that type of specimen or containing an endogenous substance at a concentration that is not a normal physiological concentration.

Batch. A number of specimens that are being handled and tested as a group.

Calibrator. A solution of known concentration in the appropriate matrix that is used to define expected outcomes of a measurement procedure or to compare the response obtained with the response of a test specimen aliquot/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.

Canceled Test. The MRO determines that the result reported by the laboratory cannot support reporting either a positive or a negative test to the employer.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of a non-negative or invalid test result.

Certifying Technician (CT). The individual responsible for verifying the chain of custody and scientific reliability of a negative test result.

Chain of Custody (COC). Procedures to account for the integrity of each specimen or aliquot by tracking its handling and storage from point of specimen collection to final disposition of the specimen and its aliquots.

Chain of Custody Document. A document used by a laboratory to maintain the security of the specimen and all aliquots of a specimen during testing and storage. The document, which may account for an entire test batch, must include the names and signatures of all individuals who handled the specimen or aliquots and the date and purpose of the access.

Collection Site. A place where donors present themselves for the purpose of providing a specimen.

Collector. A person who instructs and assists donors at a collection site and receives the specimen provided by the donor.

Confirmatory Drug Test. A second analytical procedure performed on a different aliquot of the original specimen to identify and quantify the presence of a specific drug or drug metabolite.

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

Control. A sample used to evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

Cutoff. The concentration used to establish and report a specimen as negative or positive.

Dilute Specimen. Refers to a specimen with less than normal physiological constituents.

Donor. The individual from whom a specimen is collected.

Failed to Reconfirm. The result reported when a laboratory is unable to corroborate the original result (*i.e.,* positive, adulterated, substituted) reported to the medical review officer.

Federal Drug Testing Custody and Control Form (Federal CCF). The Office of Management and Budget (OMB) approved form that is used to document the collection, custody, and transport of a specimen from the time the specimen is collected until it is received by the testing site (*i.e.,* certified laboratory, instrumented initial test facility). The form may also be used to report the test result to the Medical Review Officer.

Follow-up Test. A specimen collected from a donor to ensure that the donor remains drug-free after being reinstated to a testing designated position.

HHS. The Department of Health and Human Services.

Initial Drug Test. The test used to differentiate a negative specimen from one that requires further testing for drugs or drug metabolites.

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

Instrumented Initial Test Facility (IITF). A location where initial testing, reporting of results, and recordkeeping are performed under the supervision of a responsible technician.

Invalid Result. The result reported when a scientifically supportable analytical test result cannot be established for a specimen.

Laboratory. A location where initial and confirmatory testing is performed under the supervision of an RP and where CSs perform the final review and release of test results.

Medical Review Officer (MRO). A licensed physician who reviews, verifies, and reports a specimen test result to the agency.

Negative Result. The result reported by an HHS-certified laboratory, IITF, or POCT tester to an MRO when a specimen contains no drug or the concentration of the drug is less than the cutoff concentration for that drug or drug class.

Non-Negative Result. The result reported by an HHS-certified laboratory when a specimen is either adulterated, substituted, or contains a drug or drug metabolite at or above the established cutoff concentration.

Oxidizing Adulterant. A substance that acts alone or in combination with other substances to oxidize drug 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

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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 40.81, 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.

these agents include, but are not limited to, nitrites, pyridinium chlorochromate, chromium (VI), bleach, iodine, halogens, peroxidase, and peroxide.

Performance Testing (PT) Sample. A sample sent to a testing facility that is used to evaluate the performance of a facility's test procedure.

Point of Collection Test (POCT). A drug or validity test conducted at a collection site to obtain a preliminary result as to whether a specimen may contain a drug/drug metabolite or is not a valid specimen.

POCT Site. A collection site where a point of collection test is conducted.

Positive Result. The result reported by a laboratory when a specimen contains a drug or drug metabolite greater than or equal to the cutoff concentration.

Post-accident Test. A specimen collected from a donor after the donor is involved in a job-related accident.

Pre-employment Test. A specimen collected from a donor who is applying for a testing designated position.

Quality Control (QC) Sample. A calibrator, control, or negative sample. These samples are collectively referred to as "quality control samples'' and each as a "sample.''

Random Test. A specimen collected from a donor who is selected at random from a group of individuals who are included in a workplace drug testing program.

Reasonable Suspicion/Cause Test. A specimen collected from a donor when there is sufficient evidence to indicate that the donor may have used an illicit substance.

Reconfirmed. The result reported when a laboratory is able to corroborate the original result (*i.e.,* positive, adulterated, substituted) reported to the Medical Review Officer.

Rejected for Testing. The result reported by a laboratory or test facility when it does not perform any tests on the specimen because of a fatal flaw or an unrecovered correctable error.

Responsible Person (RP). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory.

Responsible Technician (RT). The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified instrumented initial test facility.

Return to Duty Test. A specimen collected from a donor to ensure that the donor is drug free prior to being reinstated in a testing designated position.

Sample. A representative portion of a specimen or quality control material 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. Fluid or material derived from the body which may be subdivided, concurrently collected, or two specimens collected almost simultaneously if a split specimen is required.

Split Specimen. A specimen collected at the collection site that is fluid or material derived from the body which has been subdivided or concurrently collected and independently sealed in the presence of the donor. For urine, one void that is subdivided. For hair, one harvest that is subdivided by strands. For oral fluid, one specimen collected that is subdivided or two specimens collected almost simultaneously. For sweat, two separate patches that are applied and removed simultaneously.

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

Substituted. A specimen that could not have been derived from the donor's body at the time of collection because it is inconsistent with normal physiology.

Section 1.6 What Is an Agency Required To Do To Protect Employee Records?

Consistent with 5 U.S.C. 522a(m) and 48 CFR 24.101–24.104, all agency contracts with laboratories, IITFs, POCT testers, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 522a. In addition, the contracts must require compliance with employee access and confidentiality provisions of section 503 of Public Law 100–71. The agency must establish a Privacy Act System of Records or modify an existing system, or use any applicable Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

Subpart B—Specimens

Section 2.1 What Types of Specimens May Be Collected?

A Federal agency may collect head hair, oral fluid (saliva), sweat (patch), or urine for its workplace drug-testing program in keeping with section 2.2.

Section 2.2 Under What Circumstances Can the Different Types of Specimens Be Collected?

Type of specimen	Reason for test
Hair	Pre-employment, random, return to duty, follow-up
Oral Fluid	Pre-employment, random, reasonable suspicion/ cause, post-accident
Sweat (patch)	Return to duty, follow-up
Urine	Pre-employment, random, reasonable suspicion/ cause, post-accident, return to duty, follow-up

Section 2.3 Can More Than One Type of Specimen Be Collected at the Same Time From the Same Donor?

Yes, more than one type of specimen may be collected at the same time from the donor, but only in the following circumstances:

(a) When an oral fluid specimen is collected, a urine specimen must also be collected; or

(b) If a problem occurs during the collection of one type of specimen (*e.g.,* shy bladder for a urine specimen, insufficient specimen available), permission can be obtained from the Federal agency to collect an alternative specimen.

Section 2.4 How Is Each Type of Specimen To Be Collected?

Each type of specimen is to be collected as a split specimen as described in section 2.5.

Section 2.5 What Is the Minimum Quantity of Specimen To Be Collected for Each Type of Specimen?

(a) Hair: 100 mg head hair (divided as follows: 2 samples with approximately 50 mg per sample)

(b) Oral Fluid: 2 mL collected as a "neat specimen'' (divided as follows: at least 1.5 mL for the primary specimen and at least 0.5 mL for the split specimen)

(c) Sweat: 2 FDA-cleared patches worn up to 7 days

(d) Urine: 45 mL (divided as follows: at least 30 mL for the primary specimen and at least 15 mL for the split specimen)

Subpart C—Drug and Validity Tests

Section 3.1 Which Tests Must Be Performed on a Specimen?

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

(b) Federal agency applicant and random drug testing programs are also

authorized to test for opiates, amphetamines, and phencyclidine; and

(c) Each specimen must be tested to determine if it is a valid specimen.

Section 3.2 Can a Specimen Be Tested for Additional Drugs?

(a) Any specimen collected from a donor that is suspected to contain a Schedule I or II drug of the Controlled Substances Act (other than the drugs listed in section 3.1, or when used pursuant to a valid prescription or when used as otherwise authorized by law) may be tested for that drug on a case-by-case basis. The Federal agency must request the HHS-certified laboratory to test for that additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods.

(b) A Federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in section 3.1. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under paragraph (a) of this section.

Section 3.3 May Any of the Specimens Be Used for Other Purposes?

(a) Federal agency specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines must only be tested for drugs and to determine their validity unless otherwise authorized by law.

(b) These Guidelines are not intended to prohibit any Federal agency specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

Section 3.4 What Are the Cutoff Concentrations for Hair Samples?

INITIAL TEST CUTOFF CONCENTRATION

	(pg/mg)
Marijuana metabolites	1
Cocaine metabolites	500
Opiate metabolites[1]	200
Phencyclidine	300
Amphetamines[2]	500
MDMA	500

[1] Laboratories are permitted to initial test all specimens for 6–acetylmorphine (6–AM) using a 200 pg/mg cutoff.
[2] Methamphetamine is the target analyte.

CONFIRMATORY TEST CUTOFF CONCENTRATION

	(pg/mg)
Marijuana metabolite[1]	0.05
Cocaine:	
Cocaine[2]	500
Cocaine metabolites[2]	50
Opiates:	
Morphine	200
Codeine	200
6–Acetylmorphine[3]	200
Phencyclidine	300
Amphetamines:	
Amphetamine	300
Methamphetamine[4]	300
MDMA	300
MDA	300
MDEA	300

[1] Delta–9–tetrahydrocannabinol–9–carboxylic acid.
[2] Cocaine concentration is greater than or equal to confirmatory cutoff *and* Benzoylecgonine (BZE)/Cocaine ratio is greater than or equal to 0.05 *or* Cocaethylene (CE) greater than or equal to 50 pg/mg *or* norcocaine (NC) greater than or equal to 50 pg/mg.
[3] Specimen must also contain Morphine at a concentration greater than or equal to 200 pg/mg.
[4] Specimen must also contain Amphetamine at a concentration greater than or equal to 50 pg/mg.

Section 3.5 What Are the Cutoff Concentrations for Oral Fluid Specimens?

INITIAL TEST CUTOFF CONCENTRATION

	(ng/mL)
THC Parent drug and metabolite	4
Cocaine metabolites	20
Opiate metabolites[1]	40
Phencyclidine	10
Amphetamines[2]	50
MDMA	50

[1] Labs are permitted to initial test all specimens for 6-AM using a 4 ng/mL cutoff.
[2] Methamphetamine is the target analyte.

CONFIRMATORY TEST CUTOFF CONCENTRATION

	(ng/mL)
THC Parent drug	2
Cocaine[1]	8
Opiates:	
Morphine	40
Codeine	40
6-Acetylmorphine	4
Phencyclidine	10
Amphetamines:	
Amphetamine	50
Methamphetamine[2]	50
MDMA	50
MDA	50
MDEA	50

[1] Cocaine or Benzoylecgonine.
[2] Specimen must also contain Amphetamine at a concentration greater than or equal to the limit of detection.

Section 3.6 What Are the Cutoff Concentrations for Sweat Patch Samples?

INITIAL TEST CUTOFF CONCENTRATION

	(ng/patch)
Marijuana metabolites	4
Cocaine metabolites	25
Opiate metabolites[1]	25
Phencyclidine	20
Amphetamines[2]	25
MDMA	25

[1] Labs are permitted to initial test all specimens for 6–AM at 25 ng/patch.
[2] Methamphetamine is the target analyte.

CONFIRMATORY TEST CUTOFF CONCENTRATION

	(ng/patch)
THC parent drug	1
Cocaine[1]	25
Opiates[2]	25
Phencyclidine	20
Amphetamines:	
Amphetamine	25
Methamphetamine[3]	25
MDMA	25
MDA	25
MDEA	25

[1] Cocaine or Benzoylecgonine.
[2] Morphine, Codeine, or 6-Acetylmorphine.
[3] Specimen must also contain Amphetamine at a concentration greater than or equal to the limit of detection.

Section 3.7 What Are the Cutoff Concentrations for Urine Specimens?

INITIAL TEST CUTOFF CONCENTRATION

	(ng/mL)
Marijuana metabolites	50
Cocaine metabolites	150
Opiate metabolites[1]	2000
Phencyclidine	25
Amphetamines[2]	500
MDMA	500

[1] Labs are permitted to initial test all specimens for 6–AM using a 10 ng/mL cutoff.
[2] Methamphetamine is the target analyte.

CONFIRMATORY TEST CUTOFF CONCENTRATION

	(ng/mL)
Marijuana metabolite[1]	15
Cocaine metabolite[2]	100
Opiates:	
Morphine	2000
Codeine	2000
6-acetylmorphine[3]	10
Phencyclidine	25
Amphetamines:	
Amphetamine	250

CONFIRMATORY TEST CUTOFF CONCENTRATION—Continued

	(ng/mL)
Methamphetamine[4]	250
MDMA	250
MDA	250
MDEA	250

[1] Delta-9-tetrahydrocannabinol-9-carboxylic acid.
[2] Benzoylecgonine.
[3] If a laboratory uses both initial test kits to screen a specimen concurrently, it may report 6–AM alone.
[4] Specimen must also contain Amphetamine at a concentration greater than or equal to 100 ng/mL.

Section 3.8 What Validity Tests Must Be Performed on a Hair Sample?

(a) For each primary (Sample A) head hair sample, an HHS-certified laboratory or IITF must:

(1) Determine the integrity of the head hair sample by performing a digestion test;

(2) Perform microscopic identification;

(3) Perform a dye test;

(4) Determine solubility of head hair in methanol; and

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

(i) Abnormal physical characteristics (*e.g.,* Sample A and Sample B have different hair color, mixture of different types of head hair);

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

(iii) Possible unidentified interfering substance or adulterant.

(b) The choice of additional validity tests is dependent on the observed indicators or characteristics as described in (5)(i) through (iii) of this section.

Section 3.9 What Validity Tests Must Be Performed on an Oral Fluid Specimen?

(a) For each primary (Tube A) oral fluid specimen, an HHS-certified laboratory or IITF must:

(1) Determine the immunoglobulins (IgG) concentrations on every specimen; and

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

(i) Abnormal physical characteristics (*e.g.*, unusual color or texture, unusual odor, semi-solid characteristics);

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

(iii) Possible unidentified interfering substance or adulterant.

(b) The choice of additional validity tests is dependent on the observed indicators or characteristics as described in (2)(i) through (iii) of this section.

Section 3.10 What Validity Tests Must Be Performed on a Sweat Patch Sample?

(a) For each primary (Patch A) sweat patch sample, an HHS-certified laboratory or IITF must:

(1) Determine the lactic acid concentration on every specimen; and

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

(i) Abnormal physical characteristics (*e.g.,* Patch A and Patch B have different color, unusual odor);

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

(iii) Possible unidentified interfering substance or adulterant.

(b) The choice of additional validity tests is dependent on the observed indicators or characteristics as described in (2)(i) through (iii) of this section.

Section 3.11 What Validity Tests Must Be Performed on a Urine Specimen?

(a) For each primary (Bottle A) urine specimen, an HHS-certified laboratory or IITF must:

(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 (*e.g.,* unusual odor or color, semi-solid characteristics);

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

(iii) Possible unidentified interfering substance or adulterant.

(b) The choice of additional validity tests is dependent on the observed indicators or characteristics as described in (5)(i) through (iii) of this section.

Section 3.12 What Criteria Are Used To Report a Hair Sample as Adulterated?

A primary (Sample A) head hair sample is reported adulterated when the concentration of the adulterant is above the concentration of the calibrator used to verify that the adulterant was present in the sample.

Section 3.13 What Criteria Are Used To Report an Oral Fluid Specimen as Adulterated?

A primary (Tube A) oral fluid specimen is reported adulterated when the concentration of the adulterant is above the concentration of the calibrator used to verify that the adulterant was present in the specimen.

Section 3.14 What Criteria Are Used To Report a Sweat Patch Sample as Adulterated?

A primary (Patch A) sweat patch sample is reported adulterated when the concentration of the adulterant is above the concentration of the calibrator used to verify that the adulterant was present in the sample.

Section 3.15 What Criteria Are Used To Report a Urine Specimen as Adulterated?

A primary (Bottle A) urine specimen is reported adulterated when:

(a) 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;

(b) 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;

(c) 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 limit of detection (LOD) of the confirmatory test on the second aliquot;

(d) 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;

(e) 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 gas chromatography/mass spectrometry (GC/MS) for the confirmatory test with the glutaraldehyde concentration greater than or equal to the LOD of the analysis on the second aliquot;

(f) 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;

(g) 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

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

Section 3.16 What Criteria Are Used To Report an Oral Fluid Specimen as Substituted?

A primary (Tube A) oral fluid specimen is reported substituted when the IgG concentration is less than 0.10 mcg/mL.

Section 3.17 What Criteria Are Used To Report a Urine Specimen as Substituted?

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

Section 3.18 What Criteria Are Used To Report a Urine Specimen as Dilute?

A primary (Bottle A) urine specimen 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.

Section 3.19 What Criteria Are Used To Report a Hair Sample as an Invalid Result?

A primary (Sample A) head hair sample is reported as an invalid result when:

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

(b) Interference with the drug confirmatory assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

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

(d) If the physical appearances of Samples A and B are clearly different, the test result for Sample A is one of the reasons stated in (a) through (c) of this section and/or was screened negative for drugs.

Section 3.20 What Criteria Are Used To Report an Oral Fluid Specimen as an Invalid Result?

A primary (Tube A) oral fluid specimen is reported as an invalid result when:

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

(b) Interference with the drug confirmatory assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

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

(d) If the physical appearances of Tubes A and B are clearly different, the test result for Tube A is one of the reasons stated in (a) through (c) of this section and/or was screened negative for drugs.

Section 3.21 What Criteria Are Used To Report a Sweat Patch Sample as an Invalid Result?

A primary (Patch A) sweat patch sample is reported as an invalid result when:

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

(b) Interference with the drug confirmatory assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

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

(d) If the physical appearances of Patches A and B are clearly different, the test result for Patch A is one of the reasons stated in (a) through (c) of this section and/or was screened negative for drugs.

Section 3.22 What Criteria Are Used To Report a Urine Specimen as an Invalid Result?

A primary (Bottle A) urine specimen is reported as an invalid result when:

(a) 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);

(b) 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;

(c) 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;

(d) 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;

(e) 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;

(f) 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;

(g) 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;

(h) 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;

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

(j) Interference with the drug confirmatory assay occurs on at least two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;

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

(l) If the physical appearances of Bottles A and B are clearly different, the test result for Bottle A is one of the reasons stated in (a) through (j) of this section and/or was screened negative for drugs.

Subpart D—Collectors

Section 4.1 Who May Collect a Specimen?

(a) An individual who has been trained to collect a particular type of specimen (*i.e.,* head hair, oral fluid, sweat, or urine).

(b) The immediate supervisor of a donor may not act as the collector when that donor is tested unless no other collector is available.

(c) An employee working for a testing facility must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

Section 4.2 What Are the Requirements To Be a Trained Collector For a Federal Agency?

An individual is considered to be a trained collector for a particular type of specimen when the individual has:

(a) Read and understands these Guidelines;

(b) Read and understands any guidance provided by the Federal agency, which is consistent with these Guidelines;

(c) Demonstrated proficiency by completing five consecutive error-free mock collections for a particular type of specimen; and

(d) Successfully completed a training course by an established organization for the particular type or types of specimen(s) for which the individual is being trained.

Section 4.3 How Is a Collector's Training Documented?

(a) A trainer must monitor and evaluate the knowledge and performance of the individual being trained, in person or by means that provides real-time observation and interaction between the trainer and trainee, and attest in writing that the mock collections are error-free.

(b) The trainer must be an individual who has demonstrated necessary knowledge, skills, and abilities by having:

(1) Regularly conducted collections for a period of at least one year; or

(2) Successfully completed a "train the trainer'' course given by an established organization.

Section 4.4 What Must an Organization Do Before a Collector Is Permitted To Collect Specimens for a Federal Agency?

An organization (*e.g.,* self-employed individual, third party administrator that provides a collection service, Federal agency that employs its own collectors) must:

(a) Ensure that each individual that serves as a collector has been properly trained before the individual is permitted to collect a specimen;

(b) Maintain a copy of the records that document the collector's training; and

(c) Provide to the collector the name and telephone number of the Federal agency representative to contact about problems or issues that may arise during a specimen collection procedure.

Subpart E—Collection Sites

Section 5.1 Where Can a Collection for a Drug Test Take Place?

(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.

(b) The selection of an appropriate collection site will depend on the type of specimen being collected. For example, a urine specimen is normally collected in some type of restroom, while a head hair sample may be collected in a private office.

Section 5.2 What Are the Requirements for a Collection Site?

A facility that is used as a collection site must have the following:

(a) A suitable clean surface for handling the specimen and completing the required paperwork;

(b) A secure temporary storage capability to maintain a specimen until it is tested or shipped to the laboratory;

(c) The ability to provide the donor privacy that is appropriate for the specimen being collected;

(d) The ability to restrict access to only authorized personnel during the collection;

(e) The ability to restrict access to collection supplies; and

(f) The ability to store records securely.

Section 5.3 How Long Must Collection Site Records Be Stored?

Collection site records must be stored for a minimum of 2 years by the collector or the collector's employer.

Section 5.4 How Does the Collector Ensure the Security of a Specimen at the Collection Site?

(a) A collector must do the following to maintain the security of a specimen:

(1) Not allow unauthorized personnel to enter the collection site during the collection;

(2) Perform only one specimen collection at a time;

(3) Restrict access to collection supplies before and during the collection;

(4) Ensure that he or she is the only person other than the donor to handle the unsealed specimen;

(5) Ensure that chain of custody is maintained and documented throughout the entire collection procedure;

(6) Ensure that specimens transported to an HHS-certified laboratory or IITF are placed in containers that will minimize the possibility of damage during shipment (*e.g.,* specimen boxes or padded mailers); and

(7) Ensure that the Federal CCF is enclosed with the split specimens within each container that is sealed for shipment to the HHS-certified laboratory or IITF.

(b) Since specimens are sealed in packages that would indicate any tampering during transit to the HHS-certified laboratory or IITF and couriers, express carriers, and postal service personnel do not have access to the Federal CCF or split specimens, there is no requirement that such personnel document chain of custody for the package during transit.

Section 5.5 What Are the Privacy Requirements When Collecting a Hair Sample?

The collector collects head hair from the donor. The donor must be allowed privacy while the collector obtains the head hair sample.

Section 5.6 What Are the Privacy Requirements When Collecting an Oral Fluid Specimen?

The donor provides the sample directly into an appropriate container under the direct observation of the collector. Only the collector may be present while the donor provides the oral fluid specimen.

Section 5.7 What Are the Privacy Requirements When Collecting a Sweat Patch Sample?

The sweat patch is applied to the donor's upper arm or back by the collector. The donor must be allowed privacy while the collector applies or removes the patch.

Section 5.8 What Are the Privacy Requirements When Collecting a Urine Specimen?

The collector must give the donor visual privacy while providing the specimen unless:

(a) A previous drug test was reported either positive for a drug, adulterated, substituted, invalid result, or canceled because the split specimen was not tested;

(b) The drug test is a return-to-duty or a follow-up test;

(c) The agency believes that the donor may tamper with or substitute the specimen to be provided; or

(d) During a routine collection, the temperature of the specimen collected is outside the acceptable range, the collector observed materials brought to the collection site or donor conduct indicated a possible attempt to adulterate or substitute a specimen, or the collector believes that the specimen has been adulterated (*e.g.*, the specimen is blue, exhibits excessive foaming when shaken, has smell of bleach).

Subpart F—Federal Drug Testing Custody and Control Forms

Section 6.1 What Form Is Used for Collecting a Specimen?

(a) Federal agencies are required to use an OMB-approved Federal CCF to document the collection of each type of specimen at the collection site.

(b) There is a separate OMB-approved Federal CCF for each type of specimen collected.

Section 6.2 What Happens if a Federal CCF Is Not Available or Is Not Used?

(a) When the collector either by mistake or as the only means to document a collection under difficult circumstances (*e.g.*, post-accident test with insufficient time to obtain the CCF) uses a non-Federal form for a Federal agency specimen collection, the use of a non-Federal form is not a reason for the laboratory to reject the specimen for testing or for the MRO to cancel the test.

(b) If the testing facility or the MRO discovers the use of the incorrect form, a signed statement must be obtained from the collector stating the reason why a Federal CCF was not used to collect the Federal agency specimen.

Subpart G—Collection Device

Section 7.1 What Is a Collection Device?

A collection device, for the purposes of these Guidelines, is considered to be the following for each type of specimen collected:

(a) For urine, it is the single-use plastic specimen container.

(b) For head hair, it is the foil or other specimen guide and single-use plastic bag or other container in which the specimen is placed.

(c) For oral fluid, it is the single-use plastic specimen container.

(d) For sweat, it is the patch placed on the skin.

Section 7.2 Which Collection Devices May Be Used?

(a) Only a collection device that does not affect the specimen collected may be used.

(1) If a collection device has been cleared by the FDA for the purpose of testing a specimen for drugs, it is deemed not to affect the specimen collected.

(2) If a collection device has not been cleared by the FDA, a Federal agency must only use a device that does not affect the specimen collected.

(b) These Guidelines do not determine if a collection device must be cleared by the FDA.

Subpart H—Specimen Collection Procedure

Section 8.1 What Must the Collector Do Before Starting a Specimen Collection Procedure?

The collector must:

(a) Provide identification to the donor if the donor asks;

(b) Explain the basic collection procedure to the donor;

(c) Request the donor to read the instructions on the back of the Federal CCF; and

(d) Answer any reasonable and appropriate questions the donor may have regarding the collection procedure.

Section 8.2 What Procedure Is Used To Collect a Head Hair Sample?

(a) The collector must use the following procedure to collect a head hair sample:

(1) When the 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 or an agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(2) 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 must contact the agency to obtain guidance on the action to be taken.

(3) The collector shall ask the donor to remove any unnecessary outer garments such as a coat or jacket and any hat or hood.

(4) The collector must use a Federal CCF to document collecting a head hair sample.

(5) In the presence of the donor, the collector must clean the scissors that will be used to cut the head hair with an alcohol wipe prior to obtaining a head hair sample.

(6) If the collector sees any evidence that the donor has lice in his or her head hair, the collector immediately stops the collection procedure and contacts the

agency to obtain permission to collect a different type of specimen.

(7) Using scissors, the collector will cut the donor's head hair in a line near the rear of the crown toward the back and as close to the scalp as possible. Approximately one-and-one-half inches of the hair closest to the scalp is actually tested, even if the head hair is long. If the hair is less than one-and-one-half inches long, then the width of the sample collected will need to be increased. The weight of hair needed for testing is 100 mg. The head hair sample collected from the donor must meet that requirement.

(8) The collector places the head hair sample in the foil packet (collection device), root-end extending out approximately one-quarter inch from the slated end of the foil. The collector then subdivides the head hair sample into two approximately equal head hair samples (Sample A and Sample B). Sample B is placed in a second foil.

(9) The collector folds both foils lengthwise and each sample is placed inside an envelope with root-ends to the left.

(10) The collector places the seals from the Federal CCF on the bottom of the envelopes and records the date of the collection on the tamper-evident labels/seals.

(11) The donor initials the tamper-evident labels/seals.

(12) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the head hair samples were collected from him or her.

(13) The collector must sign the Federal CCF.

(14) The split head hair samples and Federal CCF are now ready for transfer to an HHS-certified laboratory or IITF.

(15) The collector must send the split (Sample A and Sample B) head hair samples at the same time to the HHS-certified laboratory or IITF.

(b) If the split head hair samples and Federal CCF are not immediately prepared for transfer to an HHS-certified laboratory or IITF, they must be appropriately safeguarded until the head hair samples and Federal CCF are prepared for transfer to the laboratory.

Section 8.3 What Procedure Is Used To Collect an Oral Fluid Specimen?

(a) The collector must use the following procedure to collect an oral fluid specimen:

(1) 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 or an agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(2) 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 must contact the appropriate authority to obtain guidance on the action to be taken.

(3) 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 oral fluid specimen. The collector must 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 or if the item appears to be inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(4) The collector must confirm with the donor that the donor has not had anything in his or her mouth for 10 minutes prior to providing the oral fluid specimen. If the donor has had anything in his or her mouth within the last 10 minutes, wait 10 minutes prior to beginning the collection process.

(5) The collector will give the donor a clean specimen tube.

(6) Under direct observation, the collector will instruct the donor to expectorate (to spit) 2 mL of oral fluid into the specimen tube. This can be accomplished over a 15 minute time period or until the appropriate volume of specimen is collected.

(7) Both the donor and the collector must keep the specimen tube in view at all times prior to its being sealed and labeled.

(8) The collector, in the presence of the donor, mixes the specimen and transfers the oral fluid into two specimen tubes that are labeled Tube A and Tube B. A minimum of 2 mL of oral fluid is required, *i.e.*, 1.5 mL for Tube A and 0.5 mL for Tube B.

(9) The Tube A specimen, containing a minimum of 1.5 mL of oral fluid, is to be used for the drug test. If there is no additional oral fluid available for the second specimen tube (Tube B), the first specimen tube (Tube A) shall nevertheless be processed for testing.

(10) A minimum of 0.5 mL of oral fluid shall be transferred into the second specimen tube (Tube B).

(11) The collector places a tamper-evident label/seal from the Federal CCF across the top of each tube and records the date of the collection on the tamper-evident labels/seals.

(12) The donor initials the tamper-evident labels/seals on the specimen tubes.

(13) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimen identified as having been collected from him or her.

(14) The collector must sign the Federal CCF.

(15) The split oral fluid specimen and Federal CCF are now ready for transfer to an HHS-certified laboratory or IITF.

(16) After completing the oral fluid specimen collection procedure, the collector must also collect a urine specimen following the procedures described in section 8.5.

(17) The collector must send the oral fluid and urine split specimens at the same time to an HHS-certified laboratory or IITF or transfer the specimens to the POCT tester (if a POCT is being conducted).

(b) If the split specimens and Federal CCF are not immediately prepared for transfer to an HHS-certified laboratory or IITF or tested using a POCT, they must be appropriately safeguarded until the specimens and Federal CCF are prepared for transfer to an HHS-certified laboratory or IITF or tested using a POCT.

Section 8.4 What Procedure Is Used To Collect a Sweat Patch Sample?

(a) The collector must use the following procedure to collect a sweat patch sample:

(1) 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 or an agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(2) 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 must

contact the appropriate authority to obtain guidance on the action to be taken.

(3) 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 sweat patch. The collector must 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 sweat patch. If nothing is there that can be used to adulterate the sweat patch, 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 appears to be inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(4) The collector will show the donor two clean sealed sweat patches.

(5) The collector asks the donor to thoroughly clean the skin area with soap and cool water or with a disposable towelette and then the collector must thoroughly clean the skin area with alcohol wipes where the sweat patches will be worn prior to application.

(6) The collector will place the two sweat patches on the upper arm (preferable location) or the back.

(7) The donor must wear the sweat patches for no less than three and no more than seven days before returning to the collection site. A unique number is imprinted on each patch to aid with chain-of-custody identification. On rare occasions, the sweat patch can produce an allergic reaction similar to that for other adhesive bandage products. When this occurs, the donor shall return to the collection site and the collector must remove the sweat patch and then request permission from the Federal agency to collect another type of specimen. The sweat patch procedure is cancelled by the collector and notifies the medical review officer and the Federal agency.

(8) After the sweat patches (Sample A and Sample B) are worn for the proper time, the donor returns to the collection site. The collector removes the two sweat patches from the donor within several minutes.

(9) Immediately before and after the sweat patches are removed, the collector must inspect the two sweat patches to determine if there are any signs indicating that the sweat patches may not be valid samples (*e.g.*, the donor tampered with the sweat patches).

(10) Samples suspected of not being valid sweat patch samples must be forwarded to an HHS-certified laboratory or IITF for testing with any unusual findings noted on the Federal CCF.

(11) The collector must place the sweat patches in appropriate containers and secure them with tamper-evident labels/seals. The collector must record the date of the collection on the tamper-evident labels/seals.

(12) The donor must initial the tamper-evident labels/seals.

(13) The donor must be asked to read and sign a statement on the Federal CCF certifying that the sweat patch identified as having been collected from him or her.

(14) The collector must sign the Federal CCF.

(15) The split sweat patch samples and Federal CCF are now ready for transfer to an HHS-certified laboratory or IITF.

(16) The collector must send the split specimens at the same time to an HHS-certified laboratory or IITF.

(b) If the specimen and Federal CCF are not immediately prepared for transfer to the laboratory or IITF, they must be appropriately safeguarded until the specimen and Federal CCF are prepared for transfer to the laboratory or IITF.

Section 8.5 What Procedure Is Used To Collect a Urine Specimen?

(a) The collector must use the following procedure to collect a urine 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 must 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 must 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 must 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 adulterate or substitute the urine specimen. The collector must 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 or substitute the specimen. If nothing is there that can be used to adulterate or substitute 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 or substitute the specimen, a direct observation collection procedure is used. If the item appears to be inadvertently brought to the collection site, the collector must 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 must remain in the presence of the collector and must 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 will provide the donor a clean 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 must be made secure during the collection procedure. If possible, a 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 must determine the volume of urine in the specimen container.

(i) If the volume is at least 45 mL, the collector will proceed with step (11) below.

(ii) If the volume is less than 45 mL and the temperature is within the acceptable range specified in step (13) below, the specimen is discarded and a second specimen must 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 must contact the appropriate authority to obtain guidance on the action to be taken.

(iii) If the volume is less than 45 mL and the temperature is outside the acceptable range specified in step (13) below, a second specimen must be collected using the procedure specified in step (13) below.

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

(12) Immediately after the specimen is collected, the collector must 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 adulterated or substituted the specimen; another specimen must be collected under direct observation of a person of the same gender and both specimens (*i.e.*, from the first and second collections) must be forwarded to the laboratory for testing. The agency shall select the observer if there is no collector of the same gender available.

(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 must be forwarded to an HHS-certified laboratory for testing.

(16) When there is any reason to believe that a donor may have adulterated or substituted the specimen, another specimen must be obtained as soon as possible under the direct observation of a person of the same gender and both specimens (*i.e.*, from the first and second collections) shall be forwarded to an HHS-certified 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 must keep the specimen container in view at all times. The collector shall request the donor to observe the transfer of the specimen from the collection container to the two specimen bottles and the placement of the tamper-evident labels/seals on the bottles.

(18) The collector, in the presence of the donor, pours the urine into two specimen bottles that are labeled Bottle A and Bottle B, 30 mL for Bottle A and 15 mL for Bottle B.

(19) 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.

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

(21) The collector must place the tamper-evident labels/seals on the specimen bottles. The collector must record the date of the collection on the tamper-evident labels/seals.

(22) The donor must initial the tamper-evident labels/seals on the split specimen bottles.

(23) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimen identified was collected from him or her.

(24) Based on a reason to believe that the donor may adulterate or substitute the specimen to be provided, a higher level supervisor must 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 must be of the same gender. The agency shall select the observer if there is no collector of the same gender available.

(25) The collector must sign the Federal CCF.

(26) The split specimens and Federal CCF are now ready for transfer to an HHS-certified laboratory or IITF or transfer to a POCT tester (if a POCT is being conducted).

(27) The collector must send the split specimens (Bottle A and Bottle B) at the same time to an HHS-certified laboratory or IITF or transfer to a POCT tester (if a POCT is being conducted).

(b) If the split specimen bottles and Federal CCF are not immediately prepared for transfer to an HHS-certified laboratory or IITF or transferred to a POCT tester, they must be appropriately safeguarded until the split specimen bottles and Federal CCF are prepared for transfer to an HHS-certified laboratory or IITF.

Section 8.6 What Are the Responsibilities of a Federal Agency That Uses a Collection Site?

(a) A Federal agency must ensure that collectors and collection sites satisfy all requirements in subparts D, E, F, G, and H when collecting agency specimens.

(b) A Federal agency (or only one Federal agency when several agencies are using the same collection site) must conduct an annual inspection of each collection site used to collect agency specimens. Additionally, a Federal agency must respond to reports of collector and collection site deficiencies reported to them and must take appropriate action to preclude the recurrence of such deficiencies.

Subpart I—HHS Certification of Laboratories and IITFs

Section 9.1 What Are the Goals and Objectives of HHS-Certification?

(a) Drug testing is an important tool to identify drug users in a variety of settings. In the proper context, drug testing can be used to deter drug abuse in general. To be a useful tool, all testing must satisfy "good forensic laboratory practices'' and the testing procedures must be capable of detecting drugs or metabolites at established cutoff concentrations.

(b) Reliable discrimination between the presence, or absence, of specific drugs or their metabolites is critical, not only to achieve the goals of the testing program but to protect the rights of the Federal employees being tested. Thus, standards have been set in order to achieve maximum accuracy of test results.

(c) Because of the possible impact of a positive test result on an individual's livelihood or rights, extra care is required in the handling of the specimen and all other aspects of the testing procedure. Thus, the testing procedure must be carefully documented.

Section 9.2 Who Has the Authority To Certify Laboratories and IITFs That Want To Test Specimens for Federal Agencies?

(a) The Secretary has broad discretion to take appropriate action to ensure the full reliability and accuracy of drug testing and reporting, to resolve problems related to drug testing, and to enforce all standards set forth in these Guidelines. The Secretary has the authority to issue directives to any laboratory or IITF suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any laboratory or IITF to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any laboratory or IITF to send specimens or specimen aliquots to another laboratory for retesting when necessary to ensure the accuracy of testing under these Guidelines; ordering the review of results for specimens tested under the Guidelines for private sector clients to the extent necessary to ensure the full reliability of drug testing for Federal agencies; and ordering any other action necessary to address deficiencies in drug testing, analysis, specimen collection, chain of custody, reporting of results, or any other aspect of the certification program.

(b) A laboratory or IITF is prohibited from stating or implying that it is certified by HHS under these Guidelines to test a particular specimen unless it holds such certification for each type of specimen it wants to test for Federal agencies.

Section 9.3 What Is the Process for a Laboratory or IITF To Become HHS-Certified and To Maintain That Certification?

A laboratory or IITF that wants to become an HHS-certified laboratory or IITF must:

(a) Read and understand these Guidelines;

(b) Request an OMB-approved application;

(c) Submit a completed application for each type of specimen and type of certification applied for;

(d) Have its application reviewed as complete and accepted by HHS;

(e) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples as required for each type of specimen for which certification is applied for;

(f) Satisfy all the requirements for an initial inspection;

(g) Receive a letter of certification from the Secretary before being able to test specimens for Federal agencies;

(h) Successfully participate in both the maintenance PT and inspection programs (*i.e.*, successfully test the required quarterly sets of maintenance PT samples, undergo an inspection 3 months after being certified, and undergo maintenance inspections every 6 months thereafter);

(i) Respond in an appropriate, timely, and complete manner to required corrective action in the event of failure in either the maintenance PT or inspection program for which suspension and/or revocation are proposed by the Secretary;

(j) Satisfactorily complete a special inspection and corrective remedial action to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting;

(k) Stop testing Federal agency specimens should PT, maintenance inspection, special inspection, or other material deficiencies indicate that there is an imminent harm to the government and its employees requiring that immediate suspension and revocation procedures be imposed by the Secretary; and

(l) Follow the HHS procedures in subpart Q that will be used for all actions associated with the suspension and/or revocation of HHS-certification for each type of specimen and type of certification held.

Section 9.4 How Does a Laboratory or IITF Apply To Become HHS-Certified?

(a) A laboratory or IITF interested in becoming HHS-certified must submit an OMB-approved application form.

(b) The application form requires the applicant laboratory or IITF to provide detailed information on both the administrative and analytical procedures the laboratory or IITF proposes to use for testing Federal agency specimens after it is certified.

Section 9.5 What Are the Qualitative and Quantitative Specifications of a Performance Test (PT) Sample?

(a) A PT sample must satisfy one of the following criteria:

(1) Contains one or more of the drugs and metabolites in the drug classes listed in sections 3.4, 3.5, 3.6, and 3.7.

(2) The concentration of a drug or metabolite is at least 20 percent above the cutoff concentration for either the initial drug test or the confirmatory drug test depending on which is to be evaluated;

(3) The concentration of a drug or metabolite is as low as 40 percent of the cutoff concentration when the PT sample is designated as a retest sample;

(4) The concentration of drug or metabolite is at another concentration for a special purpose;

(5) A negative sample will not contain a measurable amount of a drug or metabolite; or

(6) A PT sample may contain an interfering substance or an adulterant or satisfy the criteria for a substituted specimen (as appropriate).

(b) For each PT cycle, the set of PT samples going to each laboratory or IITF will vary but, within each calendar year, each laboratory or IITF will analyze essentially the same total set of samples.

(c) The laboratory or IITF must, to the greatest extent possible, handle, test, and report a PT sample in a manner identical to that used for a donor specimen, unless otherwise specified.

Section 9.6 What Are the PT Requirements for an Applicant Laboratory To Conduct Hair Testing?

(a) An applicant laboratory that seeks certification to conduct hair testing must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify and confirm at least 90 percent of the total drug challenges on the 3 sets of PT samples;

(3) Correctly determine the quantitative values for at least 80 percent of the total drug challenges to be within ±20 percent or ±2 standard deviations of the calculated reference group mean;

(4) Have no quantitative value on a drug concentration that differs by more than 50 percent from the calculated reference group mean; and

(5) For an individual drug, must correctly detect and quantify at least 50 percent of the total drug challenges.

(6) Must not obtain any quantitative value on a validity test sample that differs by more than ±50 percent from the calculated reference group means;

(7) For qualitative validity test samples, must correctly report at least 80 percent of the challenges for each qualitative validity test sample over the 3 sets of PT samples; and

(8) Must not report any sample as adulterated with a compound that is not present in the sample.

(b) Failure to achieve any one of the requirements will result in disqualification.

Section 9.7 What Are the PT Requirements for an Applicant Laboratory To Conduct Oral Fluid Testing?

(a) An applicant laboratory that seeks certification to conduct oral fluid testing must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify and confirm at least 90 percent of the total drug challenges on the 3 sets of PT samples;

(3) Correctly determine the quantitative values for at least 80 percent of the total drug challenges to be within ±20 percent or ±2 standard deviations of the calculated reference group mean;

(4) Have no quantitative value on a drug concentration that differs by more than 50 percent from the calculated reference group mean;

(5) For an individual drug, correctly detect and quantify at least 50 percent of the total drug challenges;

(6) Must not obtain any quantitative value on a validity test sample that differs by more than ±50 percent from the calculated reference group means;

(7) For qualitative validity test samples, must correctly report at least 80 percent of the challenges for each qualitative validity test sample over the 3 sets of PT samples; and

(8) Must not report any sample as adulterated with a compound that is not present in the sample.

(b) Failure to achieve any one of the requirements will result in disqualification.

Section 9.8 What are the PT Requirements for an Applicant Laboratory To Conduct Sweat Patch Testing?

(a) An applicant laboratory that seeks certification to conduct sweat patch testing must satisfy the following criteria on 3 consecutive sets of initial PT samples:

(1) Have no false positive results;

(2) Correctly identify and confirm at least 90 percent of the total drug challenges on the 3 sets of PT samples;

(3) Correctly determine the quantitative values for at least 80 percent of the total drug challenges to be within ±20 percent or ±2 standard deviations of the calculated reference group mean;

(4) Have no quantitative value on a drug concentration that differs by more than 50 percent from the calculated reference group mean; and

(5) For an individual drug, correctly detect and quantify at least 50 percent of the total drug challenges.

(6) Must not obtain any quantitative value on a validity test sample that differs by more than ±50 percent from the calculated reference group means;

(7) For qualitative validity test samples, must correctly report at least 80 percent of the challenges for each qualitative validity test sample over the 3 sets of PT samples; and

(8) Must not report any sample as adulterated with a compound that is not present in the sample.

(b) Failure to achieve any one of the requirements will result in disqualification.

Section 9.9 What Are the PT Requirements for an Applicant Laboratory To Conduct Urine Testing?

(a) An applicant laboratory that seeks certification to conduct urine testing must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify and confirm at least 90 percent of the total drug challenges on the 3 sets of PT samples;

(3) Correctly determine the quantitative values for at least 80 percent of the total drug challenges to be within ±20 percent or ±2 standard deviations of the calculated reference group mean;

(4) Have no quantitative value on a drug concentration that differs by more than 50 percent from the calculated reference group mean;

(5) For an individual drug, correctly detect and quantify at least 50 percent of the total drug challenges;

(6) Must correctly identify and report at least 80 percent of the total validity testing challenges over the 3 sets of PT samples;

(7) For each specific validity test, must correctly report at least 80 percent of the challenges for the specific validity test over the 3 sets of PT samples;

(8) For quantitative specimen validity tests, must 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;

(9) Must 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;

(10) For qualitative specimen validity tests, must correctly report at least 80 percent of the challenges for each qualitative specimen validity test over the 3 sets of PT samples; and

(11) Must 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.

(b) Failure to achieve any one of the requirements will result in disqualification.

Section 9.10 What Are the PT Requirements for an HHS-Certified Laboratory To Conduct Hair Testing?

(a) A laboratory certified to conduct hair testing must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Have no false positive results;

(2) Correctly identify and confirm at least 90 percent of the total drug challenges over 2 consecutive PT cycles;

(3) Correctly quantify at least 80 percent of the total drug challenges within ±20 percent or ±2 standard deviations of the appropriate reference or peer group mean (whichever range is larger) over 2 consecutive PT cycles;

(4) Have no more than one quantitative result that differs by more than 50 percent from the target value over 2 consecutive PT cycles;

(5) For any individual drug, correctly detect and quantify at least 50 percent of the total drug challenges;

(6) Must not report any validity test sample as adulterated (that is not adulterated);

(7) Correctly identify and confirm at least 80 percent of the total validity test challenges over 2 consecutive PT cycles;

(8) For quantitative validity tests, must obtain quantitative values for at least 80 percent of the total challenges;

(9) Have no more than one quantitative value on a validity test sample that differs by more than ±50 percent from the calculated reference group means; and

(10) For each qualitative specimen validity test, must correctly report at least 80 percent of the challenges for each qualitative specimen validity test over 2 consecutive PT cycles.

(b) Failure to participate in a PT cycle or to participate satisfactorily may result in suspension or revocation of an HHS-certified laboratory's certification for hair testing.

Section 9.11 What Are the PT Requirements for an HHS-Certified Laboratory To Conduct Oral Fluid Testing?

(a) A laboratory certified to conduct oral fluid testing must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Have no false positive results;

(2) Correctly identify and confirm at least 90 percent of the total drug challenges over 2 consecutive PT cycles;

(3) Correctly quantify at least 80 percent of the total drug challenges within ±20 percent or ±2 standard deviations of the appropriate reference or peer group mean (whichever range is larger) over 2 consecutive PT cycles;

(4) Have no more than one quantitative result that differs by more than 50 percent from the target value over 2 consecutive PT cycles;

(5) For any individual drug, correctly detect and quantify at least 50 percent of the total drug challenges;

(6) Must not report any validity test sample as adulterated (that is not adulterated);

(7) Correctly identify and confirm at least 80 percent of the total validity test challenges over 2 consecutive PT cycles;

(8) For quantitative validity tests, must obtain quantitative values for at least 80 percent of the total challenges;

(9) Have no more than one quantitative value on a validity test sample that differs by more than ±50 percent from the calculated reference group means; and

(10) For each qualitative specimen validity test, must correctly report at least 80 percent of the challenges for each qualitative specimen validity test over 2 consecutive PT cycles.

(b) Failure to participate in a PT cycle or to participate satisfactorily may result in suspension or revocation of an HHS-certified laboratory's certification for oral fluid testing.

Section 9.12 What Are the PT Requirements for an HHS-Certified Laboratory To Conduct Sweat Patch Testing?

(a) A laboratory certified to conduct sweat patch testing must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Have no false positive results;

(2) Correctly identify and confirm at least 90 percent of the total drug challenges over 2 consecutive PT cycles;

(3) Correctly quantify at least 80 percent of the total drug challenges within ±20 percent or ±2 standard deviations of the appropriate reference or peer group mean (whichever range is larger) over 2 consecutive PT cycles;

(4) Have no more than one quantitative result that differs by more than 50 percent from the target value over 2 consecutive PT cycles;

(5) For any individual drug, correctly detect and quantify at least 50 percent of the total drug challenges;

(6) Must not report any validity test sample as adulterated (that is not adulterated);

(7) Correctly identify and confirm at least 80 percent of the total validity test challenges over 2 consecutive PT cycles;

(8) For quantitative validity tests, must obtain quantitative values for at least 80 percent of the total challenges;

(9) Have no more than one quantitative value on a validity test sample that differs by more than ±50 percent from the calculated reference group means; and

(10) For each qualitative specimen validity test, must correctly report at least 80 percent of the challenges for each qualitative specimen validity test over 2 consecutive PT cycles.

(b) Failure to participate in a PT cycle or to participate satisfactorily may result in suspension or revocation of an HHS-certified laboratory's certification for sweat patch testing.

Section 9.13 What Are the PT Requirements for an HHS-Certified Laboratory To Conduct Urine Testing?

(a) A laboratory certified to conduct urine testing must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Have no false positive results;

(2) Correctly identify and confirm at least 90 percent of the total drug challenges over 2 consecutive PT cycles;

(3) Correctly quantify at least 80 percent of the total drug challenges within ±20 percent or ±2 standard deviations of the appropriate reference or peer group mean (whichever range is larger) as measured over 2 consecutive PT cycles;

(4) Have no more than one quantitative result that differs by more than 50 percent from the target value over 2 consecutive PT cycles;

(5) For any individual drug, correctly detect and quantify at least 50 percent of the total drug challenges;

(6) Must not report any validity test sample as adulterated (that is not adulterated) or substituted (that is not substituted);

(7) Correctly identify and confirm at least 80 percent of the total validity test challenges over 2 consecutive PT cycles;

(8) For quantitative specimen validity tests, must 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;

(9) No more than one 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; and

(10) For each qualitative specimen validity test, must correctly report at least 80 percent of the challenges for each qualitative validity test over 2 consecutive PT cycles.

(b) Failure to participate in a PT cycle or to participate satisfactorily may result in suspension or revocation of an HHS-certified laboratory's certification for urine testing.

Section 9.14 What Are the PT Requirements for an Applicant IITF To Conduct Hair Testing?

(a) An applicant IITF that seeks certification to conduct hair testing must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Correctly identify and report at least 80 percent of the total drug challenges using its initial drug tests over 3 sets of PT samples;

(2) Correctly identify and report at least 80 percent of the total validity test challenges using its initial validity tests over 3 sets of PT samples;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific drug test over 3 sets of PT samples; and

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a specific validity test over 3 sets of PT samples.

(b) Failure to achieve any one of the requirements will result in disqualification.

Section 9.15 What Are the PT Requirements for an Applicant IITF To Conduct Oral Fluid Testing?

(a) An applicant IITF that seeks certification to conduct oral fluid testing must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Correctly identify and report at least 80 percent of the total drug challenges using its initial drug tests over 3 sets of PT samples;

(2) Correctly identify and report at least 80 percent of the total validity test challenges using its initial validity tests over 3 sets of PT samples;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 3 sets of PT samples; and

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a

specific initial validity test over 3 sets of PT samples.

(b) Failure to achieve any one of the requirements will result in disqualification.

Section 9.16 What Are the PT Requirements for an Applicant IITF To Conduct Sweat Patch Testing?

(a) An applicant IITF that seeks certification to conduct sweat patch testing must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Correctly identify and report at least 80 percent of the total drug challenges using its initial drug tests over 3 sets of PT samples;

(2) Correctly identify and report at least 80 percent of the total validity test challenges using its initial validity tests over 3 sets of PT samples;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 3 sets of PT samples; and

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a specific initial validity test over 3 sets of PT samples.

(b) Failure to achieve any one of the requirements will result in disqualification.

Section 9.17 What Are the PT Requirements for an Applicant IITF To Conduct Urine Testing?

(a) An applicant IITF that seeks certification to conduct urine testing must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Correctly identify and report at least 80 percent of the total drug challenges using its initial drug tests over 3 sets of PT samples;

(2) Correctly identify and report at least 80 percent of the total validity test challenges using its initial validity tests over 3 sets of PT samples;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 3 sets of PT samples;

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a specific initial validity test over 3 sets of PT samples;

(5) For quantitative specimen validity tests, must obtain quantitative values for at least 80 percent of the total initial validity test 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;

(6) Must not obtain any quantitative value on an initial validity test 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; and

(7) For qualitative initial validity tests, must correctly identify and report at least 80 percent of the challenges for each qualitative initial validity test over 3 sets of PT samples.

(b) Failure to achieve any one of the requirements will result in disqualification.

Section 9.18 What Are the PT Requirements for an HHS-Certified IITF To Conduct Hair Testing?

(a) An HHS-certified IITF must satisfy the following criteria on the maintenance PT samples to maintain its certification to conduct hair testing:

(1) Correctly identify and report at least 80 percent of the total initial drug test challenges as measured over 2 consecutive PT cycles;

(2) Correctly identify and report at least 80 percent of the initial validity test challenges over 2 consecutive PT cycles;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 2 consecutive PT cycles; and

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a specific initial validity test over 2 consecutive PT cycles.

(b) Failure to satisfy the standards may result in suspension or proposed revocation of an HHS-certified IITF's certification for hair testing.

Section 9.19 What Are the PT Requirements for an HHS-Certified IITF To Conduct Oral Fluid Testing?

(a) An HHS-certified IITF must satisfy the following criteria on the maintenance PT samples to maintain its certification to conduct oral fluid testing:

(1) Correctly identify and report at least 80 percent of the total initial drug test challenges as measured over 2 consecutive PT cycles;

(2) Correctly identify and report at least 80 percent of the initial validity test challenges over 2 consecutive PT cycles;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 2 consecutive PT cycles; and

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a specific initial validity test over 2 consecutive PT cycles.

(b) Failure to satisfy the standards may result in suspension or proposed revocation of an HHS-certified IITF's certification for oral fluid testing.

Section 9.20 What Are the PT Requirements for an HHS-Certified IITF To Conduct Sweat Patch Testing?

(a) An HHS-certified IITF must satisfy the following criteria on the maintenance PT samples to maintain its certification to conduct sweat patch testing:

(1) Correctly identify and report at least 80 percent of the total initial drug test challenges as measured over 2 consecutive PT cycles;

(2) Correctly identify and report at least 80 percent of the initial validity test challenges over 2 consecutive PT cycles;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 2 consecutive PT cycles; and

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a specific initial validity test over 2 consecutive PT cycles.

(b) Failure to satisfy the standards may result in suspension or proposed revocation of an HHS-certified IITF's certification for sweat patch testing.

Section 9.21 What Are the PT Requirements for an HHS-Certified IITF to Conduct Urine Testing?

(a) An HHS-certified IITF must satisfy the following criteria on the maintenance PT samples to maintain its certification to conduct urine testing:

(1) Correctly identify and report at least 80 percent of the total initial drug test challenges as measured over 2 consecutive PT cycles;

(2) Correctly identify and report at least 80 percent of the initial validity test challenges over 2 consecutive PT cycles;

(3) For each specific drug test, must correctly identify and report at least 50 percent of the drug challenges for a specific initial drug test over 2 consecutive PT cycles;

(4) For each specific validity test, must correctly identify and report at least 50 percent of the challenges for a

specific initial validity test over 2 consecutive PT cycles;

(5) For quantitative validity tests, must obtain quantitative values for at least 80 percent of the total initial validity test 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;

(6) Must not obtain any quantitative value on an initial validity test 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; and

(7) For qualitative validity tests, must correctly identify and report at least 80 percent of the challenges for each qualitative initial validity test over 2 consecutive PT cycles.

(b) Failure to satisfy the standards may result in suspension or proposed revocation of an HHS-certified IITF's certification for urine testing.

Section 9.22 What Are the Inspection Requirements for an Applicant Laboratory or IITF?

(a) An applicant laboratory or IITF is inspected by a team of at least two inspectors.

(b) Each inspector conducts an independent review and evaluation of all aspects of the laboratory's or IITF's testing procedures and facilities using an inspection checklist.

(c) To become certified, an applicant laboratory or IITF must satisfy the minimum requirements as stated in these Guidelines.

(d) An applicant laboratory or IITF must be separately inspected for each type of specimen for which it has applied. The inspection for each type of specimen may be conducted concurrently, but the inspectors must review all appropriate data in distinct audits.

(e) An applicant laboratory or IITF that applies for certification to conduct testing of different types of specimens, but does not satisfy the minimum requirements for each type of specimen, may be certified for those types of specimens for which it has satisfied the minimum requirements.

Section 9.23 What Are the Maintenance Inspection Requirements for an HHS-Certified Laboratory or IITF?

(a) An HHS-certified laboratory or IITF must undergo an inspection 3 months after becoming certified and then an inspection every 6 months thereafter.

(b) An HHS-certified laboratory or IITF is inspected by one or more inspectors. The number of inspectors required is dependent on the workload of the laboratory or IITF.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's or IITF's procedures for each type of specimen and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory or IITF must continue to satisfy the minimum requirements as stated in these Guidelines for that type of specimen.

Section 9.24 Who Can Inspect an HHS-Certified Laboratory or IITF and When May the Inspection Be Conducted?

(a) The Secretary or a Federal agency may conduct an inspection at any time.

(b) An individual may serve as an inspector for the Secretary if he or she satisfies the following criteria:

(1) Has experience and an educational background similar to that required for either the responsible person or the certifying scientist as described in subpart K for a laboratory or as a responsible technician as described in subpart M;

(2) Has read and thoroughly understands the policies and requirements contained in these Guidelines and in other guidance consistent with these Guidelines provided by the Secretary;

(3) Submits a resume and documentation of qualifications to HHS;

(4) Attends approved training; and

(5) Submits an acceptable inspection report and performs acceptably as a trainee inspector on an inspection.

Section 9.25 What Happens if an Applicant Laboratory or IITF Does Not Satisfy the Minimum Requirements for Either the PT Program or the Inspection Program?

If an applicant laboratory or IITF fails to satisfy the requirements established for the initial certification process, the applicant laboratory must start the initial certification process from the beginning for the type of specimen for which they were applying to become certified.

Section 9.26 What Happens if an HHS-Certified Laboratory or IITF Does Not Satisfy the Minimum Requirements for Either the PT Program or the Inspection Program?

(a) If an HHS-certified laboratory or IITF fails to satisfy the minimum requirements for certification, the laboratory or IITF is given a period of time (*e.g.,* 5 or 30 working days depending on the nature of the issue) to provide any explanation for its performance and evidence that any deficiency has been corrected.

(b) A laboratory's or IITF's certification may be revoked, suspended, or no further action taken depending on the seriousness of the errors and whether there is evidence that any deficiency has been corrected and that current performance meets the requirements for a certified laboratory or IITF.

(c) An HHS-certified laboratory or IITF may be required to undergo a special inspection or to test additional PT samples, depending on the nature of the performance, to verify that any deficiency has been corrected.

(d) If an HHS-certified laboratory's or IITF's certification is revoked or suspended in accordance with the process described in subpart Q, the laboratory or IITF is not permitted to test specimens for Federal agencies until the suspension is lifted or the laboratory or IITF has successfully completed the certification requirements as a new applicant laboratory or IITF.

Section 9.27 What Factors Are Considered in Determining Whether Revocation of a Laboratory's or IITF's Certification Is Necessary?

(a) The Secretary shall revoke certification of any laboratory or IITF certified 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) 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 inspections;

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

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

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

(c) 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 9.28 What Factors Are Considered in Determining Whether To Suspend a Laboratory or IITF?

(a) 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 (either partially or fully) a laboratory's or IITF's certification to conduct drug and validity testing for Federal agencies.

(b) 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 9.29 How Does the Secretary Notify a Laboratory or IITF That Action Is Being Taken Against the Laboratory or IITF?

(a) When a laboratory or IITF is suspended or the Secretary seeks to revoke certification, the Secretary shall immediately serve the laboratory or IITF 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) The written notice shall state that the laboratory or IITF 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 or IITF received the notice, or if expedited review is requested, within 3 days of the date the laboratory or IITF received the notice. Subpart Q contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

(c) A suspension must be effective immediately. A proposed revocation must 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 must terminate immediately and any proposed revocation shall not take effect.

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any laboratory or IITF that has its certification revoked or suspended under section 9.27 or section 9.28, respectively, and the name of any laboratory or IITF that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory or IITF 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 Q.

Section 9.30 May a Laboratory or IITF That Had Its Certification Revoked Be Recertified To Test Federal Agency Specimens?

Following revocation, a laboratory or IITF may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under section 9.29(a) or the reviewing official's decision under section 17.9(e) or 17.14(a), a laboratory or IITF which has had its certification revoked may reapply for certification as an applicant laboratory or IITF.

Section 9.31 Where Is the List of HHS-Certified Laboratories or IITFs Published?

(a) The list of HHS-certified laboratories and IITFs and the type of specimen for which each is certified is published monthly in the **Federal Register**.

(b) An applicant laboratory or IITF is not included on the list.

Subpart J—Blind Samples Submitted by an Agency

Section 10.1 What Are the Requirements for Federal Agencies To Submit Blind Samples to HHS-Certified Laboratories or IITFs?

(a) Each Federal agency is required to have both negative and non-negative blind samples for each type of donor specimen being submitted to an HHS-certified laboratory or IITF.

(b) During the initial 90-day period of a new Federal agency drug testing program, the agency must submit at least three percent blind samples along with its donor specimens.

(c) After the initial 90-day period, the agency must submit one percent blind samples along with its donor specimens based on the projected total number of specimens that will be collected per year. Every effort should be made to ensure that some of the blind samples are submitted quarterly.

(d) Of the blind samples submitted, approximately 80 percent of the blind samples must be negative and 20 percent non-negative.

Section 10.2 What Are the Requirements for a Blind Sample?

(a) A blind sample that is drug positive must be validated by the supplier as to its content using appropriate initial and confirmatory tests.

(b) A blind sample that is negative (*i.e.,* certified to contain no drug) must be validated by the supplier as negative using appropriate initial and confirmatory tests.

(c) The supplier must provide information regarding the shelf life of the blind sample.

(d) For a blind sample that is drug positive, the concentration of the drug it contains should be between 1.5 and 2 times the initial drug test cutoff concentration and must be spiked or contain one or more of the drugs or metabolites listed in sections 3.3, 3.4, 3.5, and 3.6.

(e) For hair, oral fluid, sweat patch, and urine, a blind sample that is adulterated must have the characteristics to clearly show that it is an adulterated sample at the time it is validated by the supplier.

(f) For oral fluid and urine, a blind sample that is substituted must have the characteristics to clearly show that it is a substituted sample at the time it is validated by the supplier.

Section 10.3 How Is a Blind Sample Submitted to an HHS-Certified Laboratory or IITF?

(a) A blind sample is submitted using the same Federal CCF as used for a donor specimen. The collector provides the required information to ensure that the Federal CCF has been properly completed as well as providing fictitious initials on the specimen label/seal. The collector must indicate that the sample is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector must distribute the required number of blind samples throughout the total number of donor

specimens rather than submitting them as a single group of samples.

Section 10.4 What Happens if an Inconsistent Result Is Reported on a Blind Sample?

If an HHS-certified laboratory reports an inconsistent result on a blind sample (*e.g.,* a laboratory reports a negative result on a blind sample that was supposed to be positive, a laboratory reports a positive result on a blind sample that was supposed to be negative, an IITF reports a negative result on a blind sample that was supposed to be positive, a laboratory or IITF cannot obtain a valid drug test result):

(a) The MRO must contact supplier of the blind sample and attempt to determine if the supplier made a mistake when preparing the blind sample;

(b) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for shipment to the laboratory;

(c) If there is no obvious reason for the inconsistent result, the MRO must notify both the Federal agency for which the blind sample was submitted and the Secretary; and

(d) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken by the HHS-certified laboratory or IITF must be sent to the Federal agency. The Secretary shall ensure notification of the finding to all other Federal agencies for which the laboratory or IITF is engaged in drug testing and coordinate any necessary action to prevent the recurrence of the error.

Subpart K—Laboratory

Section 11.1 What Is a Standard Operating Procedure Manual?

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all laboratory operations. When followed, it ensures that all specimens are tested using the same procedures and in a consistent manner.

(b) The SOP manual must include, but is not limited to, a detailed description of the following:

(1) Chain-of-custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, laboratory information management systems.

(c) All procedures in the SOP manual must be in compliance with these Guidelines and other guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which they were in effect must be maintained for 2 years to allow the laboratory to retrieve the procedures that were used to test a specimen.

Section 11.2 What Are the Responsibilities of the Responsible Person (RP)?

(a) Manage the day-to-day operations of the drug testing laboratory even where another individual has overall responsibility for an entire multi-specialty laboratory.

(b) Ensure that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. The RP must ensure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete, current SOP manual that is available for personnel in the drug testing laboratory, and followed by those personnel. The SOP manual must be reviewed, signed, and dated by the RP(s) whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory.

(d) Maintain a quality assurance program to assure the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and standards; monitor quality control testing; document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Implement 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, and deficiencies identified during inspections. This individual must ensure that sample 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.

(f) Qualify as a certifying scientist for positive, adulterated, and substituted test results.

Section 11.3 What Scientific Qualifications in Analytical Toxicology Must the RP Have?

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

(a) Be certified as a laboratory director by the State in forensic or clinical laboratory toxicology; have a Ph.D. in one of the natural sciences or have training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology;

(b) Have experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Have experience in forensic applications of analytical toxicology (*e.g.*, publications, court testimony, conducting research on the toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology; and

(d) Be found to fulfill RP responsibilities and qualifications upon interview by HHS-trained inspectors during each on-site inspection of the laboratory.

Section 11.4 What Happens When the RP Is Absent or Leaves an HHS-Certified Laboratory?

(a) All HHS-certified laboratories must have multiple RPs or an alternate RP. Extremely small certified laboratories may request a waiver from the Secretary to this requirement under special circumstance. An alternate RP must be able to fulfill the responsibilities of an RP, and must meet the qualifications of a certifying scientist. The laboratory must submit documentation satisfactory to the Secretary which shows the credentials of the prospective RP and which must be approved by the Secretary, and found acceptable during on-site inspections of the laboratory.

(b) When an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (*e.g.*, vacation, illness, business trip), the certified laboratory may continue testing Federal agency specimens under the direction of a certifying scientist.

(c) When an RP permanently leaves an HHS-certified laboratory:

(1) An HHS-certified laboratory may maintain its certification and continue testing Federal agency specimens under the direction of an alternate RP for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the new permanent RP.

(2) The Secretary, in accordance with these Guidelines, will suspend a

laboratory's certification for all specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(d) When a new RP candidate has been identified, the laboratory must submit to the Secretary the candidate's current resume or curriculum vitae, arrange to have official academic transcript(s) submitted by the candidate's institution(s) of higher learning, copies of diplomas and any licensures, a training plan (not to exceed 90 days) to transition into the RP position, and an itemized defense of the candidate's qualifications compared to the minimum RP qualifications described in the Guidelines.

(e) The laboratory must fulfill other inspection and PT criteria as required prior to conducting Federal agency testing under a new RP.

Section 11.5 What Qualifications Must an Individual Have To Certify a Result Reported By an HHS-Certified Laboratory?

(a) The individual (*i.e.*, the certifying scientist) who certifies a non-negative or invalid result test result must have:

(1) A bachelor's degree in the chemical or biological sciences, medical technology, or similar field;

(2) Training and experience in the analytical methods and procedures used by the laboratory that are relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

(b) The individual (*i.e.*, the certifying technician) who certifies a negative test result must have:

(1) Training and experience in the analytical methods and procedures used by the laboratory that are relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

Section 11.6 What Qualifications and Training Must Other Laboratory Personnel Have?

(a) All laboratory staff (*e.g.*, technicians, administrative staff) must have the appropriate training and skills for the tasks assigned.

(b) Each individual working in an HHS-certified laboratory must be properly trained (*i.e.*, receive training in each area of work that the individual will be performing) before he or she is permitted to work independently with regulated specimens.

Section 11.7 What Security Measures Must an HHS-Certified Laboratory Maintain?

(a) An HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (*i.e.*, for the Department, a Federal agency, a state, or other accrediting agency) or emergency personnel (such as, firefighters and medical rescue teams).

(c) A laboratory must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized escorted visitors accessing secured areas.

Section 11.8 What Are the Internal Laboratory Chain of Custody Requirements for a Specimen or an Aliquot?

(a) An HHS-certified laboratory must 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 the specimens.

(b) An HHS-certified laboratory must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process and until final disposal.

(c) The date and purpose must be documented on an appropriate chain of custody document each time a specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(d) Chain of custody must be maintained and documented by using either hard copy procedures or electronic procedures.

(e) Each individual that handles a specimen or aliquot must sign and complete the chain of custody document when the specimen or aliquot is received.

Section 11.9 Which Type of Specimens May an HHS-Certified Laboratory Test?

A laboratory must be HHS-certified separately for each type of specimen that it wants to test for a Federal agency.

Section 11.10 What Test(s) Does an HHS-Certified Laboratory Conduct on a Specimen Received After a POCT?

An HHS-certified laboratory must test the specimen in the same manner as a specimen that had not been previously tested.

Section 11.11 What Test(s) Does an HHS-Certified Laboratory Conduct on a Specimen Received From an IITF?

An HHS-certified laboratory conducts the confirmatory test(s) for the non-negative result(s) identified by the IITF.

Section 11.12 What Are the Requirements for an Initial Drug Test?

(a) An initial drug test must be an immunoassay test or a test that combines a chromatographic separation coupled with an appropriate detector.

(b) A laboratory must validate an initial drug test before using it to test specimens.

(c) Initial drug test kits must meet the FDA requirements for commercial distribution.

(d) A laboratory may conduct a second initial drug test on a specimen prior to the confirmatory drug test. If the laboratory uses a second initial drug test, the second initial drug test is subject to the same requirements as the first initial drug test.

Section 11.13 What Must an HHS-Certified Laboratory Do To Validate an Initial Drug Test?

(a) The laboratory must demonstrate and document for each initial test:

(1) The ability to differentiate positive and negative samples;

(2) The performance of the test around the cutoff concentration; and

(3) The performance of the test results at several concentrations between 0 and 150 percent of the cutoff concentration.

(b) Performance of new lots must be verified prior to being placed into service.

Section 11.14 What Are the Batch Quality Control Requirements When Conducting an Initial Drug Test?

(a) Each batch of specimens must contain the following QC samples:

(1) At least one control certified to contain no drug or metabolite;

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

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

(4) At least one control that appears as a donor specimen to the laboratory analysts.

(b) At least 10 percent of the samples in the batch must be calibrators and controls.

(c) A laboratory must document that any carryover that may occur between aliquots during the initial testing process is detectable and corrected.

Section 11.15 What Are the Requirements for a Confirmatory Drug Test?

(a) The analytical method used must combine chromatographic separation and mass spectrometric identification (*e.g.*, GC/MS, liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS).

(b) A confirmatory drug test must be validated before the laboratory can use it to test specimens.

Section 11.16 What Must an HHS-Certified Laboratory Do To Validate a Confirmatory Drug Test Method?

An HHS-certified laboratory must demonstrate and document for each confirmatory drug test:

(a) The linear range of the analysis;

(b) The limit of detection;

(c) The limit of quantitation;

(d) The accuracy and precision at the cutoff concentration;

(e) The accuracy and precision at 40 percent of the cutoff concentration; and

(f) The potential for interfering substances.

Section 11.17 What Are the Quality Control Requirements When Conducting a Confirmatory Drug Test?

(a) Each batch of specimens must contain, at a minimum, the following QC samples:

(1) A single-point calibrator with its drug concentration at the cutoff;

(2) At least one control certified to contain no drug or metabolite;

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

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

(b) At least 10 percent of the samples in each batch must be calibrators and controls.

(c) The linear range, limit of detection, and limit of quantitation must be documented and periodically re-evaluated for each confirmatory drug test.

(d) A laboratory must document that any carryover that may occur between aliquots/extracts in the confirmatory batch is detectable and corrected.

Section 11.18 What Are the Analytical and Quality Control Requirements for Conducting Validity Tests on Hair Samples?

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

(b) Each analytical run of hair samples for which an initial or confirmatory validity test is being performed must include the appropriate calibrators and controls.

Section 11.19 What Are the Analytical and Quality Control Requirements for Conducting Validity Tests on Oral Fluid Specimens?

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

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

Section 11.20 What Are the Analytical and Quality Control Requirements for Conducting Validity Tests on Sweat Patch Samples?

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

(b) Each analytical run of sweat patch samples for which an initial or confirmatory validity test is being performed must include the appropriate calibrators and controls.

Section 11.21 What Are the Analytical and Quality Control Requirements for Conducting Validity Tests on Urine Specimens?

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

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

Section 11.22 What Are the Requirements for Conducting Each Validity Test on a Hair Sample?

(a) The initial test for a specific validity test must use a different analytical principle or chemical reaction than that used for the confirmatory test;

(b) Each initial and confirmatory validity test that is quantitative must 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; and

(c) Each initial and confirmatory validity test that is qualitative must include 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.

Section 11.23 What Are the Requirements for Conducting Each Validity Test on an Oral Fluid Specimen?

(a) The initial test for a specific validity test must use a different analytical principle or chemical reaction than that used for the confirmatory test;

(b) Each initial and confirmatory validity test that is quantitative must 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; and

(c) Each initial and confirmatory validity test that is qualitative must include 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.

Section 11.24 What Are the Requirements for Conducting Each Validity Test on a Sweat Patch Sample?

(a) The initial test for a specific validity test must use a different analytical principle or chemical reaction than that used for the confirmatory test;

(b) Each initial and confirmatory validity test that is quantitative must 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; and

(c) Each initial and confirmatory validity test that is qualitative must include 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.

Section 11.25 What Are the Requirements for Conducting Each Validity Test on a Urine Specimen?

(a) The requirements for measuring creatinine concentration are as follows:

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

(2) The initial creatinine test must have a calibrator at 2 mg/dL;

(3) The initial creatinine test must 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; and

(4) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must 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.

(b) The requirements for measuring specific gravity are as follows:

(1) The refractometer must report and display specific gravity to four decimal places. The refractometer must 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 must have a calibrator or control at 1.0000; and

(3) The initial and confirmatory specific gravity tests must 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.

(c) Requirements for measuring pH are as follows:

(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 must 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 must 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; and

(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, must 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, must 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; and

(6) An initial or confirmatory pH meter test, if a pH screening test is used, must 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.

(d) Requirements for performing oxidizing adulterant tests are as follows:

(1) The initial test must include an appropriate calibrator at the cutoff specified in sections 11.29(d)(3), (4), and (6) 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; and

(2) A confirmatory test for a specific oxidizing adulterant must use a different analytical method than that used for the initial test. Each confirmatory test batch must 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.

(e) The requirements for measuring the nitrite concentration are that the initial and confirmatory nitrite tests must 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.

(f) The requirements for performing other adulterant tests are that the initial and confirmatory tests for any "other'' adulterant that may be identified in the future must 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.

Section 11.26 What Are the Requirements for an HHS-Certified Laboratory to Report a Hair Test Result?

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

(b) A primary (Sample A) head hair sample is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each validity test result indicates that the sample is a valid head hair sample.

(c) A primary (Sample A) head hair sample is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive.

(d) A primary (Sample A) head hair sample is reported adulterated for a specific adulterant when the initial validity test is positive and the confirmatory validity test is positive.

(e) A primary (Sample A) head hair sample is reported as an invalid result if an interfering substance or physical characteristic prevents the laboratory from obtaining a valid negative or positive drug test result.

(f) An HHS-certified laboratory shall reject a head hair sample for testing when a fatal flaw occurs as described in section 16.1 or when a correctable flaw as described in section 16.2 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.

(g) An HHS-certified laboratory must report all non-negative test results for a sample. For example, a head hair sample can be positive for a specific drug and adulterated.

(h) An HHS-certified laboratory must report the concentration of the drug or metabolite for a positive result.

(i) An HHS-certified laboratory must report numerical values that support a sample that is reported adulterated or invalid (as appropriate).

(j) When the concentration of an analyte exceeds the linear range of the standard curve, an HHS-certified 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 dissolved head hair sample.

(k) An HHS-certified laboratory may transmit a result to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. A laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(l) For all test results, an HHS-certified 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.

Section 11.27 What Are the Requirements for an HHS-Certified Laboratory to Report an Oral Fluid Test Result?

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

(b) A primary (Tube A) oral fluid specimen is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each validity test result indicates that the specimen is a valid oral fluid specimen.

(c) A primary (Tube A) oral fluid specimen is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive. For only those oral fluid tests that result in a confirmed positive for marijuana, the laboratory must not report the result for the oral fluid specimen to the MRO but, instead must test the primary (Bottle A) urine specimen for marijuana and report that result in accordance with section 11.29.

(d) A primary (Tube A) oral fluid specimen is reported adulterated for a specific adulterant when the initial validity test is positive and the confirmatory validity test is positive.

(e) A primary (Tube A) oral fluid specimen is reported as an invalid result if an interfering substance or physical characteristic prevents the laboratory from obtaining a valid negative or positive drug test result.

(f) A primary (Tube A) oral fluid specimen is reported substituted if the sample does not exhibit the characteristics of a normal oral fluid specimen.

(g) An HHS-certified laboratory shall reject an oral fluid specimen for testing when a fatal flaw occurs as described in section 16.1 or when a correctable flaw as described in section 16.2 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.

(h) An HHS-certified laboratory must report all non-negative test results for a specimen. For example, an oral fluid specimen can be positive for a specific drug and adulterated.

(i) An HHS-certified laboratory must report the concentration of the drug or metabolite for a positive result.

(j) An HHS-certified laboratory must report numerical values that support a specimen that is reported adulterated, substituted, or invalid (as appropriate).

(k) When the concentration of an analyte exceeds the linear range of the standard curve, an HHS-certified 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.

(l) An HHS-certified laboratory may transmit a result to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. A laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(m) For all test results, an HHS-certified 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.

Section 11.28 What Are the Requirements for an HHS-Certified Laboratory To Report a Sweat Patch Test Result?

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

(b) A primary (Patch A) sweat patch sample is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each validity test result indicates that the sample is a valid sweat patch sample.

(c) A primary (Patch A) sweat patch sample is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive.

(d) A primary (Patch A) sweat patch sample is reported adulterated for a specific adulterant when the initial validity test is positive and the confirmatory validity test is positive.

(e) A primary (Patch A) sweat patch sample is reported as an invalid result if an interfering substance or physical characteristic prevents the laboratory from obtaining a valid negative or positive drug test result.

(f) An HHS-certified laboratory shall reject a primary (Patch A) sweat patch sample for testing when a fatal flaw occurs as described in section 16.1 or when a correctable flaw as described in section 16.2 is not recovered. The laboratory will indicate on the Federal CCF that the sample was rejected for testing and provide the reason for reporting the rejected for testing result.

(g) An HHS-certified laboratory must report all non-negative test results for a sample. For example, a sweat patch sample can be positive for a specific drug and adulterated.

(h) An HHS-certified laboratory must report the concentration of the drug or metabolite for a positive result.

(i) An HHS-certified laboratory must report numerical values that support a specimen that is reported adulterated or invalid (as appropriate).

(j) When the concentration of an analyte exceeds the linear range of the standard curve, an HHS-certified 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 eluted sweat patch sample.

(k) An HHS-certified laboratory may transmit a result to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. A laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(l) For all test results, an HHS-certified 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.

Section 11.29 What Are the Requirements for an HHS-Certified Laboratory To Report a Urine Test Result?

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

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

(c) A primary (Bottle A) urine specimen is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive.

(d) A primary (Bottle A) urine specimen is reported adulterated when:

(1) 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;

(2) 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;

(3) 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;

(4) 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;

(5) 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;

(6) 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;

(7) 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

(8) 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.

(e) A primary (Bottle A) urine specimen 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.

(f) A primary (Bottle A) urine specimen 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.

(g) A primary (Bottle A) urine specimen is reported as an invalid result when:

(1) 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);

(2) 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;

(3) 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;

(4) 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;

(5) 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;

(6) 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;

(7) 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;

(8) 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;

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

(10) 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;

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

(12) If the physical appearances of Bottles A and B 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.

(h) An HHS-certified laboratory shall reject a primary (Bottle A) urine specimen for testing when a fatal flaw occurs as described in section 16.1 or when a correctable flaw as described in section 16.2 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.

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

(j) An HHS-certified laboratory must report the concentration of the drug or metabolite for a positive result.

(k) An HHS-certified laboratory must report numerical values that support a specimen that is reported adulterated, substituted, or invalid (as appropriate).

(l) When the concentration of an analyte exceeds the linear range of the standard curve, an HHS-certified 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.

(m) An HHS-certified laboratory may transmit a result to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. A laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(n) For all test results, an HHS-certified 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.

Section 11.30 How Long Must an HHS-Certified Laboratory Retain a Specimen?

(a) An HHS-certified laboratory must retain a specimen that was reported either drug positive, adulterated, substituted, or as an invalid result for a minimum of 1 year.

(b) A retained specimen must be kept in a secured location that is appropriate for that type of specimen (*e.g.,* frozen storage (− 20°C or less) for urine) to ensure its availability for any necessary retesting during an administrative or judicial proceeding.

(c) Within the 1-year storage period, a Federal agency may request a laboratory to retain a specimen for an additional period of time. If no such request is received, a specimen may be discarded, except that the laboratory must be required to maintain any specimens under legal challenge for an indefinite period.

Section 11.31 How Long Must an HHS-Certified Laboratory Retain Records?

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years.

(b) A Federal agency may instruct, in writing, the laboratory to maintain records associated with a particular specimen under legal challenge for an indefinite period.

Section 11.32 What Statistical Summary Report Must an HHS-Certified Laboratory Provide?

(a) An HHS-certified laboratory must provide to each Federal agency for which testing is conducted a semiannual statistical summary report for each type of specimen tested that contains the following information:

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

(b) The report must be submitted by mail, fax, or email within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information.

(c) The HHS-certified laboratory must make available copies of an agency's test results when requested by the Secretary or by the Federal agency for which the laboratory is performing drug-testing services.

(d) The HHS-certified laboratory must make available qualified personnel to testify in a proceeding against a Federal employee when that proceeding is based on a test result reported by the HHS-certified laboratory.

Section 11.33 What Information Is Available to the Donor?

(a) A Federal employee who is the subject of a drug test may, upon written request through the MRO and the Federal agency, have access to any records relating to his or her drug test, any records relating to the results of any relevant certification, review, or revocation of certification proceedings, and access to a documentation package.

(b) A standard documentation package provided by an HHS-certified laboratory must consist of the following items:

(1) A cover sheet that provides a brief description of the drug testing procedures and any specimen validity tests performed on the donor's specimen;

(2) A table of contents page that lists by page number all documents and materials in the package;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the laboratory, and a copy of the electronic report (if any) generated by the laboratory;

(4) A brief description of the laboratory's initial drug and validity test procedures, instrumentation, batch quality control requirements, and copies of the initial test data for the donor's specimen with all calibrators and controls identified and copies of all internal chain of custody documents related to the initial tests;

(5) A brief description of the laboratory's confirmatory drug and validity test procedures, instrumentation, batch quality control requirements, and copies of the confirmatory test data for the donor's specimen with all calibrators and controls identified and copies of all internal chain of custody documents related to the confirmatory tests; and

(6) A copy of the resume or curriculum vitae for the certifying scientist that certified the test result.

Section 11.34 What Type of Relationship Is Prohibited Between an HHS-Certified Laboratory and an MRO?

(a) An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory for which the MRO is reviewing drug test results.

(b) An MRO must not derive any financial benefit by having a Federal agency use a specific HHS-certified laboratory that may be construed as a potential conflict of interest.

Section 11.35 What Information Must an HHS-Certified Laboratory Provide To Its Private Sector Clients?

When an HHS-certified laboratory uses procedures to test private sector client specimens that are different from those for which it is certified, it must inform the private sector client that its specimens are not being tested under the Guidelines.

Subpart L—Point of Collection Test (POCT)

Section 12.1 What Is the Goal of This Subpart?

(a) Employees of Federal agencies are in some cases located in remote areas of the country if they are serving with the Department of Interior, or overseas if they are serving with the Department of State. They are often in locations with few employees as is often the case when they are serving on American Indian reservations or in embassies in small foreign countries. It is often unrealistic to expect that a drug testing program in such places would operate in the same fashion as one that serves employees in the Washington, DC, area. It is in these circumstances and in cases where it is critical to receive an immediate test result that POCT tests play an important role.

(b) Yet a POCT offers a particular challenge to the Federal Workplace Drug Testing Program because the device that is used to produce a negative test result is really equivalent to a laboratory test to which the normal laboratory procedures and requirements cannot readily apply. Thus, while the sections of the Guidelines related to specimens, collection procedures, collections sites, chain of custody, drug and validity testing and others do apply, it is necessary to establish requirements particular to POCTs.

(c) This subpart establishes the criteria for POCT devices that may be used as part of the Federal Workplace Drug Testing Program, when Federal agencies may use a POCT, what the responsibilities are of a Federal agency which chooses to use a POCT, and the procedures that must be followed in using a POCT.

Section 12.2 What POCT Devices May Be Used in a Federal Workplace Drug Testing Program?

(a) A POCT device that may be used in a Federal Workplace Drug Testing Program is one which:

(1) Is FDA-cleared; and

(2) Effectively determines the presence or absence of drugs and determines the validity of a specimen, either as an integral function of the POCT device, or as a set of compatible devices or procedures as established in section 12.6.

(b) The Secretary will publish a list of the POCT devices that are SAMHSA-certified for use in the Federal Workplace Drug Testing Program in the **Federal Register**.

Section 12.3 What Is the Rationale for the Additional Requirements To Use POCT Devices Besides FDA Clearance?

The FDA clears POCT drug test devices by making a finding of substantial equivalence to a legally marketed device. FDA's determination of substantial equivalence does not ensure that the test will satisfy minimum performance requirements that are necessary for use in the Federal Workplace Drug Testing Program. Therefore, due to the critically important nature of testing under these Guidelines, there is need for additional assurance in the Federal Workplace Drug Testing Program that the FDA-cleared kits are effectively finding drugs at the specified cutoff concentrations and effectively determining the absence of drugs.

Section 12.4 What Types of POCT Devices Are There?

POCT devices are:

(a) Non-instrumented for which the endpoint result is obtained by visual evaluation (*i.e.,* read by human eye); or

(b) Instrumented for which the result is obtained by instrumental evaluation (*e.g.,* densitometer, spectrophotometer, fluorometer).

Section 12.5 What Must a POCT Device Manufacturer Submit to the Secretary To Have Its POCT Device Initially Included on the List of SAMHSA-Certified POCTs?

A POCT device manufacturer must submit the following to the Secretary:

(a) A copy of the FDA letter stating that the FDA has cleared the specific POCT device;

(b) A copy of the labeling submitted to FDA for the cleared device;

(c) A self-certification that the device meets the requirements contained in the FDA's good manufacturing practices regulations;

(d) A description of the storage requirements for the device;

(e) A total of 100 POCT devices and related testing procedures in representative numbers from all currently available manufactured lots of the device for HHS testing to evaluate the performance of the POCT device(s) for drug and validity testing; and

(f) An accounting of the expiration date and number of devices for each existing manufactured lot of the device.

Section 12.6 What Criteria Will the Secretary Use To Place a POCT Device on the List of SAMHSA-Certified POCTs?

(a) The Secretary shall evaluate the POCT devices submitted by the manufacturer using the following criteria:

(1) Correctly identify at least 80 percent of the total drug challenges;

(2) For an individual drug, correctly identify at least 80 percent of the total drug challenges;

(3) Correctly identify at least 80 percent of the total validity test challenges;

(4) For each specific validity test, correctly report at least 80 percent of the challenges for the specific validity test; and

(5) Must not report any sample as adulterated with a compound that is not present in the sample.

(b) The Secretary will use PT samples as described in section 12.9 to evaluate the POCT device.

Section 12.7 What Is Required for a FDA Cleared POCT Device To Continue on the List of SAMHSA-Certified Devices?

To maintain a POCT device on the SAMHSA-certified list, the manufacturer:

(a) Must agree to submit any design changes or alterations made to the device after it has been SAMHSA-certified, so that the Secretary may determine whether additional testing is required; and

(b) Must submit 50 POCT devices and related testing procedures annually to the Secretary in representative numbers from all currently available manufactured lots of the device for HHS testing to evaluate the performance of the POCT device(s) for drug and validity testing using criteria established in section 12.6.

Section 12.8 What Are the Responsibilities of a Federal Agency That Wishes To Conduct POCT?

A Federal agency which seeks to conduct POCT as part of its Federal Workplace Drug Testing Program must:

(a) Use only POCT devices that are on the SAMHSA-certified list published by the Secretary in accordance with section 12.2(b);

(b) Develop a standard operating procedure manual for POCT testers to use;

(c) Ensure that POCT testers meet the requirements of section 12.16;

(d) Ensure that all other pertinent requirements of these Guidelines are adhered to including the requirements with regard to POCT sites;

(e) Inspect the POCT sites periodically to ensure compliance with these Guidelines;

(f) Ensure that on a quarterly basis sets of HHS-contractor prepared PT samples (that satisfy the requirements in section 12.9) are submitted to challenge the performance of each POCT drug and validity test device at each site;

(g) Maintain records on those who have been SAMHSA-certified as POCT testers including records of their training;

(h) Retain records on the results of the PT samples and the results of all POCTs by test and by specimen;

(i) Provide semiannual reports to the Secretary with regard to the use of the POCT device(s) in keeping with section 12.25;

(j) Investigate each failure as provided in section 12.12 and determine whether it was related to failure to follow procedure in which case to take action against the POCT tester or whether it was related to the POCT device itself; and

(k) If any failure under (j) of this section is related to the device itself, immediately inform the Secretary who shall temporarily suspend the use of the POCT device.

Section 12.9 What Are the Qualitative and Quantitative Specifications for PT Samples That Are Used To Evaluate Test Devices Submitted by Manufacturers or for a Federal Agency To Evaluate a POCT Site and Tester?

A PT sample that is used to evaluate test devices submitted by manufacturers or to challenge a POCT drug or validity test device is a sample:

(a) That contains one or more drugs or metabolites in the drug classes for which each POCT device must have the capability to test.

(b) The concentration of the drugs and/or metabolites are at least 20 percent above the cutoff concentration or between 50 and 75 percent of the cutoff concentration for the initial test.

(c) That contains no measurable amount of a target drug and/or metabolite (*i.e.,* a negative sample).

(d) That may contain an interfering substance, an adulterant, or a specimen that meets the criteria for a substituted specimen that would challenge the POCT validity tests.

(e) For urine only PT samples, the nitrite concentration must be between 650 mcg/mL and 800 mcg/mL or between 250 mcg/mL and 400 mcg/mL.

(f) For urine only PT samples, the creatinine concentration must be between 5 mg/dL and 20 mg/dL or between 1 mg/dL and 5 mg/dL.

(g) For urine only PT samples, the specific gravity must be between 1.0000 and 1.0010 or between 1.0200 and 1.0300.

(h) For urine only PT samples, the pH must be between 1 and 3 or between 10 to 12.

(i) For oral fluid only PT samples, the IgG must be between 0.1 and 1.0.

Section 12.10 What Are the Inspection Requirements for a Federal Agency Wishing To Use a POCT?

(a) Each Federal agency is to inspect each POCT site periodically to ensure compliance with these Guidelines; and

(b) The Federal agency must maintain a record of the inspections for a minimum of 2 years.

Section 12.11 What Is the Responsibility of the Secretary To Inspect a Federal Agency Using POCT?

(a) The Secretary shall conduct a semiannual inspection of each Federal agency that uses POCT.

(b) The inspection will review the Federal agency's records to include:

(1) The Federal agency's standard operating procedure manual;

(2) POCT tester training records;

(3) POCT device quarterly PT results; and

(4) POCT quality assurance data maintained by each POCT tester and site.

Section 12.12 What Is a Failure for the Purposes of the POCT?

A failure means the following:

(a) For a drug POCT, the device failed to properly identify a negative or positive PT sample;

(b) For a validity POCT, the device failed to identify a PT sample that was adulterated, substituted or diluted; or

(c) The device reported a false negative after confirmation by a laboratory in keeping with section 12.21(b).

Section 12.13 What Is the Responsibility of the Secretary When a Failure Is Reported?

(a) If, after reviewing the information from the Federal agency and all other agencies using the same device as well as the circumstances of the failure, the Secretary determines that there is a problem with the device, the Secretary may:

(1) Temporarily suspend the use of the device in the Federal Workplace Drug Testing Program if immediate action is necessary in order to protect the interests of the United States and its employees; or

(2) Remove the device from the SAMHSA-certified list.

(b) If the Secretary suspends the use of the device, the Secretary shall:

(1) Inform all Federal agencies which are using the device of the action by placing notice in the **Federal Register** of such action; and

(2) Notify the manufacturer that the device may be removed from the list of SAMHSA-certified devices. In this event, the manufacturer has 30 days from the date of notification to reply.

(3) Based on the Secretary's investigation and any information provided by the manufacturer, the Secretary shall decide whether the device should remain on the list of SAMHSA-certified devices.

(i) If the Secretary determines that the device is to be removed from the list of SAMHSA-certified devices, the list will be revised accordingly.

(ii) If the Secretary decides that it is not to be removed from the list of SAMHSA-certified devices, the suspension will be lifted by publication of a notice in the **Federal Register**.

(c) If the Secretary has cause to remove the device from the list of SAMHSA-certified devices in the absence of a need for immediate action, the Secretary shall notify the manufacturer that the device may be removed from the list of SAMHSA-certified devices. In this event, the manufacturer has 30 days from the date of notification to reply. Based on the Secretary's investigation and any information provided by the manufacturer, the Secretary will decide whether the device should remain on the approved list.

(d) If the Secretary determines that there is a problem with the device, the Secretary shall notify the FDA so that the FDA can evaluate whether any action under the Food, Drug, and Cosmetic Act is necessary.

Section 12.14 How Can a Manufacturer Apply To Have a Device Reinstated on the List of SAMHSA-Certified Devices?

(a) The manufacturer may reapply for SAMHSA-certification in accordance with section 12.5.

(b) Upon reapplication, the manufacturer must submit a statement describing what has been done to overcome the problems that resulted in the device being removed from the list of SAMHSA-certified devices.

Section 12.15 Which Types of Specimens May Be Tested Using a POCT?

(a) Oral fluid (saliva)

(b) Urine

Section 12.16 What Are the Requirements To Be a POCT Tester?

(a) An individual is considered to be a POCT tester for a specific POCT device when the Federal agency documents that the individual has:

(1) Received supervised and validated training in how to use and interpret the results of the POCT device;

(2) Received training on chain of custody, reporting, and recordkeeping procedures;

(3) Read and understands these Guidelines; and

(4) Demonstrated proficiency that has been documented by the Federal agency by completing five consecutive error-free POCTs.

(b) An individual may be trained to use all or some of the devices on the list of SAMHSA-certified devices.

Section 12.17 What Happens if a POCT Site or Tester Does Not Satisfy the Minimum Technical Requirements?

The POCT site or tester may not perform POCTs for a Federal agency until acceptable performance has been documented.

Section 12.18 What Are the Requirements for Conducting a POCT?

(a) A donor must not have access to the POCT device.

(b) After the donor leaves the collection site and after the split specimens are labeled and sealed by the collector, a POCT tester (which may be the collector) is permitted to break the label/seal on the primary specimen and remove an aliquot to conduct the POCT.

(c) The POCT tester must maintain and document chain of custody for the primary specimen and the aliquot used for the POCT on an OMB-approved custody and control form.

(d) If the aliquot tests negative on the drug POCTs, the aliquot, primary, and split specimens must be discarded unless the split specimens are to be submitted as part of the quality assurance program.

(e) If the aliquot tests presumptive drug positive, adulterated, substituted, or invalid on the POCTs, the primary specimen must be resealed using a new tamper-evident label/seal and sent with the split specimen to an HHS-certified laboratory for testing. The POCT tester must initial and date the new label/seal that was used to reseal the primary specimen. The POCT tester must report the POCT result on the OMB-approved custody and control form. The aliquot used to conduct the POCTs is discarded. When a POCT is conducted on an oral fluid specimen aliquot and it is presumptive positive for marijuana, the POCT tester must send the urine split specimen bottles to an HHS-certified laboratory for testing rather than the oral fluid specimen tubes. For all other presumptive positive drug test results on an oral fluid POCT, the POCT tester may only send the oral fluid split specimen tubes to the HHS-certified laboratory for testing.

(f) The POCT tester must complete the POCTs on an aliquot before beginning the testing of another specimen using POCTs.

Section 12.19 What Are the Quality Control Requirements When Conducting POCTs?

(a) For drug POCTs:

(1) Each day testing is performed using devices with visually read endpoints (*i.e.*, a color appearing or disappearing that indicates a positive result using that device), each individual performing drug tests using these devices must test at least one negative control (*i.e.*, a sample certified to contain no drug or drug metabolite) and one positive control (*i.e.*, a sample with the concentration of the drugs or metabolites in the range of 25 percent above the cutoff concentration) before donor specimens are tested. These quality control samples must be tested and the results interpreted with the positive control testing positive and the negative control testing negative before donor specimens are tested and reported each day.

(2) Each day testing is performed using devices with semi-automated or automated testing devices with machine read endpoints (*i.e.*, spectrophotometer), at least one negative control (*i.e.*, a sample certified to contain no drug or drug metabolite) and one positive control (*i.e.*, a sample with the concentration of the drugs or metabolites in the range of 25 percent above the cutoff concentration) must be tested on each device used. These quality control samples must be tested and the results interpreted with the positive control testing positive and the negative control testing negative before donor specimens are tested and reported each day.

(b) For validity POCTs, each day testing is performed, at least one control that is normal for the specific validity test and one control that is abnormal must be tested. The results must be correct before donor specimens are tested.

(c) At least one specimen out of every 10 specimens that test negative must be submitted to an HHS-certified laboratory as part of a quality assurance program.

Section 12.20 What Action Must Be Taken When a POCT Quality Control Sample Fails?

For (a) or (b) in section 12.19, the failed quality control sample must be sent to an HHS-certified laboratory. The POCT tester must successfully test QC samples until acceptable results are obtained before testing donor specimens. If acceptable QC results cannot be obtained, donor specimens must be sent directly to an HHS-certified laboratory.

Section 12.21 What Does a POCT Tester Do With a Specimen After Conducting a POCT?

(a) Each presumptive positive, adulterated, or substituted specimen together with its split is sent to an HHS-certified laboratory for additional testing.

(b) A POCT tester must send one of every 10 negative specimens together with its split to an HHS-certified laboratory to be tested for quality control purposes. Other negative specimens must be discarded.

Section 12.22 How is a POCT Negative Result Reported?

(a) A negative result is reported directly to an MRO within 3 (on average) working days after the POCT is conducted.

(b) A POCT tester may report a negative test result to an MRO using an electronic report format. The electronic report must be transmitted to the MRO in a manner that ensures the confidentiality and security of the information.

(c) A POCT tester may not report test results telephonically. However, the MRO may contact the POCT tester by telephone if he or she has any concern regarding the negative result.

Section 12.23 How Long Must Records Generated at the POCT Site Be Retained?

All records must be retained for at least 2 years by the POCT tester or the tester's employer.

Section 12.24 What POCT Information Is Available to the Donor?

(a) An employee tested by a Federal agency workplace drug testing program may, upon written request through the MRO and the Federal agency, have access to any records relating to his or her drug test, any records relating to the results of any relevant review of the POCT, and have access to a documentation package.

(b) The documentation package must contain the following:

(1) A brief description of the POCT procedures, quality control requirements, copies of the POCT test data for the donor's specimen with all calibrators and controls identified as related to the POCTs;

(2) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the POCT tester, and a copy of the report generated by the POCT tester;

(3) A copy of the resume or curriculum vitae for the POCT tester; and

(4) A copy of the Federal agency documentation of training of the POCT tester for the specific POCT device.

Section 12.25 What Statistical Summary Report Must a Federal Agency Provide to the Secretary?

(a) A Federal agency must provide the Secretary a semiannual statistical summary report that contains the following information:

(1) The number of specimens tested

(2) The number grouped by reason for test as follows:

(i) Random
(ii) All others reasons combined

(3) The number that were:

(i) Screened positive for each drug (listed separately)
(ii) Screened as adulterated
(iii) Screened as substituted
(iv) Invalid Result

(4) The total number of quality control samples tested

(i) The number of acceptable QC sample results
(ii) The number of failed QC sample results

(b) The report must be submitted by mail, fax, or email within 14 working days after the end of the semiannual period.

(c) The Federal agency must make available copies of an agency's POCT drug and validity test results when requested by the Secretary.

(d) The Federal agency must make available the POCT tester to testify in a proceeding against a Federal employee when that proceeding is based on a test result that begins with a POCT.

Section 12.26 What Type of Relationship Is Prohibited Between a Manufacturer of a POCT Device or a POCT Site Operation and an MRO?

(a) An MRO must not be an employee, agent of, or have any financial interest in a manufacturer of a POCT device or POCT site operation for which the MRO is reviewing drug test results.

(b) An MRO must not derive any financial benefit by having an agency use a specific POCT device that may be construed as a potential conflict of interest.

Section 12.27 What Type of Relationship Can Exist Between a Manufacturer of a POCT Device or a POCT Site Operation and an HHS-Certified Laboratory?

A manufacturer of a POCT device or a POCT site operation can freely enter into any relationship with an HHS-Certified laboratory.

Subpart M—Instrumented Initial Test Facility (IITF)

Section 13.1 What Is an HHS-Certified IITF?

An HHS-certified IITF:

(a) Is a facility at a permanent location that conducts only instrumented initial drug and validity tests (as described for an HHS-certified laboratory in subpart K);

(b) Has satisfied the certification requirements for each type of specimen the IITF wants to test;

(c) Has passed 3 consecutive sets of PT samples for each type of specimen to be tested and an initial inspection before becoming HHS-certified;

(d) Participates in a quarterly maintenance PT sample program and is inspected every 6 months; and

(e) Is managed by a full-time responsible technician (RT).

Section 13.2 Which Types of Specimens May Be Tested at an HHS-Certified IITF?

(a) Hair
(b) Oral fluid (saliva)
(c) Sweat (patch)
(d) Urine

Section 13.3 What Cutoff Concentrations Are Used by an HHS-Certified IITF for the Drug Tests?

An HHS-certified IITF must use the same cutoff concentrations for its initial drug tests as listed for a hair sample in section 3.3, for an oral fluid specimen in section 3.4, for a sweat patch sample in section 3.5, and for a urine specimen in section 3.6.

Section 13.4 What Must Be Included in the HHS-Certified IITF's Standard Operating Procedure Manual?

(a) An HHS-certified IITF must have a standard operating procedure (SOP) manual that describes, in detail, all IITF operations.

(b) The SOP manual must include, but is not limited to, a detailed description of the following:

(1) Chain-of-custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, laboratory information management systems.

(c) All procedures in the SOP manual must be in compliance with these Guidelines and other guidance documents.

(d) A copy of all procedures that have been replaced or revised and the dates on which they were in effect must be maintained by the HHS-certified IITF to allow the IITF to retrieve the procedures that were used to test a specimen.

Section 13.5 What Must the HHS-Certified IITF Do To Validate an Initial Drug Test?

The HHS-certified IITF must satisfy the same validation requirements as described in section 11.13.

Section 13.6 What Qualifications Must the Responsible Technician (RT) Have?

An RT must have the following qualifications:

(a) A bachelor's degree in the chemical or biological sciences, medical technology, or similar field;

(b) Training and experience in the analytical methods and procedures used by the IITF that are relevant to the results;

(c) Training and experience in reviewing and reporting test results, maintenance of chain of custody, recordkeeping, and understanding proper remedial action in response to problems that may arise; and

(d) Be found to fulfill RT responsibilities and qualifications upon interview by HHS-trained inspectors during each on-site inspection of the HHS-certified IITF.

Section 13.7 What Are the Responsibilities of an RT?

An RT must:

(a) Manage the day-to-day operations of the IITF.

(b) Ensure that there are enough personnel with adequate training and experience to conduct and operate the work of the IITF. The RT must ensure the continued competency of testing facility personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete, current SOP manual that is available for personnel at the IITF, and followed by those personnel. The SOP manual must be reviewed, signed, and dated by the RT whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the IITF.

(d) Verify and maintain a quality assurance program to assure the proper performance and reporting of all test results; monitor acceptable analytical performance for all controls and standards; monitor quality control testing; document the validity, reliability, accuracy, precision, and performance characteristics of each device/system used at that testing facility.

(e) Implement all remedial actions necessary to maintain satisfactory operation and performance of the testing facility in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing results. This individual must ensure that sample 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.

(f) Qualify as an operator of the initial test analyzers used at the IITF.

Section 13.8 What Happens When the RT Is Absent or Leaves an HHS-Certified IITF?

(a) All HHS-certified IITFs must have an RT and an alternate RT. An alternate RT must be able to fulfill the responsibilities of an RT and must meet the qualifications of a certifying scientist. The laboratory must submit documentation satisfactory to the Secretary which shows the credentials of the prospective RT and which must be approved by the Secretary, and found acceptable during on-site inspections of the IITF.

(b) When the HHS-certified IITF is without the RT and alternate RT for 14 calendar days or less (*e.g.,* vacation, illness, business trip), the certified IITF may continue testing Federal agency specimens under the direction of a certifying scientist.

(c) When an RT permanently leaves a certified IITF:

(1) The HHS-certified IITF may maintain its certification and continue testing Federal agency specimens under the direction of an alternate RT for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the new permanent RT.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's certification for all specimens if the IITF does not have a permanent replacement RT within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RT.

(d) When a new RT candidate has been identified, the IITF must submit to the Secretary the candidate's current resume or curriculum vitae, arrange to have official academic transcript(s) submitted by the candidate's institution(s) of higher learning, copies of diplomas and any licensures, a training plan (not to exceed 90 days) to transition into the RT position, and an itemized defense of the candidate's qualifications compared to the minimum RT qualifications described in the Guidelines.

(e) The HHS-certified IITF must fulfill other inspection and PT criteria as required prior to conducting Federal agency testing under a new RT.

Section 13.9 What Qualifications Must an Individual Have To Certify a Test Result Reported By an HHS-Certified IITF?

The individual who certifies a negative test result must have:

(a) Training and experience in the analytical methods and procedures used by the IITF that are relevant to the results that the individual certifies; and

(b) Training and experience in reviewing and reporting test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

Section 13.10 What Qualifications and Training Must Other IITF Personnel Have?

(a) All IITF staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks assigned.

(b) Each individual working in an HHS-certified IITF must be properly trained before he or she is permitted to work independently in any area of the facility with Federal agency specimens.

(c) The training file for each individual must include, at a minimum, a resume, documentation of training provided, and any applicable professional certifications or licenses. Training files should be maintained separate from personnel files.

Section 13.11 What Security Measures Must an HHS-Certified IITF Maintain?

(a) An HHS-certified IITF must control access to the facility and ensure that no unauthorized individual can gain access to specimens, aliquots, or records.

(b) Authorized visitors must be escorted at all times except for individuals authorized to conduct inspections on behalf of Federal, state, or other accrediting agencies or emergency personnel (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified IITF must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized visitors and authorized escorts to accessing secured areas.

Section 13.12 What Are the Internal IITF Chain of Custody Requirements for a Specimen or an Aliquot?

(a) An HHS-certified IITF must 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 the specimens.

(b) An HHS-certified IITF must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process and until final disposal.

(c) The date and purpose must be documented on an appropriate chain of custody document each time a specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(d) Chain of custody must be maintained and documented by using either hard copy procedures or electronic procedures.

(e) Each individual that handles a specimen or aliquot must sign and complete the chain of custody document when the specimen or aliquot is received.

Section 13.13 What Are the Batch Quality Control Requirements When Conducting the Initial Tests for Drugs?

The HHS-certified IITF must satisfy the same quality control requirements as described in section 11.14 for an HHS-certified laboratory.

Section 13.14 What Are the Analytical and Quality Control Requirements for Conducting Initial Validity Tests?

An HHS-certified IITF must satisfy the same initial validity test requirements described in sections 11.18, 11.19, 11.20, and 11.21 and sections 11.22, 11.23, 11.24, and 11.25 for each type of specimen, as appropriate.

Section 13.15 What Action Is Taken After an HHS-Certified IITF Tests a Specimen?

(a) A specimen that is negative on initial drug tests and has acceptable initial validity test results is discarded and reported as negative to the MRO within 3 days (on average) working days after receipt of the specimen.

(b) A specimen that is presumptive drug positive, adulterated, substituted, or invalid is immediately forwarded using chain of custody procedures to an HHS-certified laboratory for confirmatory testing.

Section 13.16 How Long Must an HHS-Certified IITF Retain Records?

(a) An HHS-certified IITF must retain all records generated to support test results for at least 2 years.

(b) A Federal agency may request the HHS-certified IITF to maintain records associated with a particular specimen under legal challenge for an indefinite period.

Section 13.17 What Statistical Summary Report Must an HHS-Certified IITF Provide?

(a) An HHS-certified IITF must provide to each Federal agency for which testing is conducted a semiannual statistical summary report that contains the following information:

(1) Number of specimens tested

(2) The number grouped by reason for test as follows:

(i) Random

(ii) All others reasons combined

(3) The number that were:

(i) Screened positive for each drug (listed separately)

(ii) Screened as adulterated

(iii) Screened as substituted

(iv) Rejected for Testing

(v) Invalid Result

(b) The report must be submitted by mail, fax, or e-mail within 14 working days after the end of the semiannual period.

(c) The HHS-certified IITF must make available copies of an agency's test results when requested by the Secretary or by the Federal agency for which the IITF is performing drug-testing services.

(d) The HHS-certified IITF must make available qualified personnel to testify in a proceeding against a Federal employee when that proceeding is based on a test result reported by the HHS-certified IITF.

Section 13.18 What IITF Information Is Available to the Donor?

(a) An employee tested by a Federal agency workplace drug testing program may, upon written request through the MRO and the Federal agency, have access to any records relating to his or her drug test, any records relating to the results of any relevant certification, review, or revocation of certification proceedings, and access to a documentation package.

(b) A standard documentation package provided by an HHS-certified IITF must contain the following items:

(1) A cover sheet that provides a brief description of the drug testing procedures and any specimen validity tests performed on the donor's specimen;

(2) A table of contents page that lists by page number all documents and materials in the package;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the IITF, and a copy of the electronic report (if any) generated by the IITF;

(4) A brief description of the laboratory's initial drug and validity test procedures, instrumentation, batch quality control requirements, and copies of the initial test data for the donor's specimen with all calibrators and controls identified and copies of all internal chain of custody documents related to the initial tests; and

(5) A copy of the resume or curriculum vitae for the certifying scientist that certified the test result.

Section 13.19 What Type of Relationship Is Prohibited Between an HHS-Certified IITF and an MRO?

(a) An MRO must not be an employee, agent of, or have any financial interest in an IITF for which the MRO is reviewing drug test results.

(b) An MRO must not derive any financial benefit by having an agency use a specific instrumented initial test facility or have any agreement with the IITF that may be construed as a potential conflict of interest.

Section 13.20 What Type of Relationship Can Exist Between an HHS-Certified IITF and an HHS-Certified Laboratory?

An HHS-certified IITF can freely enter into any relationship with an HHS-certified laboratory.

Section 13.21 How Does an HHS-Certified IITF Report a Negative Test Result?

(a) An HHS-certified IITF may transmit a result to the MRO by various electronic means (for example, teleprinters, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. An IITF must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(b) For all test results, an HHS-certified IITF 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.

Section 13.22 How Does an HHS-Certified IITF Handle a Specimen That Is Presumptive Drug Positive, Adulterated, Substituted, or Invalid?

(a) The remaining specimen is resealed using a tamper-evident label/seal;

(b) The individual resealing the remaining specimen initials and dates the tamper-evident label/seal;

(c) The resealed specimen and split specimen are sent to an HHS-certified laboratory for confirmatory testing within one day after completing the initial drug and/or validity tests; and

(d) The HHS-certified IITF provides the test result(s) on the OMB-approved chain of custody form used to report initial test results.

Section 13.23 Where Is the List of HHS-Certified IITFs Published?

(a) The list of current HHS-certified IITFs is published monthly in the **Federal Register.**

(b) An applicant IITF is not included on the list.

Subpart N—Medical Review Officer (MRO)

Section 14.1 Who May Serve as an MRO?

(a) A licensed physician who:

(1) Has either a Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;

(2) Has knowledge regarding the pharmacology and toxicology of illicit drugs;

(3) Has the training necessary to serve as an MRO as set out in section 14.2; and

(4) Has satisfactorily completed an examination administered by a nationally recognized entity that certifies MROs or subspecialty board for physicians performing a review of Federal employee drug test results, which has been approved by the Secretary.

(b) Nationally recognized entities that certify MROs or subspecialty boards for physicians performing a review of Federal employee drug test results that seek approval by the Secretary must submit their qualifications and sample examination. Based on an annual objective review of the qualifications and content of the examination, the Secretary shall annually publish a list in the **Federal Register** of those entities and boards that have been approved.

Section 14.2 What Are the Training Requirements Before a Physician Can Serve as an MRO?

A physician must receive training that includes a thorough review of:

(a) The collection procedures for each type of specimen collected;

(b) The procedures for conducting POCT tests;

(c) How to interpret test results reported by laboratories;

(d) Chain of custody, reporting, and recordkeeping requirements for regulated specimens; and

(e) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Section 14.3 What Are the Responsibilities of the MRO?

(a) The MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the HHS-certified laboratory, HHS-certified IITF, or POCT site;

(2) Interview the donor when required;

(3) Make a determination regarding the test result;

(4) Report the verified result to the Federal agency; and

(5) Maintain the records (for a minimum of 2 years) and the confidentiality of the information.

(b) The review of a non-negative test result must 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. The MRO must cancel the result for any agency's specimen that is not collected or tested in accordance with these Guidelines.

Section 14.4 What Must an MRO Do When Reviewing a Hair Test Result?

(a) When the HHS-certified laboratory or IITF reports a negative result on the primary (Sample A) head hair sample, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory reports a positive result on the primary (Sample A) head hair sample, the MRO contacts the donor to determine if there is any valid medical explanation for the positive result. If the donor provides a valid medical explanation, the MRO reports the test result as negative to the agency. If the donor is unable to provide a valid medical explanation, the MRO reports a positive result to the agency.

(c) When an HHS-certified laboratory reports an adulterated result on the primary (Sample A) head hair sample, the MRO contacts the donor to determine if there is a valid medical explanation for the adulterated result. If the donor is unable to provide a valid explanation, the MRO reports a refusal to test to the agency because the specimen was adulterated.

(d) When an HHS-certified laboratory or IITF reports an invalid result on the primary (Sample A) head hair sample, the MRO contacts the donor to determine if there is a valid medical explanation for the invalid result. If the donor is unable to provide an explanation, the MRO reports a test cancelled result and directs the agency to collect another specimen from the donor. If the second specimen collected exhibits the same behavior as the first specimen, the MRO again reports the result for the second specimen as test cancelled and recommends to the agency that no further action is required.

(e) When an HHS-certified laboratory or IITF reports a rejected for testing result (*e.g.,* lice) on the primary (Sample A) head hair sample, the MRO reports a test cancelled result to the agency and directs the agency to collect another sample from the donor.

Section 14.5 What Must an MRO Do When Reviewing an Oral Fluid Test Result?

(a) When a HHS-certified laboratory, HHS-certified IITF, or POCT tester reports a negative result on the primary (Tube A) oral fluid specimen, the MRO reports a negative result to the agency.

(b) When an HHS-certified laboratory reports a positive result on the primary (Tube A) oral fluid specimen, the MRO contacts the donor to determine if there is any valid medical explanation for the positive result. If the donor provides a valid medical explanation, the MRO reports the test result as negative to the agency. If the donor is unable to provide a valid medical explanation, the MRO reports a positive result to the agency.

(c) When an HHS-certified laboratory reports an adulterated or substituted result on the primary (Tube A) oral fluid specimen, the MRO contacts the donor to determine if there is a valid explanation for the adulterated or substituted result. If the donor is unable to provide a valid explanation, the MRO reports a refusal to test to the agency because the specimen was adulterated or substituted.

(d) When an HHS-certified laboratory or IITF reports an invalid result on the primary (Tube A) oral fluid specimen, the MRO contacts the donor to determine if there is a valid explanation for the invalid result. If the donor is unable to provide an explanation, the MRO reports a test cancelled result and directs the agency to collect another specimen from the donor. If the second specimen collected exhibits the same behavior as the first specimen, the MRO

again reports the result for the second specimen as test cancelled and recommends to the agency that no further action is required.

(e) When an HHS-certified laboratory or IITF reports a rejected for testing result on the primary (Tube A) oral fluid specimen, the MRO reports a test cancelled result to the agency and directs the agency to collect another specimen from the donor.

Section 14.6 What Must an MRO Do When Reviewing a Sweat Patch Test Result?

(a) When an HHS-certified laboratory or IITF reports a negative result on the primary (Patch A) sweat patch sample, the MRO reports a negative result to the agency.

(b) When an HHS-certified laboratory reports a positive result on the primary (Patch A) sweat patch sample, the MRO contacts the donor to determine if there is any valid medical explanation for the positive result. If the donor provides a valid medical explanation, the MRO reports the test result as negative to the agency. If the donor is unable to provide a valid medical explanation, the MRO reports a positive result to the agency.

(c) When an HHS-certified laboratory reports an adulterated result on the primary (Patch A) sweat patch sample, the MRO contacts the donor to determine if there is a valid explanation for the adulterated result. If the donor is unable to provide a valid explanation, the MRP reports a refusal to test to the agency because the specimen was adulterated.

(d) When an HHS-certified laboratory or IITF reports an invalid result on the primary (Patch A) sweat patch sample, the MRO contacts the donor to determine if there is a valid explanation for the invalid result. If the donor is unable to provide an explanation, the MRO reports a test cancelled result and directs the agency to collect another specimen from the donor. If the second specimen collected using a direct observed collection procedure exhibits the same behavior as the first specimen, the MRO again reports the result for the second specimen as test cancelled and recommends to the agency that no further action is required.

(e) When an HHS-certified laboratory or IITF reports a rejected for testing result on the primary (Patch A) sweat patch sample, the MRO reports a test cancelled result to the agency and directs the agency to collect another sample.

Section 14.7 What Must an MRO Do When Reviewing a Urine Test Result?

(a) When an HHS-certified laboratory, HHS-certified IITF, or POCT tester reports a negative result on the primary (Bottle A) urine specimen, the MRO reports a negative result to the agency.

(b) When an HHS-certified laboratory, HHS-certified IITF, or POCT tester reports a negative and dilute result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is any possible explanation for the urine specimen being dilute. If there appears to be a legitimate medical explanation, the MRO reports a negative result to the agency without indicating that the specimen was dilute. If there is no legitimate medical explanation, the MRO directs the agency to immediately collect another specimen from the donor.

(c) When an HHS-certified laboratory reports a positive result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is any valid medical explanation for the positive result. If the donor provides a valid medical explanation, the MRO reports the test result as negative to the agency. If the donor is unable to provide a valid medical explanation, the MRO reports a positive result to the agency. If a laboratory also reports that the specimen is dilute, the MRO directs the agency to have the donor provide another specimen using a direct observed collection procedure (when the MRO was reporting the result as negative). For a positive result, the MRO may ignore the dilute result.

(d) When an HHS-certified laboratory reports a positive result for opiates on the primary (Bottle A) urine specimen, the MRO must 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. However, 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) When an HHS-certified laboratory reports an adulterated or substituted result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is a valid medical explanation for the adulterated or substituted result. If the donor is unable to provide a valid medical explanation, the MRO reports a refusal to test to the agency because the specimen was adulterated or substituted.

(f) When an HHS-certified laboratory or IITF reports an invalid result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is a valid medical explanation for the invalid result. If the donor is unable to provide an explanation, provides a valid prescription for some medications (*e.g.,* Tolmetin, Flagyl, Cipro), or denies having tampered with the specimen, the MRO reports a test cancelled result and directs the agency to collect another specimen from the donor using a direct observed collection. If the second specimen collected using a direct observed collection procedure exhibits the same behavior as the first specimen, the MRO again reports the result for the second specimen as test cancelled and recommends to the agency that no further action is required because the donor is taking a valid prescription medication that interferes with the drug test or there is some unknown endogenous substance present in the donor's urine that prevents getting a valid drug test result.

(g) When an HHS-certified laboratory or IITF reports a rejected for testing result on the primary (Bottle A) urine specimen, the MRO reports a test cancelled result to the agency and directs the agency to immediately collect another specimen from the donor.

Section 14.8 Who May Request a Test of a Split Specimen?

(a) For a positive, adulterated, or substituted result reported on a primary specimen, a donor may request through the MRO that the split specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory.

(b) 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 test of the split specimen. The MRO must inform the donor that he or she has the right to request a test of the split specimen when the MRO informs the donor that a positive, adulterated, or substituted result is being reported to the Federal agency on the primary specimen.

Section 14.9 How Does the MRO Report a Primary Specimen Test Result to an Agency?

(a) The MRO must report all verified results to an agency by either faxing a completed MRO copy of the Federal CCF, transmitting a scanned image of the completed MRO copy of the Federal CCF, or faxing a separate report using a letter/memorandum format.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a hard copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all non-negative results.

(d) The MRO must not disclose numerical values to the Federal agency.

Section 14.10 What Type of Relationship Is Prohibited Between an MRO and an HHS-Certified Laboratory, POCT Tester, or an HHS-Certified IITF?

(a) An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory, POCT tester, or HHS-certified IITF for which the MRO is reviewing drug test results.

(b) An MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory, POCT tester, or HHS-certified IITF or have any agreement with the laboratory, POCT tester, or IITF that may be construed as a potential conflict of interest.

Subpart O—Split Specimen Tests

Section 15.1 When May a Split Specimen Be Tested?

(a) A donor has the right to request through the MRO that the split specimen be tested at a different HHS-certified laboratory when the primary specimen was determined by the MRO to be positive, adulterated, or substituted (as appropriate for each type of specimen collected).

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The donor must document this request in writing to the MRO.

(c) If the split specimen cannot be tested by a second laboratory (*e.g.,* insufficient specimen, lost in transit, split not available), the MRO shall direct the Federal agency to immediately collect another specimen.

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

Section 15.2 How Does an HHS-Certified Laboratory Test a Split Hair, Oral Fluid, Sweat, or Urine Specimen When the Primary Specimen Was Reported Positive?

(a) The testing of a split head hair, oral fluid, sweat, or urine specimen for a drug or metabolite is not subject to the testing cutoff concentrations established for each type of specimen collected.

(b) The laboratory is only required to confirm the presence of the drug or metabolite that was reported present in the primary head hair, oral fluid, sweat, or urine specimen.

(c) For urine only, 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 must conduct validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug or drug metabolite. The second laboratory should conduct the same validity tests as it would conduct on a primary specimen and reports those results to the MRO.

Section 15.3 How Does an HHS-Certified Laboratory Test a Split Hair Sample for Adulterants When the Primary Sample Was Reported Adulterated?

(a) The second laboratory must test the split head hair sample using the laboratory's confirmatory test(s) for the adulterant(s) reported in the primary sample.

(b) The second laboratory is only required to confirm the presence of the adulterant(s) using the limit of detection (LOD) of its confirmatory test(s).

(c) The second laboratory may only conduct the confirmatory test(s) needed to reconfirm the adulterant(s) reported by the primary laboratory.

Section 15.4 How Does an HHS-Certified Laboratory Test a Split Oral Fluid Specimen for Adulterants When the Primary Specimen Was Reported Adulterated?

(a) The second laboratory must test the split oral fluid specimen using the laboratory's confirmatory test(s) for the adulterant(s) reported in the primary specimen.

(b) The second laboratory is only required to confirm the presence of the adulterant(s) using the limit of detection (LOD) of its confirmatory test(s).

(c) The second laboratory may only conduct the confirmatory test(s) needed to reconfirm the adulterant(s) reported by the primary laboratory.

Section 15.5 How Does an HHS-Certified Laboratory Test a Split Sweat Patch Sample for Adulterants When the Primary Sample Was Reported Adulterated?

(a) The second laboratory must test the split sweat patch sample using the laboratory's confirmatory test(s) for the adulterant(s) reported in the primary sample.

(b) The second laboratory is only required to confirm the presence of the adulterant(s) using the limit of detection (LOD) of its confirmatory test(s).

(c) The second laboratory may only conduct the confirmatory test(s) needed to reconfirm the adulterant(s) reported by the primary laboratory.

Section 15.6 How Does an HHS-Certified Laboratory Test a Split Urine Specimen for Adulterants When the Primary Specimen Was Reported Adulterated?

(a) A laboratory must use one of the following criteria to reconfirm an adulterated result when testing a split (Bottle B) specimen:

(1) pH must be measured using the laboratory's confirmatory pH test with the appropriate cutoff (*i.e.,* either less than 3 or greater than or equal to 11);

(2) Nitrite must be measured using the laboratory's confirmatory nitrite test with a cutoff concentration of greater than or equal to 500 mcg/mL; or

(3) For adulterants without a specified cutoff (*e.g.,* glutaraldehyde, surfactant, chromium (VI), pyridine, halogens (such as bleach, iodine), peroxidase, peroxide, other oxidizing agents), the laboratory must use its confirmatory validity test at an established limit of detection (LOD) to reconfirm the presence of the adulterant.

(b) The second laboratory may only conduct the confirmatory validity test(s) needed to reconfirm the adulterant result reported by the primary laboratory.

Section 15.7 How Does an HHS-Certified Laboratory Test a Split Oral Fluid Specimen for Substitution When the Primary Specimen Was Reported Substituted?

The second laboratory must test the split (Tube B) specimen using the laboratory's confirmatory IgG test and determine that the IgG concentration is less than 0.10 mcg/mL.

Section 15.8 How Does an HHS-Certified Laboratory Test a Split Urine Specimen for Substitution When the Primary Specimen Was Reported Substituted?

(a) A laboratory must use the following criteria to reconfirm a

substituted result when testing a split (Bottle B) specimen:

(1) The creatinine must be measured using the laboratory's confirmatory creatinine test with a cutoff concentration of less than 2 mg/dL; and

(2) The specific gravity must be measured using the laboratory's confirmatory specific gravity test with the specified cutoffs of less than 1.0010 or greater than or equal to 1.0200.

(b) The second laboratory may only conduct the confirmatory validity test(s) needed to reconfirm the validity test result(s) reported by the primary laboratory.

Section 15.9 Who Receives the Split Specimen Result?

The second laboratory must transmit the result directly to the MRO.

Section 15.10 What Action(s) Does the MRO Take After Receiving the Split Hair Sample Result From the Second Laboratory?

The MRO takes the following actions when the second laboratory reports the result for the split head hair sample as:

(a) *Reconfirmed the drug(s).* The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm the drug(s).* The MRO reports to the agency a failed to reconfirm result (specify drug(s)), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(c) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs.* The MRO reports to the agency a failed to reconfirm result (specify drug(s)) and a reconfirmed result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although the second laboratory failed to reconfirm one or more drugs.

(d) *Failed to reconfirm the adulteration result.* The MRO reports to the agency a failed to reconfirm result (specify not adulterated), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

Section 15.11 What Action(s) Does the MRO Take After Receiving the Split Oral Fluid Specimen Result From the Second Laboratory?

The MRO takes the following actions when the second laboratory reports the result for the split oral fluid specimen as:

(a) *Reconfirmed the drug(s), adulteration, and/or substitution result.* The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm the drug(s).* The MRO reports to the agency a failed to reconfirm result (specify drug(s)), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(c) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs.* The MRO reports to the agency a failed to reconfirm result (specify drug(s)) and a reconfirmed result (specify drug(s)). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although the second laboratory failed to reconfirm one or more drugs.

(d) *Failed to reconfirm the adulteration or substitution result.* The MRO reports to the agency a failed to reconfirm result (specify not adulterated or substituted), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

Section 15.12 What Action(s) Does the MRO Take After Receiving the Split Sweat Patch Sample Result From the Second Laboratory?

The MRO takes the following actions when the second laboratory reports the result for the split sweat patch sample as:

(a) *Reconfirmed the drug(s) and/or adulteration result.* The MRO reports reconfirmed to the agency.

(b) *Failed to reconfirm the drug(s).* The MRO reports to the agency a failed to reconfirm result (specify drug(s)), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(c) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs.* The MRO reports to the agency a failed to reconfirm result (specify drug(s)) and a reconfirmed result (specify drug(s)). The MRO tells the agency that it may action based on the reconfirmed drug(s) although the second laboratory failed to reconfirm one or more drugs.

(d) *Failed to reconfirm the adulteration result.* The MRO reports to the agency a failed to reconfirm result (specify not adulterated), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

Section 15.13 What Action(s) Does the MRO Take After Receiving the Split Urine Specimen Result From the Second Laboratory?

The MRO takes the following actions when the second laboratory reports the result for the split urine specimen as:

(a) *Reconfirmed the drug(s), adulteration, and/or substitution result.* The MRO reports reconfirmed to the agency.

(b) *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 retest the primary 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.

(c) *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 primary 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 HHS office responsible for coordination of the drug-free workplace program about the failed to reconfirm and cancelled test.

(d) *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 HHS office responsible for coordination of the drug-free workplace program.

(e) *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 HHS office

responsible for coordination of the drug-free workplace program.

(f) *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 HHS office official responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(g) *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 HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(h) *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 HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) *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 HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(j) *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 HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(k) *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.

(l) *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 HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(m) *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.

(n) *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.

(o) *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 HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(p) *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.

(q) *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.

Section 15.14 How Does an MRO Report a Split Specimen Test Result to an Agency?

(a) The MRO must report all verified results to an agency by either faxing a completed MRO copy of the Federal CCF, transmitting a scanned image of the completed MRO copy of the Federal CCF, or faxing a separate report using a letter/memorandum format.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a hard copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all non-negative results.

(d) The MRO must not disclose numerical values to the agency.

Section 15.15 How Long Must an HHS-Certified Laboratory Retain a Split Specimen?

A split specimen is retained for the same period of time that a primary specimen is retained and under the same storage conditions. This applies even for those cases when the split specimen is tested by a second laboratory and the second laboratory does not confirm the original result reported by the first laboratory on the primary specimen.

Subpart P—Criteria for Rejecting a Specimen for Testing

Section 16.1 What Discrepancies Require an HHS-Certified Laboratory or IITF to Report a Hair, Oral Fluid, Sweat, or Urine Specimen as Rejected for Testing?

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

(a) The specimen ID number on the specimen 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 label/seal;

(b) The specimen label/seal is broken or shows evidence of tampering on the primary specimen and the split specimen cannot be re-designated as the primary specimen;

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

(d) There is an insufficient amount of specimen/sample for analysis in the primary specimen unless the split specimen can be re-designated as the primary specimen.

(e) For hair only, an HHS-certified laboratory or IITF may reject a head hair sample if it contains lice.

Section 16.2 What Discrepancies Require an HHS-Certified Laboratory or IITF to Report a Hair, Oral Fluid, Sweat, or Urine Specimen as Rejected for Testing Unless the Problem is Corrected?

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the laboratory or IITF 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 or IITF may report the test result for the specimen. If the laboratory or IITF cannot recover the collector's signature, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-Federal form or an expired Federal CCF, the laboratory or IITF 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 or IITF cannot obtain a memorandum for record from the collector, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

Section 16.3 What Discrepancies Are Not Sufficient To Require a Laboratory or IITF To Reject a Hair, Oral Fluid, Sweat, or Urine Specimen for Testing or an MRO To Cancel a Test?

(a) The following omissions and discrepancies on the Federal CCF that is received by the HHS-certified laboratory or IITF are considered insignificant and should not cause an HHS-certified laboratory or IITF to reject a specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appears at the top of the form;

(2) Incomplete/incorrect/unreadable employer name or address;

(3) MRO name is missing;

(4) Incomplete/incorrect MRO address;

(5) A transposition of numbers in the donor's SSN;

(6) A phone number is missing/incorrect;

(7) A fax number is missing/incorrect;

(8) A "reason for test'' box is not marked;

(9) A "drug tests to be performed'' box is not marked;

(10) A specimen collection box is not marked;

(11) The observed box is not marked (if applicable);

(12) The collection site address is missing;

(13) The collector's printed name is missing but the collector's signature is properly recorded;

(14) The time of collection is not indicated;

(15) The date of collection is not indicated;

(16) Incorrect name of delivery service;

(17) The collector has changed or corrected information by crossing out the original information on either the Federal CCF or specimen label/seal without dating and initialing the change; or

(18) The donor's name inadvertently appears on the laboratory copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(19) For urine only, the collector failed to check the specimen temperature box and the "Remarks'' line did not have a comment regarding the temperature being out of range. If the collector cannot provide a memorandum for record (MFR) to attest to the fact that he or she did measure the specimen temperature, the laboratory may report the test result for the specimen but indicates that the collector could not provide an MFR to recover the omission.

(b) The following omissions and discrepancies on the Federal CCF that are made at the laboratory or IITF are considered insignificant and should not cause an MRO to cancel a test:

(1) The testing laboratory or IITF fails to indicate the correct name and address in the results section when a different laboratory or IITF name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print his or her name;

(3) The certifying scientist fails to print his or her name;

(4) The certifying scientist accidentally initials the Federal CCF rather than providing a signature for a non-negative result (CS initials are acceptable for a negative result);

(5) The accessioner fails to mark one of the "primary specimen bottle seal intact'' boxes, but the laboratory reported a "rejected for testing'' result with an appropriate comment on the "Remarks'' line.

(c) The above omissions and discrepancies are considered insignificant only when they occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory and IITF will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an error occurs more than once a month, the MRO must direct the collector, laboratory, or IITF (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

Section 16.4 What Discrepancies May Require an MRO To Cancel a Test?

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the hard copy (Copy 1) of the Federal CCF for a specimen being reported drug positive, adulterated, substituted, rejected for testing, or invalid test result (as appropriate for each type of specimen collected); or

(3) The electronic report provided by the HHS-certified laboratory or IITF does not contain all the data elements required for the HHS standard electronic laboratory or IITF report for a specimen being reported drug positive, adulterated, substituted, rejected for testing, or invalid test result.

(b) If error (a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If the collector cannot provide such a statement, the MRO must cancel the test.

(c) If error (a)(2) occurs, the MRO must obtain a statement from the CS that he or she inadvertently forgot to sign the CCF, but did, in fact, properly conduct the certification review.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory or IITF and require the HHS-certified laboratory or IITF to modify its electronic reports and to retransmit a corrected electronic report.

Subpart Q—Laboratory or IITF Suspension/Revocation Procedures

Section 17.1 When May an HHS-Certified Laboratory or IITF Be Suspended?

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory or IITF in writing that its certification to perform drug

testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory or IITF 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 17.2 What Definitions Are Used for This Subpart?

Appellant. Means the HHS-certified laboratory or IITF which has been notified of its suspension or proposed revocation of its certification to perform 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.

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 17.3 Are There Any 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 these Guidelines shall not be subject to review under these procedures.

Section 17.4 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 17.5 When Must a Request for Informal Review Be Submitted?

(a) 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.

(b) 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 17.6 What Is an 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 or IITF attempts to regain compliance with the Guidelines 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 17.7 What Procedure Is Used To Prepare 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 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 17.8 When Is There an 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 17.9 Are There Expedited Procedures for Review of Immediate Suspension?

(a) *Applicability.* When the Secretary notifies a laboratory or IITF in writing that its certification to perform 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 or IITF 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 prehearing conference in accordance with section 17.8(c) and will conduct the oral presentation in accordance with the procedures of sections 17.8(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 17.14 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 17.10 Are Any Types of Communications Prohibited?

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 17.11 How Are Communications Transmitted by the Reviewing Official?

(a) 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.

(b) 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 17.12 What Is the Authority and Responsibilities of the 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 17.13 What Administrative Records Are Maintained?

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 17.14 What Are the Requirements for a 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 17.15 Is There a Review of the Final Administrative Action?

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 17.9(e) or 17.14(a), constitutes final agency action and is ripe for judicial review as of the date of the decision.

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