Model Plan for a Comprehensive Federal Drug-Free Workplace Program

Second Edition

HHS Publication No. (ADM)90-1635

Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention
Division of Workplace Programs

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Acknowledgements

The first edition of this model plan was developed by a federal Interagency Coordinating Group composed of representatives from the Department of Health and Human Services (HHS), the Office of Personnel Management (OPM), and the Department of Justice (DOJ) and distributed to federal agencies by the former National Drug Policy Board in 1989. It has served as the standard for federal agency drug-free workplace plans and programs ever since. It has also been widely adapted and adopted in the private and non-federal public sectors and incorporated into numerous collectively bargained agreements throughout the American economy.

The model plan has proven to be an exceptionally durable document and continues to be the standard for federal agency drug-free workplace plans and programs. The second edition updates legal citations and terms of art, incorporates the addition of four semi-synthetic opioids to the list of drugs routinely tested for, and adds the use of oral fluid in lieu of urine drug testing.

The second edition has been shared with the successor group, the Interagency Coordinating Group Executive Committee, which is convened by the Office of National Drug Control Policy (ONDCP) and has the same representation as the predecessor group.

This publication is made available online to federal agencies and the public through the Substance Abuse and Mental Health Services Administration website.

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I. Introduction

A. Background

On September 15, 1986, President Reagan signed Executive Order 12564, establishing the goal of a Drug-Free Federal Workplace. The Order made it a condition of employment for all federal employees to refrain from using illegal drugs on or off duty. The Executive Order recognized that illegal drug use was seriously impairing a portion of the national work force, resulting in the loss of billions of dollars each year. As the largest employer in the Nation, the Federal Government had a compelling proprietary interest in establishing reasonable conditions of employment. Prohibiting employee drug use is one such condition.

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

The Executive Order and Public Law assigned significant responsibilities to HHS, DOJ, and OPM. Representatives of these three agencies came together to form the Interagency Coordinating Group which authored the original Model Plan in 1989. In 1990, the former General Accounting Office conducted a review of the Federal Drug-Free Workplace Program, concluding that, while the three agencies were fulfilling their responsibilities, no single agency was designated as the lead. On March 5, 1991, President Bush designated the ONDCP as the lead agency for Federal Drug-Free Workplace Program implementation. ONDCP subsequently convened the three agencies as the Interagency Coordinating Group Executive Committee to become the policy-setting body for the program and to offer concurrence on substantive changes in agency plans and on addition of positions designated for random testing, a role that it continues to play.

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

B. Statement of Policy

The [**Agency/Department**], as a result of its [**describe type of**] responsibilities, as well as the sensitive nature of its work, has a compelling obligation to eliminate illicit drug and illegal opioid use from its workplace. [**Insert a one-page summary that describes the two or three most significant aspects of your agency's/ Department's mission and the risk posed by employee use of illicit drugs and illegal opioids.**]

The success of a drug-free workplace program depends on how well the [**Agency/Department**] informs its employees of the hazards of drug use, and on how much assistance it can provide drug users. Equally important is the assurance to employees that personal dignity and privacy will be respected in reaching the [**Agency's/Department's**] goal of a drug-free workplace. Therefore, this plan includes policies and procedures for: (1) employee assistance; (2) supervisory training; (3)

employee education; and (4) identification of illicit drug and illegal opioid use through drug testing on a carefully controlled and monitored basis.

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

Section 503 of the Act requires the [**Agency/Department**] Plan to specify the nature, frequency, and type of drug testing to be instituted. The [**Agency/Department**] Plan includes the following types of drug testing: (1) applicant testing; (2) random testing of those employees in sensitive positions selected as testing designated positions (TDPs); (3) reasonable suspicion testing; (4) accident or unsafe practice testing; (5) voluntary testing, and (6) testing as part of or as a follow-up to counseling or rehabilitation.

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

D. Drugs for Which Individuals Are Tested

Section 503 of the Act requires the [**Agency/Department**] to specify the drugs for which individuals shall be tested. The [**Agency/Department**] will test for the following drugs listed by the Drug Enforcement Administration Schedule I and II of the Controlled Substance Act: Marijuana, Cocaine. [**Agency/Department may also test for additional Schedule I or Schedule II drugs on a case-by-case basis for reasonable suspicion or post-accident testing: Amphetamines, including Amphetamine, Methamphetamine, Methylenedioxymethamphetamine (MDMA), and Methylenedioxyamphetamine (MDA); Opioids, including 6-Acetylmorphine, Codeine, Morphine, Hydrocodone, Hydromorphone, Oxycodone, and Oxymorphone; and Phencyclidine (PCP).**]

If the Agency/Department desires to test for any other Schedule I or II drug on a routine basis, advance written approval from the Secretary, HHS is required.

E. Scope

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

F. Union Cooperation

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

G. References

1. Authorities

a. Executive Order 12564, Drug-Free Federal Workplace.

b. Executive Order 13467, Reforming Processes Related to Suitability for Government Employment, Fitness for Contractor Employees, and Eligibility for Access to Classified National Security Information, June 30, 2008, as amended by Executive Order 13764, Amending the Civil Service Rules, Executive Order 13488, and Executive Order 13467 to Modernize the Executive Branch-Wide Governance Structure and Processes for Security Clearances, Suitability and Fitness for Employment, and Credentialing, and Related Matters, January 17, 2017.

c. Executive Order 13526, Classified National Security Information.

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

e. Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine [UrMG], which includes scientific and technical requirements and certification of laboratories engaged in urine drug testing, 82 FR 7920 (2017) as amended.

f. Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid [OFMG] which includes scientific and technical requirements and certification of laboratories engaged in oral fluid drug testing, 84 FR 57554 (2019).

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

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

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

j. Regulations implementing the Privacy Act of 1974 for the [**Agency**].

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

l. [**Add any relevant Agency/Department orders, including appropriate personnel orders.**]

2. Guidance

a. Guidance for Selection of Testing Designated Positions, Substance Abuse and Mental Health Services Administration, 2013.

b. [**Add any appropriate Agency/Department guidance documents.**]

II. Definitions

A. Applicant

Any individual tentatively selected—either—

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

B. Department of Health and Human Services (HHS)/Substance Abuse and Mental Health Services Administration (SAMHSA)/Center for Substance Abuse Prevention (CSAP)/Division of Workplace Programs

The organization given HHS' responsibilities under the Federal Drug-Free Workplace Program, including certification of Agency/Department plans and maintenance of the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

C. Employee Assistance Program (EAP)

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

D. EAP Administrator

The individual responsible for ensuring the development, implementation, and review of the agency EAP.

E. EAP Coordinator

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

F. Employees in Sensitive Positions

1. Employees in positions designated by the [**Agency head**] as Special Sensitive, Critical Sensitive, or Noncritical-Sensitive or employees in positions designated by the [**Agency head**] as sensitive in accordance with Executive Order No. 13467, as amended by Executive Order No. 13764.

2. Employees granted access to classified information or who may be granted access to classified information pursuant to a determination of trustworthiness by the [**Agency head**] under Executive Order No. 13526.

3. Individuals serving under Presidential appointments.

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

5. Other positions that the [**Agency head**] determines involve law enforcement, national security, the protection of life and property, or public health or safety.

G. Illicit Drugs

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

H. Interagency Coordinating Group Executive Committee (ICGEC)

The group chaired by ONDCP and consisting of representatives of HHS, DOJ, and OPM that sets policy for the Federal Drug-Free Workplace Program and offers concurrence on substantive changes in Agency/Department plans and on addition of positions designated for random testing.

I. Medical Review Officer (MRO)

The individual responsible for receiving laboratory results generated from the [**Agency**] Drug-Free Workplace Program who is a licensed physician with knowledge of pharmacology and toxicology of illicit drugs and the appropriate medical training to interpret and evaluate all positive test results together with an individual's medical history and any other relevant biomedical information.

J. Random Testing

A system of drug testing imposed without individualized suspicion that a particular individual is using illicit drugs or illegal opioids, and may either be:

1. Uniform--unannounced testing of testing designated employees occupying a specified area, element or position.

2. A statistically random sampling of such employees based on a neutral criterion, such as social security numbers.

K. Supervisor

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

L. Testing Designated Positions (TDPs)

Employment positions within the [**Agency/Department**] that have been designated for random testing under Section IX(B) of this plan.

M. Verified Positive Test Result

A test result that was positive on an initial FDA-approved immunoassay test, confirmed by a Gas Chromatography/Mass Spectrometry assay, (or other confirmatory tests approved by HHS), and reviewed and verified by the Medical Review Officer in accordance with this plan and the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

III. Employee Assistance Programs (EAPs)

A. Function

The [**Agency**] Employee Assistance Program (EAP) plays an important role in preventing and resolving employee drug use by: demonstrating the [**Agency's**] commitment to eliminating illicit drug and illegal opioid use; providing employees an opportunity, with appropriate assistance, to discontinue their drug use; providing educational materials to supervisors and employees on drug use issues; assisting supervisors in confronting employees who have performance and/or conduct problems and making referrals to appropriate treatment and rehabilitative facilities; and following-up with individuals during the rehabilitation period to track their progress and encourage successful completion of the program.

The EAP, however, shall not be involved in the collection of specimens or the initial reporting of test results.

The EAP shall:

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

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

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

B. Referral and Availability

Any employee found to be using drugs shall be referred to the EAP. The EAP shall be administered separately from the testing program and shall be available to all employees without regard to a finding of drug use.

The EAP shall provide counseling or rehabilitation for all referrals, as well as education and training regarding illicit drug and illegal opioid use. The EAP shall be available not only to [**Agency/Department**] employees, but, when feasible, to the families of employees with drug problems, and to employees with family members who have drug problems.

In the event the employee is not satisfied with the program of treatment or rehabilitation, such employee may seek review of the EAP Counselor's referral by notifying the EAP Administrator prior to completion of the program. The decision of the EAP Administrator shall be final and shall not be subject to further administrative review.

Regardless of the treatment program chosen, the employee remains responsible for successful completion of the treatment, and assertions that the counselor failed to consider one or more of the factors in Section VI(D)(5) in making a referral shall not constitute either an excuse for continuing to use illicit drugs or illegal opioids or a defense to disciplinary action if the employee does not complete treatment.

C. Leave Allowance

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

D. Records and Confidentiality

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

E. Structure

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

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

IV. Supervisory Training

A. Objectives

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

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

2. The responsibilities of offering EAP services.

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

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

5. The ways to use [**the Agency/Department**] EAP.

6. The process of reintegrating employees into the workforce.

B. Implementation

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

C. Training Package

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

1. Overall Agency/Department policy.

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

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

4. How to recognize employees with possible problems.

5. Documentation of employee performance or behavior.

6. Skills in confronting employees with possible problems.

7. Agency procedures for referring employees to EAP.

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

9. Reintegration of employees into the workforce.

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

V. Employee Education

A. Objectives

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

1. Types and effects of drugs.

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

3. The relationship of the EAP to drug testing.

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

B. Means of Education

Drug education activities may include:

1. Distribution of written materials.

2. Audio-visual media.

3. Lunchtime employee forums.

4. Employee drug awareness events.

VI. Special Duties and Responsibilities

[**Smaller agencies may choose to combine several of the duties listed into a single position upon advice from the Department of Health and Human Services, Division of Workplace Programs. Larger agencies may choose to add a higher level Drug Program Administrator to oversee and coordinate the work of component level or site Coordinators or Managers. It is recommended that duties/roles be clearly described so that differences among duties/roles are distinct and do not overlap.**]

A. Drug Program Coordinator

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

1. Arrange for all testing authorized under this order.

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

3. Document, through written inspection reports, all results of laboratory and collection site inspections conducted.

4. Coordinate with and report to the [**Agency/Department head**] on DPC activities and findings that may affect the reliability or accuracy of laboratory results.

5. In coordination with the EAP Administrator, publicize and disseminate drug program educational materials, and oversee training and education sessions regarding drug use and rehabilitation.
6. Coordinate all DPC duties in field offices wherever possible to conserve resources and to efficiently and speedily accomplish reliable and accurate testing objectives.

7. Liaise with the HHS/SAMHSA/CSAP/Division of Workplace Programs to maintain currency of drug program policy and practice and provide Annual Summary Report data.

B. Employee Assistance Program Administrator

The EAP Administrator shall:

1. Receive verified positive test results from the DPC or other official designated by [**Agency/Department**] to receive test results from the MRO.

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

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

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

C. Employee Assistance Program Coordinator

The EAP Coordinator shall:

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

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

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

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

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

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

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

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

    a. Name, address, phone number, email(s), and website.

    b. Types of services provided.

    c. Hours of operation, including emergency hours.

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

    e. Fee structure, including insurance coverage.

    f. Client specialization.

    g. Other pertinent information.

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

D. EAP Counselors

EAP Counselors shall:

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

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

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

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

5. In making referrals, consider the:

    a. Nature and severity of the problem.

b. Location of the treatment.

c. Cost of the treatment.

d. Intensity of the treatment environment.

e. Availability of inpatient/outpatient care.

f. Other special needs, such as transportation and childcare.

g. The preferences of the employee.

E. Medical Review Officer

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

1. Receive all laboratory test results.

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

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

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

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

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

F. Supervisors

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

1. Attend training sessions on illicit drug and illegal opioid use in the workplace.

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

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

4. Initiate appropriate disciplinary action upon a finding of illicit drug or illegal opioid use.

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

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

G. Implementation

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

H. General Program/Structural Provisions

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

I. Government Contractors

Wherever existing facilities are inadequate to implement this order, the [**appropriate Agency/Department official**] shall:

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

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

3. Establish, by contract or with [**Agency/Department**] employees as deemed appropriate, the positions and specific responsibilities of the DPC and the MRO as required by the Mandatory Guidelines.

VII. Notice

A. General Notice

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

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

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

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

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

5. The circumstances under which testing may occur.

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

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

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

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

B. Individual Notice

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

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

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

required;" If there is a safe harbor, add: "and shall not be subject to disciplinary action."].

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

3. That the employee's position will be subject to random testing no sooner than thirty (30) days following the notice.

C. Signed Acknowledgement

Each employee in a Testing Designated Position shall be asked to acknowledge in writing that the employee has received and read the notice that states that the employee's position has been designated for random drug testing, and that refusal to submit to testing will result in initiation of disciplinary action, up to and including dismissal. If the employee refuses to sign the acknowledgement, the employee's supervisor shall note on the acknowledgement form that the employee received the notice. This acknowledgement, which is advisory only, shall be centrally collected for easy retrieval by the [**operating unit head**]. An employee's failure to sign the notice shall not preclude testing that employee, or otherwise affect the implementation of this order since the general 60-day notice will previously have notified all agency employees of the requirement to be drug-free.

D. Administrative Relief

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

VIII. Finding of Drug Use and Disciplinary Consequences

A. Determination

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

1. Direct observation.

2. Evidence obtained from an arrest or criminal conviction.

3. A verified positive test result.

4. An employee's voluntary admission.

B. Mandatory Administrative Actions

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

C. Range of Consequences

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

[**Insert either**]

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

[**or if a safe harbor exists, insert:**] but shall not discipline an employee who voluntarily admits to illicit or illegal drug use in accordance with subsection VIII(F) of this plan.

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

1. Reprimanding the employee in writing.

2. Placing the employee in an enforced leave status.

3. Suspending the employee for 14 days or less.

4. Suspending the employee for 15 days or more.

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

6. Removing the employee from service.

7. Reducing the employee in pay or grade.

D. Initiation of Mandatory Removal from Service

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

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

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

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

E. Refusal to Take Drug Test When Required

An employee who refuses to be tested when so required will be subject to the full range of disciplinary action, including dismissal. A refusal occurs when an employee fails to:

1. Appear or remain at the collection site.

2. Provide a specimen of sufficient quantity for testing without a legitimate medical explanation.

3. Participate in an alternative specimen collection.

4. Undergo a medical examination as directed by the MRO.

5. Cooperate with the collection process.

A refusal also occurs if an employee brings materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen, or attempts or admits to adulterating, substituting, or diluting the specimen.

No applicant who refuses to be tested shall be extended an offer of employment.

F. Voluntary Referral

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

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

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

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

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

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

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

   b. Obtains counseling or rehabilitation through an EAP.

   c. Thereafter refrains from such use.

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

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

   a. Being asked to provide a urine or oral fluid specimen in accordance with this plan.

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

IX. Random Testing

A. Sensitive Positions Designated for Random Testing

The Executive Order requires testing for employees in sensitive positions. As specified in Section XV of this plan, the [**Agency/Department head**] has determined that some of these sensitive positions are testing designated positions subject to random testing. Position titles designated for random drug testing are listed in Section XV, which also provides a brief description of relevant duties, the justification for designation, and the number of incumbents.

B. Determining TDPs

To determine TDPs, the [**Agency/Department head**] applied the Guidance for Selection of Testing Designated Positions issued by the Interagency Coordinating Group Executive Committee, which defines:

1. Presumptive Testing Designated Positions
   a. Employees Who Carry Firearms

   b. Motor Vehicle Operators Carrying Passengers

   c. Aviation Flight Crew Members and Air Traffic Controllers

   d. Railroad Operating Crews

2. Preferred Testing Designated Positions

   a. Certain Health and Safety Positions

      1). Employees authorized to carry firearms

      2). Railroad Employees Engaged in Safety Sensitive Tasks

      3). Aviation Personnel

   b. Presidential Appointees Requiring Senate Confirmation (PAS)

   c. Front Line Law Enforcement Personnel

   d. Drug Rehabilitation Employees

   e. Personnel Having Access to "Truly Sensitive Information"

      1). Top Secret and Higher Clearances

      2). Secret Clearances

3. Discretionary Designations. Given the unique Agency/Department missions, there are a number of other, non-court tested TDPs that may be appropriate for inclusion within Agency/Department plans.

4. Specifically Disfavored Testing Designated Positions

   a. Positions designated based upon the need to foster public trust or generalized requirements for integrity, honesty, or responsibility.

   b. Positions designated based upon access to sensitive information not meeting the "truly sensitive" criteria [e.g., personnel files, budget and financial information, and grand jury information].

The [**Agency/Department head**] reserves the right to add or delete TDPs pursuant to the criteria established in the Guidance for Selection of Testing Designated Positions. The concurrence of [**Agency/Department**] general counsel and of the Interagency Coordinating Group Executive Committee will be sought for all new TDPs and the deletion of any presumptive TDPs.

The [**Agency/Department head**] has determined, pursuant to 42 U.S.C. 290dd, that all positions which have been or will be designated as TDPs under this plan are

"sensitive positions" and are therefore exempted from provisions prohibiting employment deprivation based on prior substance misuse.

C. Implementing Random Testing

In implementing the program of random testing, the DPC shall:

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

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

The number of sensitive employees occupying TDPs and the rate of random tests will be administered are specified in Section XV.

D. Notification of Selection

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

E. Deferral of Testing

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

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

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

3. In an undercover assignment in a law enforcement investigation that would be unduly jeopardized by the requirement to appear for testing.

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

X. Reasonable Suspicion Testing

Reasonable suspicion testing may be required of any employee in a position which is designated for random testing when there is a reasonable suspicion that the employee uses illicit drugs or illegal opioids whether on or off duty. Reasonable suspicion testing may also be required of any employee in any position when there is a reasonable suspicion of on-duty use or on-duty impairment.

A. Grounds

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

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

2. A pattern of abnormal conduct or erratic behavior.

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

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

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

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

B. Procedures

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

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

C. Supervisory Training

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

XI. Applicant Testing

A. Objectives

To maintain the high professional standards of the [**Agency's/Department's**] workforce, it is imperative that individuals who use illicit drugs or illegal opioids be screened out during the initial employment process before they are placed on the

employment rolls of the [**Agency/Department**]. Drug testing shall be required of all applicants as defined in Section II.

B. Vacancy Announcements

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

"All applicants tentatively selected for this position will be required to submit to screening for illicit and illegal drug use prior to appointment."

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

C. Procedures

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

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

D. Personnel Officials

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

E. Consequences

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

XII. Additional Types of Drug Testing

A. Accident or Unsafe Practice Testing

[**Agency/Department**] is committed to providing a safe and secure working environment. It also has a legitimate interest in determining the cause of serious

accidents so that it can undertake appropriate corrective measures. Post-accident drug testing can provide invaluable information in furtherance of that interest. Accordingly, employees may be subject to testing when, based upon the circumstances of the accident, their actions are reasonably suspected of having caused or contributed to an accident that meets the following criteria:

1. The accident results in a death or personal injury requiring immediate hospitalization.

2. The accident results in damage to government or private property estimated to be in excess of $10,000.

If an employee is suspected of having caused or contributed to an accident meeting the above criteria, the appropriate supervisor will present the facts leading to this suspicion to the [**Agency/Department Official**] for approval. Once approval has been obtained and arrangements made for testing, the supervisor will prepare a written report detailing the facts and circumstances that warranted the testing.

B. Voluntary Testing

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

C. Follow-up Testing

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

XIII. Test Procedures in General

A. Mandatory Guidelines for Federal Workplace Drug Testing Programs

Drug testing is used to make significant career decisions for federal civilian employees, and HHS has established exacting scientific and technical standards for its conduct. At the inception of the program, the Department concluded that only urine drug testing met these standards. It published the original Mandatory Guidelines for Federal Workplace Drug Testing Programs on April 11, 1988 [53 FR 11979]. These guidelines were subsequently revised on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and

November 25, 2008 [73 FR 71858], and were ultimately re-named to indicate that they apply only to urine drug testing on January 23, 2017 [82 FR 7920].

In 2015, HHS concluded that oral fluid drug testing met its standards and could be used in federal workplace drug testing programs. The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid, which authorized the use of this alternative specimen, were published on October 25, 2019 [84 FR 57554].

A federal agency may use urine, oral fluid, or both in their testing programs. HHS continues to monitor the evolving forensic science of drug testing and considers the use of alternative specimens in consultation with its Drug Testing Advisory Board and with the review and comment of the public, the scientific community, the drug testing industry, and other federal agencies. The Department may publish additional guidelines for alternative specimens and technologies when these meet its standards for use with federal civilian employees.

The [**Agency/Department**] shall adhere to the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine and the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid promulgated by HHS. The [**Agency/Department's**] drug testing component shall have professionally trained collection personnel, quality assurance requirements for laboratory procedures, and strict confidentiality requirements.

B. Privacy Assurance

1. Urine Collection

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

a. The individual:

1). Has previously been found by the [**Agency**] to be an illicit or illegal drug user.

2). Has previously tampered with a specimen.

b. Facts and circumstances suggest that the individual:

1). Is an illicit or illegal drug user.

2). Is under the influence of drugs at the time of the test.

3). Has equipment or implements capable of tampering with or altering urine specimens.

c. The specimen:

1). Has a temperature outside the range of 32-38 degrees C / 90-100 degrees F.

2). Shows signs of contaminants.

2. Oral Fluid Collection

Any individual subject to oral fluid testing under this plan shall provide specimens in a restricted access area with the collector present and in visual contact throughout the collection procedure. The collector is not required to be the same gender as the donor.

The collector shall inspect the individual's oral cavity to ensure that it is free of any items that could impede or interfere with the collection of an oral fluid specimen (e.g., candy, gum, food, tobacco) or could be used to adulterate, substitute, or dilute the specimen. If an item is present that appears to have been brought to the collection site with the intent to adulterate, substitute, or dilute the specimen, this is considered a refusal to test.

C. Failure to Appear for Testing

Failure to appear for testing without a deferral will be considered refusal to participate in testing and will subject an employee to the range of disciplinary actions, including dismissal, and an applicant to the cancellation of an offer of employment.

If an individual fails to appear at the collection site at the assigned time, the collector shall contact the Drug Program Coordinator to obtain guidance on action to be taken.

D. Opportunity to Justify a Positive Test Result

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

1. A valid prescription.

2. A verification from the individual's physician verifying a valid prescription. Individuals are not entitled, however, to present evidence to the MRO in a trial-type administrative proceeding, although the MRO has the discretion to accept evidence in any manner deemed most efficient or necessary. If the MRO determines there is no justification for the positive result, such result will then be considered a verified positive test result. The MRO shall immediately contact the appropriate management official upon obtaining a verified positive test result.

E. Employee Counseling and Assistance

While participating in a counseling or rehabilitation program, and at the request of the program, the employee may be exempted from the random testing designated positions pool for a period not to exceed sixty (60) days, or for a time period specified in an abeyance contract or rehabilitation plan approved by the Agency head. Upon completion of the program, the employee immediately shall be subject to follow-up testing pursuant to Section XII(C).

F. Savings Clause

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

XIV. Records and Reports

A. Confidentiality of Test Results

The laboratory may disclose laboratory test results only to the MRO or the staff of the MRO. Any positive result which the MRO justifies by acceptable and appropriate medical or scientific documentation to account for the result as other than the intentional ingestion of an illicit drug or the illegal use of a licit drug will be treated as a negative test result and may not be released for purposes of identifying illicit or illegal drug use. Test results will be protected under the provisions of the Privacy Act, 5 U.S.C. §552a, et seq. and Section 503(e) of the Act and may not be released in violation of either this Act or of the Supplemental Appropriations Act of 1987, Pub. L. 100-71, Section 503.

The MRO may maintain only those records necessary for compliance with this order. Any records of the MRO, including drug test results, may be released to any management official for purposes of auditing the activities of the MRO, except that the disclosure of the results of any audit may not include personal identifying information on any employee.

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

1. To the MRO.

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

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

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

For purposes of this Section, "management official" includes any management, government, security, or personnel official whose duties necessitate review of the test results in order to process adverse personnel action against the employee.

Test results, with all identifying information removed, shall also be made available to [**Agency/Department**] personnel, including the DPC, for data collection and other activities necessary to comply with Section 503(f) of the Act.

B. Employee Access to Records

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

1. Such employee's drug test.

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

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

C. Confidentiality of Records in General

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

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

D. Employee Assistance Program Records

The EAP Administrator shall maintain only those records necessary to comply with this order. After [**an operating unit head**] refers an employee to an EAP, the EAP will maintain all records necessary to carry out its duties. All medical and or rehabilitation records concerning the employee's drug misuse, including EAP records of the identity, diagnosis, prognosis, or treatment are confidential and may be disclosed only as authorized by 42 CFR Part 2, including the provision of written consent by the employee. With written consent, the patient may authorize the disclosure of those records to the patient's employer for verification of treatment or for a general evaluation of treatment progress.

E. Maintenance of Records

The [**Agency/Department**] shall establish or amend a recordkeeping system to maintain the records of the [**Agency/Department's**] Drug-Free Workplace Program consistent with the [**Agency/Department's**] Privacy Act System of Records and with

all applicable Federal laws, rules and regulations regarding confidentiality of records including the Privacy Act (5 U.S.C. §552a). If necessary, records may be maintained as required by subsequent administrative or judicial proceedings, or at the discretion of the [**Agency/Department head**]. The recordkeeping system should capture sufficient documents to meet the operational and statistical needs of this order, and include:

1. Notices of verified positive test results referred by the MRO.

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

3. Anonymous statistical reports.

4. Other documents the DPC, MRO, or EAP Administrator deems necessary for efficient compliance with this order.

F. Records Maintained by Government Contractors

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

G. Statistical Information

The DPC shall collect and compile anonymous statistical data for reporting the number of:

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

2. Verified positive test results.

3. Voluntary drug counseling referrals.

4. Involuntary drug counseling referrals.

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

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

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

8. Employees who successfully complete EAP.

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

XV. Position Titles Designated for Random Testing

[**List position titles designated for random drug testing; indicate relevant duties; explain the justification for inclusion; and provide the current number of incumbents in the position. State the rate at which random tests will be administered.**]

APPENDIX A

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Title 3–The President

Executive Order 12564 of September 15, 1986

Drug-Free Federal Workplace

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

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

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

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

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

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

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

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

The use of illegal drugs, on or off duty, by Federal employees in certain positions evidences less than the complete reliability, stability, and good judgment that is consistent with access to sensitive information and creates the possibility of coercion, influence, and irresponsible action under pressure that may pose a serious risk to national security, the public safety, and the effective enforcement of the law; and Federal employees who use illegal drugs must themselves be primarily responsible for changing their behavior and, if necessary, begin the process of rehabilitating themselves.

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

Section 1. Drug-Free Workplace.

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

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

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

Section 2. Agency Responsibilities.

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

(b) Each agency plan shall include:

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

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

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

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

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

Section 3. Drug Testing Programs.

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

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

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

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

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

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

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

Section 4. Drug Testing Procedures.

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

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

(c) Drug testing programs shall contain procedures for timely submission of requests for retention of records and specimens; procedures for retesting; and procedures, consistent with applicable law, to protect the confidentiality of test results and related medical and rehabilitation records. Procedures for providing urine specimens must allow individual privacy, unless the agency has reason to believe that a particular individual may alter or substitute the specimen to be provided.

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

Section 5. Personnel Actions.

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

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

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

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

(3) Thereafter refrains from using illegal drugs.

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

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

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

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

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

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

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

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

Section 6. Coordination of Agency Programs.

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

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

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

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

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

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

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

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

Section 7. Definitions.

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

(b) For purposes of this Order, the term "agency" means an Executive agency, as defined in 5 U.S.C. 105; the Uniformed Services, as defined in 5 U.S.C. 2101 (3) (but excluding the armed forces as defined by 5 U.S.C. 2101(2)); or any other employing unit or authority of the Federal government, except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches.

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

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

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

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

(3) Individuals serving under Presidential appointments;

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

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

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

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

Section 8. Effective Date. This Order is effective immediately.

Ronald Reagan

THE WHITE HOUSE, September 15, 1986.

[FR Doc. 86-21168
Filed 9-15-86: 3:47 pm] Billing code 3195-O1-M

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

APPENDIX B

101 STAT. 468
PUBLIC LAW 100-71–July 11, 1987

TITLE 5
GENERAL PROVISIONS

Regulations	Applicable Sections
Drugs and drug abuse. Government organization and employees. 5 USC 7301 note. 3 CFR, 1986 Comp., p. 224.	Sec. 501. No part of any appropriation contained in this Act shall remain available for obligation beyond the current fiscal year unless expressly so provided herein. Sec. 502. Except where specifically increased or decreased elsewhere in this Act, the restrictions contained within appropriations, or provisions affecting appropriations or other funds, available during fiscal year 1987, limiting the amount which may be expended for personal services, or for purposes involving personal services, or amounts which may be transferred between appropriations or authorizations available for or involving such services, are hereby increased to the extent necessary to meet increased pay costs authorized by or pursuant to law. Sec. 503. (a)(1) Except as provided in subsection (b) or (c), none of the funds appropriated or made available by this Act, or any other Act, with respect to any fiscal year, shall be available to administer or implement any drug testing pursuant to Executive Order Numbered 12564 (dated September 15, 1986), or any subsequent order, unless and until-- (A) the Secretary of Health and Human Services certifies in writing to the Committees on Appropriations of the House of Representatives and the Senate, and other appropriate committees of the Congress, that–

Regulations	Applicable Sections
3 CFR, 1986 Comp., p.224.	(i) each agency has developed a plan for achieving a drug-free workplace in accordance with Executive Order Numbered 12564 and applicable provisions of law (including applicable provisions of this section); (ii) the Department of Health and Human Services, in addition to the scientific and technical guidelines dated February 13, 1987, and any subsequent amendments thereto, has, in accordance with paragraph (3), published mandatory guidelines which– (I) establish comprehensive standards for all aspects of laboratory drug testing and laboratory procedures to be applied in carrying out Executive Order Numbered 12564, including standards which require the use of the best available technology for enduring the full reliability and accuracy of drug tests and strict procedures governing the chain of custody of specimens collected for drug testing; (II) specify the drugs for which Federal employees may be tested; and (III) establish appropriate standards and procedures for periodic review of laboratories and criteria for certification and revocation of certification of laboratories to perform drug testing in carrying out Executive Order Numbered 12564; and (iii) all agency drug-testing programs and plans established pursuant to Executive Order Numbered 12564 comply with applicable provisions of law, including applicable provisions of the Rehabilitation Act of 1973 (29 U.S.C. 701 et seq.), title 5 of the United States Code, and the mandatory guidelines under clause (ii); (B) the Secretary of Health and Human Services has submitted to the Congress, in writing, a detailed, agency-by-agency analysis relating to– (i) the criteria and procedures to be applied in designating employees or positions for drug testing, including the justification for such criteria and procedures; (ii) the position titles designated for random drug testing; and (iii) the nature, frequency, and type of drug testing proposed to be instituted; and (C) the Director of the Office of Management and Budget has submitted in writing to the Committees on Appropriations of the House of Representatives and the Senate a detailed, agency-by-agency analysis (as of the time of certification under subparagraph (A)) of the anticipated annual costs associated with carrying out Executive Order Numbered 12564 and all other requirements under this section during the 5-year period beginning on the date of the enactment of this Act. (2) Notwithstanding subsection (g), for purposes of this subsection, the term "agency" means– (A) the Executive Office of the President; (B) an Executive department under section 101 of title 5, United States Code; (C) the Environmental Protection Agency; (D) the General Services Administration; (E) the National Aeronautics and Space Administration; (F) the Office of Personnel Management; (G) the Small Business Administration; (H) the United States Information Agency; and (I) the Veteran's Administration; except that such term does not include the Department of Transportation or any other entity (or component thereof) covered by subsection (b).

Regulations	C
Federal Register, publication. 5 USC 500 et seq.	(3) Notwithstanding any provision of chapter 5 of title 5, United States Code, the mandatory guidelines to be published pursuant to subsection (a)(l)(A)(ii) shall be published and made effective exclusively according to the provisions of this paragraph. Notice of the mandatory guidelines proposed by the Secretary of Health and Human Services shall be published in the Federal Register, and interested persons shall be given not less than 60 days to submit written comments on the proposed mandatory guidelines. Following review and consideration of written comments, final mandatory guidelines shall be published in the Federal Register and shall become effective upon publication. (b)(1) Nothing in subsection (a) shall limit or otherwise affect the availability of funds for drug testing by– (A) the Department of Transportation; (B) Department of Energy, for employees specifically involved in the handling of nuclear weapons or nuclear materials; (C) any agency with an agency-wide drug-testing program in existence as of September 15.1986; or (D) any component of an agency if such component had a drug-testing program in existence as of September 15, 1986. (2) The Departments of Transportation and Energy and any agency or component thereof with a drug-testing program in existence as of September 15, 1986– (A) shall be brought into full compliance with Executive Order Numbered 12564 no later than the end of the 6-month period beginning on the date of the enactment of this Act; and
3 CFR, 1986 Comp., p. 224.	(B) shall take such actions as may be necessary to ensure that their respective drug-testing programs or plans are brought into full compliance with the mandatory guidelines published under subsection (a)(1)(A)(ii) no later than 90 days after such mandatory guidelines take effect, except that any judicial challenge that affects such guidelines should not affect drug-testing programs or plans subject to this paragraph. (c) In the case of an agency (or component thereof) other than an agency as defined by subsection (a)(2) or an agency (or component thereof) covered by subsection (b), none of the funds appropriated or made available by this Act, or any other Act, with respect to any fiscal year, shall be available to administer or implement any drug testing pursuant to Executive Order Numbered 12564, or any subsequent order, unless and until– (1) the Secretary of Health and Human Services provides written certification with respect to that agency (or component) in accordance with clauses (i) and (iii) of subsection (a)(1)(A); (2) the Secretary of Health and Human Services has submitted a written, detailed analysis with respect to that agency (or component) in accordance with subsection (a)(1)(B); and (3) the Director of the Office of Management and Budget has submitted a written, detailed analysis with respect to that agency (or component) in accordance with subsection (a)(1)(C). (d) Any Federal employee who is the subject of a drug test under any program or plan shall, upon written request, have access to– (1) any records relating to such employee's drug test; and (2) any records relating to the results of any relevant certification, review, or revocation-of-certification proceedings, as referred to in subsection (a)(1)(A)(ii)(III).

Regulations	Applicable Sections
Classified information.	(e) The results of a drug test of a Federal employee may not be disclosed without the prior written consent of such employee, unless the disclosure would be– (1) to the employee's medical review official (as defined in the scientific and technical guidelines referred to in subsection (a)(l)(A)(ii)); (2) to the administrator of any Employee Assistance Program in which the employee is receiving counseling or treatment or is otherwise participating; (3) to any supervisory or management official within the employee's agency having authority to take the adverse personnel action against such employee; or (4) pursuant to the order of a court of competent jurisdiction where required by the United States Government to defend against any challenge against any adverse personnel action.
Reports. 3 CFR, 1986 Comp., p. 224.	(f) Each agency covered by Executive Order Numbered 12564 shall submit to the Committees on Appropriations of the House of Representatives and the Senate, and other appropriate committees of the Congress, an annual report relating to drug-testing activities conducted by such agency pursuant to such executive order. Each such annual report shall be submitted at the time of the President's budget submission to the Congress under section 1105(a) of title 31, United States Code. (g) For purposes of this section, the terms "agency" and "Employee Assistance Program" each has the meaning given such term under section 7(b) of Executive Order Numbered 12564, as in effect on September 15, 1986. Sec. 504. None of the funds appropriated by this Act may be obligated for the centralization, consolidation, or redeployment of the Customs Service Air Operations unless the Secretary of the Treasury submits a report to the Committees on Appropriations which sets forth specific details for the use of such funds thirty days in advance of such implementation.
Vessels.	Sec. 505. None of the funds appropriated or made available by this or any other Act or otherwise appropriated or made available to the Secretary of Transportation or the Maritime Administrator for purposes of administering the Merchant Marine Act, 1936, as amended (46 U.S.C. 1101 et seq.), shall be used by the United States Department of Transportation or the United States Maritime Administration to propose, promulgate, or implement any rule or regulation, or, with regard to vessels which repaid subsidy pursuant to the rule promulgated by the Secretary May 3, 1985 and vacated by Order of the U.S. Court of Appeals for the D.C. Circuit January 16, 1987, conduct any adjudicatory or other regulatory proceeding, execute or perform any contract, or participate in any judicial action with respect to the repayment of construction differential subsidy for the permanent release of vessels from the restrictions in section 506 of the Merchant Marine Act, 1936, as amended: Provided,
46 USC 1156.	That such funds may be used to the extent such expenditure relates to a rule which conforms to statutory standards hereafter enacted by Congress. Sec. 506. Notwithstanding any other provision of this Act, appropriations made by the title I of this Act for the following account shall be as follows:

APPENDIX C

Guidance for Selection of Testing Designated Positions

Substance Abuse and Mental Health Services Administration
SAMHSA
5600 Fishers Lane • Rockville, MD 20857
www.samhsa.gov • 1-877-SAMHSA-7 (1-877-726-4727)

DATE: May 6, 2013
TO: Federal Executive Branch Agencies
FROM: Interagency Coordinating Group Executive Committee
SUBJECT: Updated Guidelines for Selection of Testing Designated Positions

2013 Guidance for Selection of Testing Designated Positions (TDPs)

I. Purpose

Effective immediately, this guidance supersedes, but does not fundamentally change, the previous Testing Designated Position (TDP) guidance initially issued on August 2, 1999 and updated on April 5, 2010. This guidance document will serve as the primary agency reference for selecting and/or reviewing positions designated for random testing under the Federal Drug- Free Workplace Program established pursuant to Executive Order No. 12564.

A. Selection Categories

Note: ***Agency requests for categorical inclusions of TDPs will not be considered. TDP submissions must provide specific position title(s)/classification(s)/justifications which includes a concurrence memo from their agency OGC.***

The 1999 guidance consolidated the results of court decisions and established specific categories of TDPs. In January 2010, the Department of Justice reviewed legal activity since the issuance of the 1999 guidance and concluded that there were no decisions altering the following TDP categories:

- **Presumptive Positions:** Must be included in all plans. Agencies desiring to ***exclude*** any of these positions must submit a written justification for doing so. Exclusions require the prior written approval of the Interagency Coordination Group Executive Committee (ICGEC).
- **Preferred Positions:** Should, but may not be included in all plans. Agencies desiring to ***exclude*** any of positions must provide a clear justification for doing so.
- **Discretionary Positions:** Agency specific. Agencies desiring to ***include*** such positions must present a clear justification for doing so, including a detailed description/statement of the immediate risks posed by incumbents using illegal drugs.
- **Disfavored Positions:** May not be included in any plan.

B. Review Process

The 1999 TDP Guidance established the role of the Office of National Drug Control Policy in assuring appropriate consistency among the Executive Branch agencies implementing Executive Order 12564 and to convene the Interagency Coordinating Group Executive Committee (consisting of representatives of the Office of National Drug Control Policy, Department of Health and Human Services, Department of Justice and Office of Personnel Management) to provide concurrence reviews on agencies seeking to implementing substantive changes in their agency plans or TDP lists. These roles and processes remain in place.

Agencies are encouraged to seek informal, preliminary consultation on proposed substantive changes and submit their draft proposals to: The ICG Executive Committee, c/o Hyden S. Shen, Esq., Policy Oversight Lead, Federal Drug Free Workplace Program, Department of Health and Human Services, Substance Abuse and Mental Health Services Administration (SAMHSA), Division of Workplace Programs, 5600 Fishers Lane, Rockville, Maryland, 20857[1]. Telephone: (240) 276-2600. E-Mail: Hyden.Shen@samhsa.hhs.gov

Agency proposals should consist of the following information:

- A detailed statement describing the change(s) sought in the plan and the proposed language.
- Job descriptions or a summary of the duties performed by positions proposed for inclusion in the random testing pool.
- Justification for inclusion of each position (In some cases, group justifications may suffice for positions that share common duties and fall under the same TDP category.)
- **Supporting opinion from agency General Counsel**

II. The Legal Framework

Based upon the prior agency program litigation, the courts have been able to establish "limits" on the TDP justifications for the presumptive, preferred, discretionary and disfavored positions noted below. However, given unique agency missions, a substantial gray area continues to exist within the TDP categories.

Agencies are advised to seek agency counsel review prior to proposing changes or additions to their TDP lists. The most significant and instructive cases in this field continues to be the early pronouncements within United States Supreme Court in *Skinner v. Railway Labor Executives' Assn.*, 489 U.S. 602 (1989), and *National Treasury Employees Union v. Von Raab*, 489 U.S. 656 (1989). Additionally, the Supreme Court has upheld the constitutionality of drug testing programs in other contexts, such as interscholastic athletics. See *Vernonia School District 47J v. Acton, 515 U.S. 646 (1995)* and "students in

[1] SAMHSA Address Updated: January 2017

competitive extra-curricula activities," *Board of Education Independent School District No. 92 of Pottawatomie County v. Earls, 536 U.S. 822 (2002).*

A. Presumptive Testing Designated Positions

In light of the well established case law and clear public interest in testing certain categories of positions, the positions set forth below have been approved for inclusion in agency testing plans without the prior approval of the ICG Executive Committee. In order to improve consistency, it is essential that individual agencies include all positions in these categories in their plans, unless a clear and compelling reason can be provided for not doing so. Indeed, almost all agencies already test these positions.

Since courts have consistently found that testing of these safety-sensitive positions is justified, agencies need not submit for consultative review, their plan to include these positions as TDPs. However, an information copy of implemented changes should be forwarded to the ICG Executive Committee. If an agency head is of the opinion, that unique agency circumstances warrant the exclusion of all or some of the positions in these categories, these circumstances should be presented in writing to the ICG Executive Committee for consultative review. The positions that **must** be included in your agency plan are as follows:

1. Employees Who Carry Firearms

NTEU v. Von Raab, 489 U.S. 656, 109 S. Ct. 1384, 1393-94 (1989). This category was narrowed from "employees authorized to carry firearms" in order to distinguish various investigators and guards who do not carry a firearm on a daily basis, but are merely authorized to carry firearms. Employees in the latter category should be placed in the appropriate preferred TDP category. However, employees who actually carry firearms on a daily or regular basis are included in this presumptive category and should be included.

2. Motor Vehicle Operators Carrying Passengers

NTEU v. Yeutter, 918 F.2d 968, 972 (D.C. Cir. 1990). *AFGE v. Skinner,* 885 F.2d 884, 889 n.8 (D.C. Cir. 1989), *cert. denied*, 495 U.S. 923 (1990). This category also includes operators of motor vehicles weighing more than 26,001 pounds and operators of motor vehicles transporting hazardous materials. *Intern. Broth. of Teamsters v. Department of Transportation*, 932 F.2d 1292 (9th Cir. 1991). Note: Department of Transportation regulations implementing the Omnibus Transportation Employee Testing Act of 1991 require random testing for drugs and alcohol of Federal employees who operate vehicles that require a commercial driver's license. A commercial license is required for vehicle operators who: (1) carry 16 or more passengers, (2) transport hazardous materials, or (3) operate vehicles weighing 26,001 pounds or more.

3. Aviation Flight Crew Members and Air Traffic Controllers

Bluestein v. Skinner, 908 F.2d 451 (9th Cir. 1990). *AFGE v. Skinner,* 885 F.2d at 889 n.8.

4. Railroad Operating Crews

Skinner v. RLEA, 489 U.S. 602, 109 S. Ct. 1402 (1989). *RLEA v. Skinner,* 934 F.2d 1096 (9th Cir. 1991). *AFGE v. Skinner,* 885 F.2d at 889 n.8.

B. Preferred Testing Designated Positions

The well established law and clear public interest applicable to drug testing make it evident that the categories set out under this section represents strong government interests for drug testing and should almost always need established judicial standards. However, inclusion of the following positions as TDPs is not presumptive. To ensure reasonable uniformity, agencies will be required to present for ICGEC consultative review, agency-specific justifications for testing these positions. Agencies choosing to exclude one or more positions as a TDP will be required to justify their decision to the ICG Executive Committee.

1. Certain Health and Safety Positions

The first major category includes certain health and safety responsibilities that could cause immediate, substantial physical injury if carried out under the influence of drugs, usually involving a potentially dangerous instrument or machine. These positions are:

a. Employees authorized to carry firearms

NTEU v. Von Raab, 489 U.S. 656, 109 S. Ct. 1384, 1393-94 (1989). This category was changed from "employees having access to firearms". In many cases, there are guards or security personnel who do not regularly carry a firearm, but are authorized to carry one in some circumstances, e.g. emergencies. The rationale for including these positions as TDPs is the same as employees with a security clearance who see classified documents only rarely--granting security clearances in advance proved flexibility and ensures employees can be given access to classified material as soon as the need arises. See *Harmon v. Thornburgh*, 878 F.2d 484, 492 (D.C. Cir. 1989), *cert. denied*, 493 U.S. 1056 (1990).

b. Railroad Employees Engaged in Safety Sensitive Tasks

This includes persons engaged in handling train movement orders, safety inspectors and those engaged in maintenance and repair of signal systems. *Skinner v. RLEA,* 489 U.S. 602, 109 S. Ct. 1402 (1989). *RLEA v. Skinner,* 934 F.2d 1096 (9th Cir. 1991). *AFGE v. Skinner,* 885 F.2d at 889 n.8.

c. Aviation Personnel

This includes flight attendants, flight instructors, ground instructors, flight testing personnel, aircraft dispatchers, maintenance personnel, aviation security and screening personnel, and aircraft safety inspectors. Bluestein v. Skinner, 908 F.2d 451 (9th Cir. 1990). *AFGE v. Skinner,* 885 F.2d at 889 n.8. In 1992, two federal district courts in California considered challenges to Air Force and Navy TDPs respectively. In *AFGE v. Wilson,* 5-89-1274 (E.D.

Cal. Aug. 17, 1992), the Air Force had included an employee who made tools used by aircraft mechanics to maintain and repair their aircraft. The court held that the danger of a defective tool causing a crash was too remote to support random testing. Only Air Force employees with direct aircraft maintenance responsibilities were approved for random testing. In *AFGE v. Cheney,* C-89-4443 (N.D. Cal. Aug. 14, 1992) a different court considered several categories of employees who performed maintenance on Navy ships, submarines and planes. Those approved as TDPs were able to show a nexus between the work performed and a "compelling government interest in safety," such that small errors or momentary lapses in judgment could have "catastrophic consequences for crew members". This care highlights the principle that agencies may randomly test employees with direct and critical responsibilities for maintenance, but not those in general support roles.

2. Presidential Appointees Requiring Senate Confirmation (PAS)

The second major preferred category involves presidential appointees requiring Senate confirmation (PAS). While including PAS positions as TDPs is strongly preferred, an agency head may determine that it is impractical for part-time presidential appointees who sit on commissions or boards which meet only three or four times to be included in the TDP. In this instance, the PAS may potentially qualify for an exclusion.

3. Front Line Law Enforcement Personnel

The third major preferred category is front line law enforcement personnel with close proximity to criminals, drugs, or drug traffickers. These positions include guards and law enforcement personnel who have access to firearms (but do not carry weapons or otherwise meet the standards for a presumptive TDP) and those directly involved in drug interdiction duties. *Von Raab,* 109 S. Ct. at 1393-94; *Guiney v. Roache,* 873 F.2d 1557 (1st Cir.), *cert. denied,* 110 S. Ct. 404 (1989).

4. Drug Rehabilitation Employees

The fourth major preferred category is drug rehabilitation or equivalent employee assistance duties that are so inimical to illegal drug use that such employees can expect inquiries into their fitness. These positions include direct service staff of alcohol and drug abuse treatment centers. *NFFE v. Cheney,* 884 F.2d 603, 614 (D.C. Cir. 1989), *cert. denied,* 493 U.S. 1056 (1990). Although, some agencies believed that all employees associated with the drug program should be included in the random testing pool, the courts have taken a narrower view. In *NFFE v. Cheney,* the court approved drug counselors with direct client contact as TDPs; however, it refused to approve either drug laboratory testing personnel or to those employees in the biochemical chain of custody. Regarding the latter two categories, the court found an insufficient nexus between a drug-related lapse and any irreparable harm. Based on the holdings of this case, only drug program employees who have direct client contact should be included as TDPs. NOTE: Unless, supervisors of drug counselors meet this test, they should not be included as

TDPs. Additionally, computer employees who help select personnel for random tests do not qualify as TDPs. The court was not persuaded that the "credibility" or "integrity" of the drug testing program justified random testing for every employee associated with drug testing.

5. Personnel Having Access to "Truly Sensitive Information"

The fifth major preferred category is personnel having access to "truly sensitive information". For example, individuals with access to national security material that a "reasonable person" would consider damaging to national interests if compromised. *Von Raab,* 109 S. Ct. at 1396. Specifically, these positions include:

a. Top Secret and Higher Clearances

Harmon v. Thornburgh, 878 F.2d 484, 492 (D.C. Cir. 1989), *cert. denied,* 110 S. Ct. 865 (1990). *AFGE Local1533 v. Cheney,* No. 90-15834 (9th Cir. Sept. 11, 1991)

b. Secret Clearances

Hartness v. Bush, 919 F.2d 170, 173 (D.C. Cir. 1990), *cert. denied,* 59 USLW 3865 (U.S. 1991).

C. Discretionary Designations

In addition to the categories of positions identified for presumptive and preferred inclusion in agency plans, there are other agency specific sensitive positions which may warrant designation for testing. The presumptive and preferred testing categories are not exhaustive of TDPs supported by case law. For example, courts have supported testing for: confidential security clearances holders, *NTEU V. Hallet,* No. 86-3522 (E.D. LA. Feb 7, 1991); health care professionals responsible for direct patient care, and firefighters, AFGE *v. Derwinski,* 777 F. Supp. 1493 (N.D. Cal. 1991). Other federal district courts also have upheld random testing for medical doctors (except for doctors performing research or administrative duties), nurses, nursing assistants, pharmacists, and medical technicians because they were involved in direct patient care.

Given the unique agency missions, there are a number of other, non-court tested TDPs that may be appropriate for inclusion within agency plans. To the extent that agencies have identified potential TDP positions, they will be required to submit Appendix A of its plan with supporting documentation to the ICG Executive Committee for consultative review. The agency's plan must contain a statement indicating a clear nexus between the employee's duties and the feared harm to others for each TDP.

D. Specifically Disfavored Testing Designated Positions

It is possible to identify positions which uniformly have been found by the courts not to warrant *random* testing. If an agency has TDPs based solely on the criteria below, exceptional justifications will be required to be submitted to the ICG Executive Committee for consultative review. These positions are:

1. Positions designated based upon the need to foster public trust or generalized requirements for integrity, honesty, or responsibility. *NTEU v. Yeutter, 918 F.2d 968, 972 (D.C. Cir. 1990)* and *Chandler v. Miller, 502 U.S. 305 (1997)* in which random testing cannot be utilized merely for "symbolic" testing. The Chandler case involved candidates for public office.

2. Positions designated based upon access to sensitive information not meeting the "truly sensitive" criteria, e.g. personnel files, budget and financial information, and grand jury information also is inadequate. *Harmon v. Thornburgh,* 878 F.2d 484, 492 (D.C. Cir. 1989), *cert. denied,* 110 S. Ct. 865 (1990). Many questions were raised about including inspector general employees because of their access to sensitive information and budget or financial employees because of their influence on large sums of money. Under current case law, neither group qualifies as a TDP. The rationale for excluding inspector general employees is contained in the *Harmon case.* In *Harmon,* the court approved employees with top secret clearances as TDPs because of their access to "truly sensitive" information, but it refused to approve as TDPs federal prosecutors or employees with access to secret grand jury proceedings. The court stated that "truly sensitive" does not include all information which is confidential or closed to public view. The rationale for excluding budget and financial employees is found in *AFGE v. Carazoes,* 721 F. Supp. 1361 (D.D.C. 1989), where the court refused to approve as TDPs a group of computer employees involved with billions of dollars of government resources who might be subjected to bribery, fraud, waste or mismanagement. The court concluded that program information which affects large sums of money does not necessarily mean the information is "truly sensitive". The clearest examples of "truly sensitive" remain information requiring a top secret clearance, where by definition, national security would be seriously damaged by an unauthorized disclosure.

APPENDIX D

Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine [UrMG]

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 (SAMHSA), HHS.

ACTION: Revised Mandatory Guidelines by the Secretary of Health and Human Services.

SUMMARY: The Department of Health and Human Services (''HHS'' or ''Department'') has revised the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines), 73 FR 71858 (November 25, 2008) for urine testing.

DATES: *Effective Date:* October 1, 2017.

FOR FURTHER INFORMATION CONTACT: Charles LoDico, M.S., F–ABFT, Division of Workplace Programs, Center for Substance Abuse Prevention (CSAP), SAMHSA mail to: 5600 Fishers Lane, Room 16N03A, Rockville, MD 20857, telephone (240) 276–2600 or email at *charles.lodico@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: In particular, these revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) allow federal executive branch agencies to test for additional Schedule II drugs of the Controlled Substances Act (*i.e.,* oxycodone, oxymorphone, hydrocodone and hydromorphone) in federal drug-free workplace programs, remove methylenedioxyethylamphetamine (MDEA) from the authorized drugs in Section 3.4, add methylenedioxyamphetamine (MDA) as an initial test analyte, raise the lower pH cutoff from 3 to 4 for identifying specimens as adulterated, require MRO requalification training and re-examination at least every five years after initial MRO certification, and allow federal agencies to authorize collection of an alternate specimen (*e.g.,* oral fluid) when a donor in their program is unable to provide a sufficient amount of urine specimen at the collection site. Many of the wording changes and reorganization of the UrMG were made for clarity, to use current scientific terminology or preferred grammar, and for consistency with the OFMG.

Background

The Department of Health and Human Services (HHS), by the authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order No. 12564, has established the scientific and technical guidelines for federal workplace drug testing programs and established standards for certification of laboratories engaged in urine drug testing for federal agencies. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** [FR] on April 11, 1988 [53 FR 11979]. The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008; [73 FR 75122]). The effective date of the Guidelines was further changed to October 1, 2010 on April 30, 2010 [75 FR 22809].

The proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) published in the **Federal Register** on May 15, 2015 (80 FR 28101) include revisions to the initial and confirmatory drug test analytes and methods for urine testing, the cutoff for reporting a urine specimen as adulterated based on low pH, and the requalification requirements for individuals serving as Medical Review Officers (MROs) and, where appropriate, include references to the use of an alternate specimen in federal workplace drug testing programs. References to an alternate specimen are not applicable until final Guidelines are implemented for the use of the alternative specimen matrix. The Department published a separate Notice in the May 15, 2015 **Federal Register** (80 FR 28054) proposing Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) to allow federal agencies to collect and test oral fluid specimens in their workplace drug testing programs. There was a 60-day public comment period for both **Federal Register** Notices, during which 125 commenters submitted comments on the proposed changes to the Guidelines. These commenters were comprised of individuals, organizations, and private sector companies. The comments are available for public view at *http://www.regulations.gov/.* All comments were reviewed and taken into consideration in the preparation of the revised Guidelines. The issues and concerns raised in the public comments for the UrMG are set out below. Similar comments are considered together in the discussion.

Summary of Public Comments and HHS's Response

The following comments were directed to the information and questions in the preamble.

Costs and Benefits

The Department requested comments on costs and benefits. One commenter disagreed that the cost increase for laboratories to add analytes to regulated testing will be minimal, stating that significant costs would be incurred for information technology (IT) development, as well as incremental costs for additional immunoassays (if required); for additional calibrators, controls, and internal standards; and for increased confirmatory testing costs (including data review and result certification) based on an expected increased positivity rate for opioids. One commenter disagreed with the Department's estimated 3% cost increase for Medical Review Officers (MROs) and estimated that the increase will be 10%. The commenters did not provide any substantive evidence or data to support these comments. The Department recognizes that there will be start-up costs to laboratories to implement testing for the additional analytes for regulated specimens including administrative costs, and agrees that the estimated increased costs for some MROs may exceed the 3% estimate. The Department's cost analysis was based on information provided by multiple HHS-certified laboratories and MROs, as well as the estimated number of additional positives resulting from the inclusion of the new opioid analytes. Costs are expected to vary among individual laboratories and MROs, depending on their processes and testing populations. Additional information on the estimated costs associated with these Guidelines is included under *Regulatory Impact and Notices* below.

Proposed New Analytes: Oxycodone, Oxymorphone, Hydrocodone, and Hydromorphone

Seven commenters specifically agreed with the addition of these drugs to the Guidelines. Two commenters expressed concerns over the added drugs, indicating that individuals who follow their physician's treatment plan of taking legally prescribed medication would produce positive tests, leading to greater reliance on MROs to determine whether tests are truly positive (as a result of illegal use) or are positive due to prescribed usage of the drugs, and a greater number of workers will be subject to scrutiny and their medical

records examined at length. One of the commenters maintained that such testing would exceed the legal mandate under Executive Order No. 12564 and the promulgation of scientific Guidelines by HHS pursuant to it. The Guidelines include requirements to protect individuals' privacy while maintaining public safety, including procedures for MRO review to verify legitimate drug use and maintain the confidentiality of donor drug testing records. The Department provides additional guidance in the Medical Review Officer Manual for Federal Workplace Drug Testing Programs. The inclusion of these additional drugs in the Guidelines is within the scope of the Department's regulatory authority to test for illegal drug use under Section 503(a)(1)(A)(ii)(II) of Public Law 100–71 and Executive Order No. 12564.

New Analytes—Cutoff Concentrations

Eight commenters addressed the proposed cutoffs for the added drugs: Three commenters agreed with the proposed cutoffs; four disagreed with the cutoffs for one or more of the added drugs. Of these, three commenters stated that the cutoffs are too low: Two of these commenters believe that these cutoffs will unnecessarily identify workers using prescription drugs and one commenter noted that these cutoffs will affect accurate quantitation in routine specimens. The Department recognizes that the added analytes will result in an increased number of positive opioid results requiring MRO review, and has incorporated requirements for MRO requalification and retraining at least every five years. Additional guidance and information on the added drugs will be provided in the Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs. The Department disagrees that the cutoffs will affect accurate quantitation in routine specimens. Information from HHS-certified laboratories indicates that testing at these cutoffs can be accomplished with current instrumentation. However, the Department has raised the confirmatory test cutoffs for oxycodone and oxymorphone from 50 ng/mL to 100 ng/mL. These higher cutoffs are supported by a single dose study which showed similar detection rates for oxycodone and oxymorphone using either a 50 ng/mL or 100 ng/mL cutoff.[1] Use of the 100 ng/mL confirmatory test cutoffs is expected to be less analytically challenging for laboratories.

One commenter suggested changing the oxycodone and oxymorphone initial test cutoff to 300 ng/mL and changing the hydrocodone and hydromorphone initial test cutoff to 100 ng/mL, to equate the detection times for these drugs. One commenter requested that the Department provide the justification and data used to determine the cutoff levels for the added opioids. The Department raised the oxycodone and oxymorphone confirmatory test cutoffs to 100 ng/mL as described above. The Department has evaluated the comments and has concluded that no further change is needed. The selection of cutoff concentration is not based solely on the factor of detection times and must take into consideration a variety of factors, both pharmacological and chemical. Drug potency, disposition in urine, impact and prevalence must be considered. For example, oxycodone is approximately twice as potent as hydrocodone and may be prescribed in lower doses, thus a cutoff lower than that for hydrocodone is warranted. Therefore, in selecting the cutoffs, the Department considered the detection times of equipotent doses as well as dispositional patterns of each drug in urine. Data on the disposition of hydrocodone and oxycodone in urine following administration of a single dose can be found in two recently published scientific articles.[1 2]

Medical Review Officer (MRO) Requalification—Continuing Education Units (CEUs)

The Department requested comments on requiring MRO requalification continuing education units (CEUs) and on the optimum number of credits and the appropriate CEU accreditation bodies should CEUs be required as part of MRO requalification. Three commenters agreed with requiring MRO recertification, but disagreed with the addition of CEU requirements to the Guidelines. Two commenters disagreed with specifying the number of CEUs required. Two commenters indicated that certification entities already enforce training requirements and recommended that acceptance of CEUs be handled by MRO certification boards, not the Department. Two commenters recommended a requirement of annual CEUs: One suggested 16 CEUs and the other recommended three CEUs. One commenter recommended 12 CEUs prior to initial certification, eight CEUs every five years, and also recommended two CEUs related to the new requirements/topics within two years of implementation of the revised Guidelines. The Department has evaluated the comments and has concluded that requirements for continuing education units will remain with the MRO certification entities and will not be included in the Guidelines. The Department has removed references to MRO training entities in Sections 13.2 and 13.3, because training documentation is maintained by MRO certification entities. The Department agrees with the comment that MROs should receive training on revisions to the Guidelines, and has added item Section 13.3(b) to require such training prior to the effective date of revised Guidelines.

Discussion of Sections

The Department has not included a discussion in the preamble of any sections for which public comments were not submitted or where minor typographical or grammatical changes were made.

Subpart A—Applicability

1.5 What do the terms used in these Guidelines mean?

One commenter disagreed with the definition for ''dilute specimen'' because it does not include numerical values for creatinine and specific gravity. The Department has concluded that no change is needed; the analytical (numerical) criteria for a dilute specimen are provided in Section 3.8.

One commenter requested that ''external service provider'' be defined, because this is a new term included in the proposed Guidelines. The Department agrees and has added the definition.

The Department has added the definition for ''gender identity'' to Section 1.5. This term is now used in Guidelines sections addressing observed and monitored collections as described in this preamble under Sections 4.4, 8.1, 8.10, and 8.12. Gender identity means an individual's internal sense of being male or female, which may be different from an individual's sex assigned at birth.

Two commenters disagreed with the proposed definition for ''invalid result'' which indicated that an invalid result was reported only when an HHS-certified laboratory could not complete testing or obtain a valid drug test result. The Department agrees with the commenters and has reinstituted the definition from the Guidelines effective October 1, 2010 (73 FR 71858).

To address comments described in this preamble under Section 13.1, the Department deleted the definition for ''non-medical use of a drug.''

Two commenters found the definition of ''specimen'' confusing, because the term ''sample'' used in the definition was also defined as a representative portion of a donor's specimen. The

Department agrees, and has reinstituted some wording for the definition of ''specimen'' from the Guidelines effective October 1, 2010 (73 FR 71858) for clarity.

1.6 What is an agency required to do to protect employee records?

One commenter suggested that the non-applicability of the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) should be clearly stated in the Guidelines. The Department has evaluated the comment and has concluded that the applicability of HIPAA and other relevant privacy laws is clearly stated in Section 1.6. Accordingly, except for minor rewording for clarity, no further revisions are necessary.

1.7 What is a refusal to take a federally regulated drug test?

One commenter noted that, per Sections 8.4(c) and 8.9(b), when a collector finds an adulterant or substitution product or observes an attempt to substitute a urine specimen, this prompts a direct observed collection, not a refusal to test. The commenter suggested bringing an adulterant or a substitution product to the collection should be a refusal to test. The Department has evaluated the comment, and agrees that the collector must report a refusal to test when a donor brings materials for adulterating, substituting, or diluting the specimen to the collection site, or when the collector observes a donor's clear attempt to tamper with a specimen. The Department has revised Sections 1.7, 8.3(h), 8.4(c), and 8.9(b) accordingly.

One commenter noted that the collector does not report a refusal to test when a donor leaves the collection site before the collection process begins for a pre-employment test. The commenter recommended defining the beginning of the pre-employment test collection process as the point at which the donor is asked to present photo identification. The Department agrees with the suggestion to define the beginning of the collection process specifically for this situation. However, the Department has designated the beginning as the step described in Section 8.4(a), when the collector provides or the donor selects a specimen collection container. The Department has revised Sections 1.7(a)(2) and (3) to include a reference to this section. All subsequent items in Section 1.7(a) (*i.e.,* items 4–13) apply once the donor has arrived for the pre-employment test collection.

1.8 What are the potential consequences for refusing to take a federally regulated drug test?

The Department reworded Section 1.8(b) to clarify that the requirements in this section apply to donors who fail to appear at the collection site in a reasonable time for any test (except a pre-employment test), as described in Section 1.7(a)(1).

Subpart B—Urine Specimens

2.1 What type of specimen may be collected?

Two commenters requested clarification on the collection/testing scenario where the federal agency authorizes collection of an oral fluid specimen, but the contracted laboratory does not perform oral fluid testing. The Department has evaluated the comments and has concluded that no change is needed. This will be addressed in the federal agency plan.

2.2 Under what circumstances may a urine specimen be collected?

One commenter suggested that the cost of mandatory random drug and alcohol testing among airline pilots outweighs the benefit. The Department has evaluated the comment and has concluded that no change is needed. Airline pilots are subject to drug and alcohol testing under DOT regulations. Therefore, this public comment is not relevant to the Guidelines. In regard to drug testing of federal agency employees and applicants, each federal agency establishes its agency plan based on its mission, its employees' duties, and the potential consequences to the public health and safety or national security that could result from the failure of an employee to adequately perform their duties and responsibilities.

Subpart C—Urine Specimen Tests

3.1 Which tests are conducted on a urine specimen?

One commenter suggested changing the term ''opiates'' to ''opioids'' in the Guidelines. The Department agrees with the commenter and has changed the term ''opiates'' to ''opioids'' where appropriate to refer to oxycodone, oxymorphone, hydrocodone, and hydromorphone in addition to codeine, morphine, and 6-acetylmorphine (6-AM).

3.2 May a specimen be tested for additional drugs?

The Department reworded Section 3.2(a) to clarify the additional drug tests that may be performed on federal employee specimens.

3.3 May any of the specimens be used for other purposes?

Section 3.3 states that specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines may not be used for purposes other than drug and validity testing in accordance with Subpart C of the Guidelines. One commenter disagreed with prohibiting employees from using their drug test specimens for other purposes (*e.g.,* deoxyribonucleic acid, DNA, testing). The Department has evaluated this comment and has concluded that no change is needed. While the Guidelines do not authorize the release of urine specimens, or portions thereof, to federal employees, the Guidelines afford employees a variety of protections that ensure the identity, security and integrity of their specimens. For example, see Sections 8.5(b), 8.8, and 15.1(a).

In addition, under Public Law 100–71, Section 503(a)(1)(A)(ii)(I), HHS is mandated to establish ''strict procedures governing the chain of custody of specimens collected for drug testing . . . .'' Sections 11.7(a) and 11.20(a) also provide that an ''HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records,'' and must retain specimens that, among other things, have been reported ''drug positive'' for a minimum of one year. Therefore, the release of specimens to employees, or to an employee's designee, is inconsistent with the mandates of the federal drug testing process, and could significantly compromise a specimen's integrity, security, and an HHS-certified laboratory's ability to fulfill its regulatory duties under the Guidelines.

One commenter requested further clarification of the phrase ''unless authorized in accordance with [applicable] federal law'' in Section 3.3. The phrase ''unless otherwise authorized in accordance with applicable law in Section 3.3(a) does not represent a significant change from the intent of the prior Guidelines language. Section 3.3, among others, is intended to prohibit the use of specimens for purposes other than those specifically authorized by the Guidelines. However, there may be circumstances in which federal law authorizes an HHS-certified laboratory to handle a specimen in a manner that differs from the Guidelines. Therefore, the phrase ''unless authorized in accordance with applicable federal law'' in Section 3.3 of the Guidelines is intended to avoid conflict with other applicable federal law.

It should be noted that Section 3.3 specifically prohibits conducting deoxyribonucleic acid (DNA) testing on urine specimens, unless authorized in accordance with applicable federal law.

3.4 What are the drug test cutoff concentrations for urine?

The Department proposed methylenedioxyamphetamine (MDA) and methylenedioxyethylamphetamine (MDEA) as initial test analytes. Three commenters disagreed with the addition of MDA and MDEA as target analytes, stating this change would require modification of current immunoassay reagents, laboratory processes, or both. The commenters noted that this imposes an unnecessary burden for compounds with such low incidence in workplace testing. The Department has evaluated the comments and has removed MDEA from the Guidelines (*i.e.,* MDEA is no longer included as an authorized drug in Section 3.4). The number of positive MDEA specimens reported by HHS-certified laboratories (*i.e.,* information provided to the Department through the NLCP) does not support testing all specimens for MDEA in federal workplace drug testing programs. Because MDEA is a Schedule I drug, a federal agency may test specimens for MDEA in accordance with Section 3.2 (*i.e.,* on a case-by-case basis for reasonable suspicion or post accident testing, routinely with a waiver from the Secretary). The Department understands that MDA and some other analytes also have a low incidence, but believes that continued testing for these analytes is warranted in a deterrent program. In particular, inclusion of MDA as an initial and confirmatory test analyte is warranted because, in addition to being a drug of abuse, it is a metabolite of MDEA and MDMA.

An HHS-certified laboratory or Instrumented Initial Test Facility (IITF) may group analytes for initial testing. For clarity, the Department has defined the term ''grouped analytes'' where used in footnote 1 of the table in Section 3.4: ''(*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff).''

The Department proposed criteria for immunoassays for grouped analytes such as opioids and amphetamines, specifying the minimum cross-reactivity to the other analyte(s) within the group. Two commenters disagreed with the added cross-reactivity requirements, noting this section should not attempt to provide equivalence between immunoassay and other initial testing technologies. One of these commenters suggested the Department develop separate requirements for initial test methods using an alternate technology or, alternatively, require the combined cross-reactivity of low-reacting compounds (*e.g.,* hydrocodone and hydromorphone for an opiate assay; MDA and MDEA for an amphetamines assay) to be equal to or greater than the cutoff. The other commenter recommended not allowing methods other than immunoassay for urine initial testing. One commenter stated that cross-reactivity specifications for hydromorphone are not necessary, based on their non-regulated testing results (*i.e.,* confirmatory test concentrations detected after using an immunoassay with 60% cross-reactivity for hydromorphone). The Department has evaluated the comments and has concluded that no change is needed for immunoassay cross-reactivity requirements. The requirements in Section 3.4 are necessary to ensure consistency in testing among laboratories using different immunoassay kits, as well as those using different test methods for initial drug testing. Cross-reactivity must be demonstrated and documented by the manufacturer (*e.g.,* package insert) and by the HHS-certified laboratory or IITF (*i.e.,* assay validation studies, reagent lot verification, and batch quality control for any analyte that exhibits less than 100% cross-reactivity). The Department will continue to allow the use of methods other than immunoassay for initial testing.

However, the Department has revised Section 3.4 regarding the use of alternate technology initial tests for THCA and benzoylecgonine. Depending on the technology, the confirmatory test cutoff (*i.e.,* 15 ng/mL for THCA, 100 ng/mL for benzoylecgonine) must be used as the cutoff for an initial test using an alternate technology to ensure consistent treatment of specimens. For these analytes, the immunoassay test is not specific for the target analyte for the confirmatory test. For example, immunoassays for cannabinoids react with multiple compounds that are excreted as a result of marijuana use. Therefore, it is necessary to use an immunoassay cutoff higher than that of the confirmatory test in order to detect the target analyte (THCA) at or above the confirmatory test cutoff. An initial test using an alternate technology with specificity comparable to the confirmatory test requires use of the confirmatory test cutoff.

Also in Section 3.4, the Department did not specify the target analyte to be used to calibrate an initial test for grouped analytes such as amphetamines or opioids. Three commenters noted that when an immunoassay is calibrated with a low-reacting drug, other analytes may exhibit high cross-reactivity, leading to false initial test positives. Two of these commenters also noted that this may result in possibly different cross-reactivity profiles for some structurally unrelated and concomitantly used prescription and/or over the counter drugs. One commenter noted that the option to ''include a control containing the lowest reacting analyte at its cutoff concentration in each batch'' was described in the preamble to the proposed Guidelines, but was not specified in Section 3.4 of the Guidelines. It was not the Department's intent for the laboratory or IITF to calibrate an immunoassay test using an analyte other than that specified by the manufacturer. In the preamble to the proposed UrMG, the Department described using a control containing the lowest reacting analyte at its cutoff concentration to establish the decision point (*i.e.,* when an immunoassay for grouped analytes did not demonstrate at least 80% cross-reactivity to each analyte). The Department has determined that this approach is not necessary, and will not be permitted. There are current immunoassays that meet the requirements of this section for two or more analytes in a group (*i.e.,* analytes in the same drug class that have the same initial test cutoff). As indicated in Section 3.4, the laboratory or IITF may use multiple test kits or a single kit to meet the requirements.

3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

One commenter recommended that HHS maintain a list of allowable additional tests and reporting criteria (*e.g.,* threshold for reporting as positive, adulterated, substituted, and/or invalid, and a limit of detection as appropriate), to ensure consistency among laboratories and within the testing program. The Department has evaluated the comment and has concluded that no change is needed. The Department does not want to limit the analytes that may be tested, and will provide guidance to laboratories as needed. It is also noted that the section requires all tests to meet appropriate validation and quality control requirements. The procedures and specimen records for such tests will be reviewed at NLCP inspections. The Department will continue to maintain a list of HHS-certified laboratories that choose to perform additional tests for regulated specimens.

One commenter asked whether an MRO could submit a blanket request to perform additional testing (*e.g.,* additional opioid metabolites) for all confirmatory specimens (*i.e.,* would laboratories be permitted to monitor the additional compounds in all confirmatory test assays?). The Department believes that testing all specimens for additional analytes may not be appropriate for some tests, especially hydrocodone, hydromorphone, oxycodone and oxymorphone. Recent studies show that testing for norhydrocodone and or noroxycodone is not necessary for the interpretation of all results.[1] [2] Norhydrocodone and noroxycodone metabolites may be helpful for the MRO to interpret test results only when a donor's prescription does not support the test results. For example, a hydrocodone dose may result in urine concentrations of only hydromorphone metabolite above the cutoff. The presence of norhydrocodone metabolite would support the use of hydrocodone and validate the donor's prescription. The same could be said for interpreting test results following an oxycodone dose. The presence of noroxycodone metabolite would support the use of oxycodone when only oxymorphone was reported as positive. The Department will provide guidance on these and other additional tests that may provide useful information for the MRO in the Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs. The Department has revised Section 3.5 to clarify that HHS-certified laboratories are authorized to perform additional tests upon MRO request on a case-by-case basis, but are not authorized to routinely perform such tests without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D,L stereoisomers of amphetamine and methamphetamine. The Department will continue to allow HHS-certified laboratories to test for D,L amphetamine and methamphetamine routinely or upon MRO request. The Department will provide guidance on these and other additional tests that may provide useful information for the MRO (*e.g.,* tetrahydrocannabivarin) in the Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs.

Additional drug and specimen validity testing under Section 3.5 does not include DNA testing.

3.6 What criteria are used to report a urine specimen as adulterated?

Two commenters agreed and one disagreed with raising the lower pH cutoff from 3.0 to 4.0 for identifying specimens as adulterated. One commenter advised caution in changing specimen validity test cutoffs, and indicated that the proposed change will require updates to computer systems for reporting, calibrators, and controls. One commenter indicated that previous review of data (more than 10 years ago) indicated this change would have more than doubled the number of low pH/adulterated results reported. The commenter that disagreed with changing the pH cutoff believes HHS does not have enough scientific evidence supporting the change. The Department has evaluated the comments and has concluded that no change is needed to the proposed cutoff (*i.e.,* 4.0). As stated in the preamble to the proposed Guidelines (80 FR 28101), this decision is based on the fact that the physiologically minimum achievable urine pH that can be produced by the kidneys is about pH 4.5. Furthermore, the Department is not aware of any medical conditions or medications that would cause urine pH to be less than 4.5.

3.8 What criteria are used to report a urine specimen as dilute?

One commenter suggested removing the three-decimal place criteria for reporting a specimen as dilute. One commenter indicated that the criteria for reporting a specimen as dilute in Section 3.8 and 11.19(f) were not consistent, and that Section 3.8 does not address the situation when creatinine is between 5 and 20 mg/dL and the specific gravity is less than 1.0020. This section was intended to clarify that only HHS-certified laboratories (and not HHS-certified IITFs) may report a specimen as dilute when the creatinine concentration is greater than or equal to 2.0 mg/dL and less than or equal to 5 mg/dL, and the laboratory must use a four-decimal place refractometer for the specific gravity test. The Department will retain the three-decimal place criteria in Section 3.8(a) because both HHS-certified IITFs and laboratories may use a three-decimal place refractometer for a specific gravity screening test when the creatinine concentration is greater than 5 mg/dL and less than 20 mg/dL. However, the Department agrees that this section did not address all situations, so has revised the wording in Section 3.8(b) to be consistent with the wording in 11.19(f).

3.9 What criteria are used to report an invalid result for a urine specimen?

One commenter suggested increasing the acceptable pH range upper end from 9.0 to 9.5 due to heat during summer months. One commenter recommended that the Department define requirements to be met before a new validity marker is implemented. One commenter suggested that additional biomarkers used to support a result of invalid should be standardized across all HHS-certified laboratories and one solution to donor subversion might be random assignment of collection of alternative specimens. The Department has evaluated the comments and has concluded that no change is needed. A 2006 study on the stability of regulated drug analytes in urine slightly below and within the high pH invalid range supports the pH 9.0 decision point due to the loss of drug analytes at a pH between 9.0 and 9.5.[3]

Subpart D—Collectors

4.4 What are the requirements to be an observer for a direct observed collection?

One commenter disagreed with the requirement for an observer to be the same gender as the donor, and suggested that a physician or health care professional (regardless of gender) should be allowed to function as an observer. The commenter indicated that gender determination can be challenging (*i.e.,* transgender employees). The Department has evaluated these comments and agrees that all observed collections must be conducted in a professional manner that minimizes discomfort to the donor. The Department has revised Sections 4.4(b), 8.1(b), and 8.10 to allow the donor to be observed by a person whose gender matches the donor's gender, which is determined by the donor's gender identity (defined in Section 1.5). The donor's gender identity may be the same as or different from the donor's sex assigned at birth. The Department also revised Sections 8.1(b) and 8.12 for monitored collections, to allow the donor to be monitored by a person whose gender matches the donor's gender, unless the monitor is a medical professional (as described in Section 8.12).

The Department disagrees with the commenter's suggestion to allow an individual to serve as an observer based solely on their credentials as a physician or health care professional. Such credentials alone would not guarantee that these individuals could appropriately perform the functions of an observer (*i.e.,* as specified in Section 4.4).

The same commenter expressed concerns over the requirement for an observer to have received training, indicating that this would require

documentation and may make finding short notice observers more difficult. The Department disagrees with this comment. These are the same requirements as in the Guidelines effective October 1, 2010 (73 FR 71858). As stated in the preamble to those Guidelines, the training elements are included to ensure that the observer interacts with the donor in a professional manner, respecting the donor's modesty and privacy, and that the collector maintains the confidentiality and integrity of collection information.

Subpart F—Federal Drug Testing Custody and Control Form (CCF)

6.1 What federal form is used to document custody and control?

Two commenters recommended that the Department provide instructions on recording results for the added drugs on the CCF until the Federal CCF is revised. Three commenters recommended that the CCF be revised to address the addition of the oral fluid specimen matrix. One commenter encouraged SAMHSA to modify the CCF to account for collections where multiple specimens are collected during a single collection event. The Department will publish a **Federal Register** Notice with the revised Federal CCF, including changes for the added analytes, with the same effective date as these Guidelines. Guidance on the use of the revised Federal CCF will be posted on the SAMHSA Web site *http://www.samhsa.gov/workplace.* In regard to when the collector submits multiple urine specimens (*i.e.,* different voids) collected during the same testing event, the Department has concluded that no change is needed; the collector must use a separate Federal CCF for each specimen.

6.2 What happens if the correct OMB approved Federal CCF is not available or is not used?

One commenter questioned the purpose of a Memorandum for the Record (MFR) obtained from the collector when an incorrect CCF was used for the collection. The commenter suggested that if certain information is required to be in the MFR, these requirements should be specified in the Guidelines. The commenter suggested that if the purpose of the MFR is to correct the collector's behavior (*i.e.,* using an incorrect form), then it would be more effective to reject the specimen upon receipt and indicate that it was rejected due to the use of an incorrect form. The Department has evaluated the comments and has concluded that no change is needed. Section 6.2 describes the information required in the MFR from the collector. However, the Department reworded items 6.2(b) and (c) for clarity.

Subpart H—Urine Specimen Collection Procedure

8.1 What privacy must the donor be given when providing a urine specimen?

As described in this preamble under Section 4.4, the Department has revised Section 8.1(b) to require that the gender of the observer matches the donor's gender, and that the gender of the monitor matches the donor's gender unless the monitor is a medical professional as described in Section 8.12.

8.3 What are the preliminary steps in the urine specimen collection procedure?

One commenter was concerned that the Guidelines do not mention alcohol testing, which was added to the Department of Transportation (DOT) program in 1991. Alcohol testing is outside of the scope of the Department's regulatory authority granted by Executive Order 12564 and Public Law 100–71.

In response to comments described under Sections 1.7 and 8.4 in this preamble, the Department revised Section 8.3(h) to require the collector to report a refusal to test when a donor brings materials for adulterating, substituting, or diluting a specimen to the collection site.

8.4 What steps does the collector take in the collection procedure before the donor provides a urine specimen?

The proposed section included the same requirement as the Guidelines effective October 1, 2010 (73 FR 71858) for the collector to perform an observed collection when the donor exhibits conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute). One commenter stated that if the collector finds an adulterant or substitution product or observes the donor attempt to substitute a urine specimen, this should be a refusal to test. As noted under Section 1.7 in this preamble, the Department agrees that the collector must report a refusal to test when a donor brings materials for adulterating, substituting, or diluting a specimen to the collection site, or when the collector observes a donor's clear attempt to tamper with a specimen. The Department has revised Section 8.4 accordingly.

8.5 What steps does the collector take during and after the urine specimen collection procedure?

8.6 What procedure is used when the donor states that they are unable to provide a urine specimen?

Comments on these two sections are addressed here. Numerous commenters expressed concern with the Department's urine collection policy, stating that 7 to 10% of Americans have a condition (''paruresis''), described as a social anxiety disorder which prevents a person from producing urine on demand or in the presence of other people. These commenters stated that if the government wants to seek the largest group of qualified applicants, the Guidelines should specify that a diagnosis of paruresis means non-urine (*i.e.,* oral fluid) testing will automatically be provided, and that donors should not have to attempt to provide a urine specimen first. The Department has evaluated the comments and has concluded that no change is needed. The Guidelines will allow a federal agency to use any authorized specimen types (*e.g.,* urine, oral fluid, or both) in their drug testing programs. The Guidelines will continue to require that the donor be allowed reasonable attempts to provide a urine specimen as described in Sections 8.5 and 8.6, and allow collection of an authorized alternate specimen (*i.e.,* oral fluid).

Three commenters disagreed with the requirement for the collector to contact the agency representative for authorization to collect an alternate specimen each time a donor is unable to provide a sufficient volume. These commenters suggested that the Guidelines allow this to be addressed in established standard protocols for the agency. The Department agrees with the commenters. Each federal agency may decide whether to require notification in each case or whether to provide a standard protocol for collectors to follow. Sections 8.5 and 8.6 have been revised accordingly.

Also in regard to Section 8.6, one commenter indicated that some employers may wish to retain urine testing as the primary test due to a longer detection window. This commenter raised concern that some donors may claim they are unable to provide a urine specimen so that an alternative specimen (*i.e.,* OF) with a shorter detection window will be collected. The commenter suggested that the Guidelines be changed to indicate that an alternative specimen

may be collected when a donor is physiologically unable to provide a urine specimen, and not just when the donor states that they are unable to provide a urine specimen. The Department disagrees; collectors are not qualified to conduct a medical evaluation to verify or refute the donor's claim. It will be the agency's decision to collect urine or an authorized alternate specimen, and Sections 13.6 and 13.7 include procedures for medical evaluation as needed during the MRO review process.

The Department reworded Section 8.5(d) to clarify that the collector must record comments on both CCFs when two specimens from the same collection event are forwarded to a laboratory.

8.7 If the donor is unable to provide a urine specimen, may another specimen type be collected for testing?

The Department proposed within Section 8.7 that when the donor is unable to provide a urine specimen, another specimen type may be collected only if specifically authorized by the agency. One commenter disagreed with the Guidelines as written and suggested that when a donor cannot provide the primary specimen type, an alternate specimen should be collected immediately. The commenter cited the additional time and cost (evaluation of donor for ''shy bladder'') as well as the fact that the collector may not know the agency's policy on alternate specimen types. The Department has concluded that no change is needed for Section 8.7 in response to this comment. The Guidelines will continue to require that the donor be allowed reasonable attempts to provide a urine specimen as described in Sections 8.5 and 8.6. The Department has revised those sections to allow a federal agency to either require notification in each case or provide a standard protocol for collectors to follow when the donor is unable to provide a urine specimen. The Department has reworded this section to state ''Yes, if . . .'' rather than ''No, unless . . . .'' in response to a federal agency's comment and to enhance clarity. The meaning of this section remains the same.

8.8 How does the collector prepare the urine specimens?

In response to a federal agency comment, the Department deleted a sentence in item 8.8(h) that required the collector to send a copy of the Federal CCF to the HHS-certified laboratory or IITF. The Department agreed with the federal agency that this instruction is redundant because item 8.8(g) instructs the collector to distribute copies of the Federal CCF as required.

8.9 When is a direct observed collection conducted?

The proposed section included requirements for the collector to perform an observed collection when the donor exhibits conduct that clearly indicates an attempt to tamper with a specimen or the collector observed materials brought by the donor to the collection site for the purpose of adulterating, substituting, or diluting the specimen. One commenter stated that if the collector finds an adulterant or substitution product or observes the donor attempt to substitute a urine specimen, this should be a refusal to test. As noted in this preamble under Sections 1.7 and 8.4, the Department agrees that the collector must report a refusal to test when a donor brings materials for adulterating, substituting, or diluting the specimen to the collection site, or when the collector observes a donor's clear attempt to tamper with a specimen. The Department has revised Section 8.9 accordingly.

8.10 How is a direct observed collection conducted?

To address a comment described in this preamble under Section 4.4, the Department has revised Section 8.10 to allow the donor to be observed by an observer whose gender matches the donor's gender. At the beginning of the observed collection, the collector requests that the donor document the donor's gender on the Federal CCF and initial the annotation. An observer of the same gender is provided, and the collector records the name and gender of the observer on the Federal CCF.

8.12 How is a monitored collection conducted?

To address a comment described in this preamble under Section 4.4, the Department has revised Section 8.12 to allow the donor to be monitored by a monitor whose gender matches the donor's gender, unless the monitor is a medical professional (*e.g.,* nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). As described in Section 8.10, at the beginning of the monitored collection, the collector follows the same procedure as for observer selection in Section 8.10(b). That is, the collector requests that the donor document the donor's gender on the Federal CCF and initial the annotation. A monitor of the same gender is provided, and the collector records the name and gender of the monitor on the Federal CCF. A medical professional may serve as the monitor, regardless of gender.

Subpart I—HHS Certification of Laboratories and IITFs

9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

One commenter noted that, because proposed initial test requirements allow calibration with a low-reacting analyte, PT schemes would likely need to be designed based on the specific implementation at each laboratory. The commenter provided an example: When an immunoassay is calibrated with a drug/metabolite that exhibits 50% cross-reactivity, the intended target analyte (''calibrant'') at the cutoff concentration would elicit a response well in excess of the cutoff. This could result in inaccurate initial test results (*i.e.,* a positive initial test result for a specimen containing the calibrant at a concentration below the cutoff). The commenter stated that this result could be scored as a ''false positive'' PT result. The Department has evaluated the comment and has concluded that no change is needed. As noted above regarding Section 3.4, it was not the Department's intent for the laboratory or IITF to calibrate an immunoassay test using an analyte other than that specified by the manufacturer. NLCP PT schemes are designed based on known cross-reactivity profiles of the initial tests used by HHS-certified laboratories.

Also in regard to proposed Section 9.5, one commenter suggested that the Guidelines use the same wording as in the Guidelines effective October 1, 2010 (73 FR 71858) for retest PT sample specifications (*i.e.,* ''. . . may be as low as . . .'' rather than the proposed wording ''. . . may be less than. . .''). The Department agrees and has reinstituted wording from Section 9.3 of the Guidelines effective October 1, 2010 (73 FR 71858) into Section 9.5(a)(1)(ii).

Subpart J—Blind Samples Submitted by an Agency

10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories or IITFs?

Two commenters disagreed with the proposed limit to the number of blind samples required (*i.e.,* a maximum of 400 blind samples per year) in Section 10.1(b). The commenters indicated that for a large agency, there is a very large difference between 3% and 400 samples and suggested keeping only the 3% requirement. Another commenter disagreed with the 3% requirement for

blind samples and requested that the amount to be lowered to 1% to lessen the burden on employers. One commenter suggested that the wording be modified to clarify that employers are responsible for ensuring blind samples are sent to the laboratories, but that collectors are tasked with submitting the blind samples. The Department has evaluated the comments and has concluded that no change is needed. The 400 sample limit was added to reduce the burden on large agencies based on the Department's review of agencies' blind testing programs. The wording in Section 10.1(a) clearly describes the responsibilities of the federal agency and the role of the collector in blind sample submission; however, the Department reworded Section 10.3(a) for clarity as described below.

10.3 How is a blind sample submitted to an HHS-certified laboratory?

The Department has reworded Section 10.3(a) to clarify that the collector sends a blind sample to a laboratory or IITF as a split specimen (*i.e.,* Bottle A and Bottle B).

Subpart K—Laboratory

11.10 What are the requirements for an initial drug test?

One commenter noted that HHS previously required initial and confirmatory testing using different techniques, and asked whether this requirement had been removed with allowance of technologies other than immunoassay for initial testing. The commenter expressed concern that an error in the initial drug test could be repeated in the confirmatory drug test using the same method. The Department has evaluated the comments and has concluded that no change is needed. The Guidelines maintain the requirement for initial and confirmatory tests on two separate aliquots to report a result other than negative. The NLCP will review validation and quality control records, as well as specimen records, to ensure that the initial and confirmatory testing methods meet Guidelines requirements and provide scientifically and forensically supportable results.

Also in regard to the proposed Section 11.10, one commenter asked whether non-FDA cleared immunoassays were included in the category of alternate initial drug test technology. The Department has evaluated the comment and has concluded that no change is needed. This section clearly distinguishes initial tests using immunoassay from those using an alternate technology. Furthermore, Section 1.5 includes the definition for ''alternate technology initial drug test.''

11.11 What must an HHS-certified laboratory do to validate an initial drug test?

One commenter noted that an immunoassay initial test calibrated with a low-reacting analyte may not be able to meet Guidelines requirements for performance of the test around the cutoff concentration. The Department has evaluated the comments and has concluded that no change is needed. All tests must be validated by the HHS-certified laboratory to meet the requirements prior to use for regulated drug testing.

One commenter noted that the requirement in section 11.11(b) for reagent verification prior to use is an operational, not a validation, requirement. The Departments agrees with the commenter but has concluded that no change is needed. While this section addresses initial drug test validation requirements, the verification of each new reagent lot is essential to verify that lot-to-lot differences have not significantly affected assay performance as demonstrated and documented during validation. Therefore, this is the most appropriate section of the Guidelines to include the requirement.

11.12 What are the batch quality control requirements when conducting an initial drug test?

One commenter noted that this and other sections use inconsistent terminology when describing quality controls samples relative to the cutoff concentration (*i.e.,* ''25 percent above the cutoff,'' ''75 percent of the cutoff''). The commenter suggested that the Department use one version consistently. The Department has considered the comment and has concluded that no change is needed. These terms have been used in the Guidelines, in NLCP documents, and in other guidance to HHS-certified laboratories without issue.

One commenter asked whether the added analytes affect quality control content requirements. The Department has evaluated the comment and has concluded that no change is needed. The initial drug test quality control requirements in the Guidelines apply to each analyte used to calibrate the test (*i.e.,* immunoassay or alternate technology initial drug test). When a single immunoassay test is used for two or more analytes in a drug class, the HHS-certified laboratory or IITF must include a control in accordance with item 11.12(a)(2) for each analyte that has less than 100% cross-reactivity with the assay, to demonstrate that the requirement for at least 80% cross-reactivity has been met.

11.12 What are the batch quality control requirements when conducting an initial drug test?

11.15 What are the batch quality control requirements when conducting a confirmatory drug test?

Comments on these two sections are addressed here. One commenter requested clarification for the requirement for a drug-free control in initial and confirmatory drug test batches (*i.e.,* whether the control should contain no drug or whether the control should not contain the specific analyte for that test). The Department has evaluated the comment and has concluded that no change is needed. These Guidelines sections list the requirement for ''at least one control certified to contain no drug or drug metabolite,'' meaning that the control must contain no regulated drug analytes.

11.16 What are the analytical and quality control requirements for conducting specimen validity tests?

One commenter found the wording of Section 11.16(a) to be confusing, noting that a specimen would not be subjected to a second specimen validity test when the first test was in the acceptable range. The Department agrees with the comment and has revised Section 11.16(a) to correctly reflect requirements.

11.18 What are the requirements for conducting each specimen validity test?

One commenter noted that the proposed changes in the lower pH cutoff for identifying adulterated specimens and lower pH decision point for identifying invalid specimens may cause additional costs for manufacturers and laboratories. The Department has evaluated the comment and has concluded that no change is needed. The Department recognizes that the revised cutoff will necessitate changes by HHS-certified laboratories as well as by manufacturers of commercial quality control samples; however, the 4.0 pH cutoff is supported by scientific studies and workplace drug testing data, and is expected to reduce the incidence of undetected attempts to subvert the drug test.

11.19 What are the requirements for an HHS-certified laboratory to report a test result?

One commenter suggested that the Department remove the requirement for

an executed CCF as the official report for ''non-negative'' specimens and permit the use of an electronic report with the required information. The Department has evaluated the comment and has concluded that no change is needed. The Federal CCF serves as the chain of custody for the specimen from the time of collection until receipt by the laboratory and also contains the certification statement signed by the certifying scientist. The Federal CCF may be paper or electronic.

11.21 How long must an HHS-certified laboratory retain records?

In Section 11.21, the Department proposed that laboratories be allowed to convert hardcopy records to electronic records for storage and then discard the hardcopy records after six months. One commenter stated their assumption that this section did not require laboratories to convert electronic records to hardcopy records and maintain them for six months. This assumption is correct; the intent is to allow laboratories to maintain records in electronic format for the required storage period. The Department has concluded that no change is needed.

11.22 What statistical summary reports must an HHS-certified laboratory provide for urine testing?

One commenter asked why the proposed Guidelines include a requirement for a copy of the semiannual statistical summary report to be sent to the Secretary or designated HHS representative. The Department included the requirement in Section 11.22 (and in Section 12.19 for IITFs) to facilitate compilation of statistical information for the federal drug-free workplace program. This will not place an additional burden on the test facilities other than transmission of the report. The Department will continue to evaluate the effectiveness of this requirement.

Subpart M—Medical Review Officer (MRO)

13.1 Who may serve as an MRO?

Three commenters disagreed with the term ''nonmedical use of a drug'' used in Section 13.1 (and defined in Section 1.5) and indicated that the term changes the role of an MRO from review, verify and ''report a non-negative result'' to review, verify and ''interpret before reporting a result as negative or nonmedical use of a drug.'' Two commenters disagreed with use of ''interpretation of results'' to supplant ''alternative medical explanation.'' One commenter noted that this perceived change in the MRO's role represents an unjustified shifting of risk to the MRO. One commenter believes the term presents a possible legal flaw to the Guidelines, stating that this term is legally different from ''safety concern'' and places MROs in the position of being in conflict with the prescribing physician and subject to lawsuits. This commenter stated that even a lack of a finding of nonmedical use could be an issue if the donor subsequently had an accident after using the drug. The same commenter submitted five recommendations related to inclusion of prescription drugs in federal workplace drug testing programs, to address the commenter's concerns with the proposed Guidelines. These five specific recommendations pertain to matters that are outside the scope of these Guidelines, and therefore are not addressed in the Department's response below.

The responsibilities of an MRO to interpret results have largely remained the same between the Guidelines effective October 1, 2010 (73 FR 71858) and these Guidelines. As stated in Section 13.5(c) of these Guidelines, ''if the donor provides a legitimate medical explanation (*e.g.,* a valid prescription) for the positive result, the MRO reports the test result as negative to the agency.'' Accordingly, the intent of the Guidelines, in this context, is to confirm whether a positive drug test is the result of drug use under a valid prescription. Furthermore, the term ''alternate medical explanation'' has never been used in the Guidelines, but has been used in the HHS Medical Review Officer Manual for Federal Workplace Drug Testing Programs.

For the reasons above, the Department believes that the definition of ''nonmedical use of a drug'' and the requirement for a physician serving as an MRO to have knowledge of this topic do not fundamentally change the MRO's responsibilities. However, to address the commenters' concerns, the Department has removed this term from the Guidelines (*i.e.,* revised Sections 1.5 and 13.1).

The Department proposed within Section 13.1 who may serve as an MRO. One commenter requested clarification that it is the federal agency's burden to ensure that the MRO is certified. One commenter asked how the laboratory will be informed that an MRO has met requirements for re-qualification. The Department evaluated the comments and concluded that no change is needed. The MRO is an employee or a contractor of the agency. Therefore, it is the agency's responsibility to ensure that the MRO meets the Guidelines qualification requirements.

Two commenters disagreed with the requirement for MRO recertification every five years, and recommended that MROs complete training every three years. Five commenters stated support for five year requalification and examination requirements. The Department has evaluated the comments and has concluded that no change is needed. The Department will keep the five-year recertification requirement as proposed.

13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

One commenter agreed with MRO certification/training entities submitting the delivery method and content of the MRO examination as applicable along with other required documents. One commenter agreed with extending time from one to two years for approved MRO certification/training entities' resubmission of qualifications for HHS approval. The commenter noted that they would support further extension to 3 years. One commenter recommended that approval of MRO educational courses and content be at the discretion of the MRO certification entities, not HHS. Since the certification entities and their examinations are subject to HHS oversight and approval, the commenter noted that it may be burdensome for HHS to review and approve the courses and content, and be a disincentive to development of new courses. One commenter recommended that examinations be allowed to be in-person or online with appropriate security precautions for each delivery method. The Department has evaluated the comments and agrees that the submission of training materials to HHS would possibly discourage the development of new training courses. Therefore, the review of MRO educational courses and content will not be part of the approval process for MRO certification entities. As described under *Medical Review Officer (MRO) requalification—continuing education units (CEUs)* in this preamble, the Department has removed references to MRO training entities in Section 13.2, because training documentation is maintained by MRO certification entities. The Department will only require the MRO certification entities to submit their examination and any other necessary supporting examination materials (*e.g.,* answers, examination statistics or background information on questions) that will help in the Department's evaluation of the examination. The Department will

review and evaluate the examination delivery method (*e.g.,* in-person or online) when reviewing submitted training materials to ensure that the delivery method employs appropriate security and identification procedures.

13.3 What training is required before a physician may serve as an MRO?

Five commenters disagreed and one commenter agreed with the added requirement for MRO training to include information about how to discuss substance misuse and abuse and how to access those services. The Department has evaluated the comments and has revised Section 13.3 to remove this requirement. Federal agencies may provide this information to employees and applicants to facilitate their access to effective treatment and support recovery. The Department provides information to the public on help and treatment for substance misuse and abuse, and how to access those services, on the SAMHSA Web site *http://www.samhsa.gov/.*

One commenter stated that the Department should add a requirement for MRO training on what constitutes a refusal to test. One commenter suggested that the Department should add a requirement for MRO training on when and how to report safety concerns to employers when prescription and/or over-the-counter medications may affect performance. The Department has evaluated the comments and has concluded that no change is needed. Criteria for reporting a refusal to test are covered under the topics listed in Section 13.3 such as items (a)(4) training on the Guidelines and (a)(5) procedures for interpretation, review, and reporting of results. When a donor provides a legitimate medical explanation for a positive drug test result (*e.g.,* a valid prescription), the Guidelines do not require MROs to contact federal agency employers for the purpose of reporting a safety concern. Accordingly, MRO training related to reporting ''safety concerns'' does not relate to a mandatory function under the Guidelines and, therefore, is not an essential component of required MRO training. The Department will provide additional guidance in the HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs.

In addition, the Department revised Section 13.3 as described under *Medical Review Officer (MRO) requalification—continuing education units (CEUs)* in this preamble. The Department removed references to MRO training entities, because training documentation is maintained by MRO certification entities, and added item 13.3(b) to require MRO training on revised Guidelines prior to their effective date.

13.4 What are the responsibilities of an MRO?

One commenter suggested creating a subset of medical professionals trained specifically to determine fitness for duty since an MRO cannot determine fitness for duty over the telephone. The Department has evaluated the comment and has concluded that no change is needed. Fitness for duty evaluations fall outside the purview of the Guidelines.

13.5 What must an MRO do when reviewing a urine specimen's test results?

The Department has revised Section 13.5(d)(1) to include an example of documentation to support a medical explanation for a positive drug test result.

Three commenters disagreed with MRO procedures for ''a positive result for opiates'' (*i.e.,* requirement for clinical evidence of illegal use in addition to positive result) and noted that the proposed Guidelines wording was not changed to clarify that the described procedures do not apply to the added opioids. The Department agrees with the commenters and has revised Section 13.5(d) to clarify that the procedures do not apply to the added opioid analytes. Wording in Section 13.5(d)(2)(i) regarding ''clinical evidence of illegal use'' was also edited for clarity and for consistency with the wording in the OFMG.

One commenter disagreed with requirements concerning two separate specimens collected at a single test event and sent to the laboratory for testing (*e.g.,* a urine specimen outside the acceptable temperature range and the subsequently collected specimen). The proposed Guidelines require that, when one of the two specimens is negative and other is not, the MRO reports only the verified result other than negative. This commenter suggested that the MRO cancel the negative result. The Department has evaluated the comments and has concluded no change is needed. Cancellation of the test may be confusing in the situation referenced by the commenter and lead to inappropriate specimen recollection. Both the MRO and the federal agency employer will receive their Federal CCF copies with explanatory collector remarks in Step 2 including the specimen identification number of the associated specimen, and the MRO may provide additional comment in the MRO's report.

The Department also revised Section 13.5(d) to reflect the policy of the Department that passive exposure to marijuana smoke and ingestion of food products containing marijuana are not acceptable medical explanations for a positive drug test result. Individuals who are passively exposed to marijuana smoke or who consume food products containing marijuana can pose public safety and/or security risks.[4 5] Marijuana is listed as a Schedule I drug under the Controlled Substances Act.

13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of urine for a drug test?

One commenter suggested the Guidelines define ''appropriate expertise'' of a physician with a list of conditions and an appropriate type of physician in an appendix. The same commenter requested medical referral information on the employer's actions when a donor could not provide a urine specimen and then could not provide an oral fluid specimen. The Department has evaluated the comments and has concluded that no change is needed. A physician who is a trained MRO will have the knowledge necessary to identify another physician with appropriate expertise for the medical evaluation. The Department will provide additional guidance in the HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs as appropriate when alternate specimen types (*e.g.,* oral fluid) are allowed in federal workplace drug testing programs.

The Department clarified the definition of ''permanent or long-term medical conditions'' in Section 13.6(b)(1) based on a federal agency comment.

Subpart O—Criteria for Rejecting a Specimen for Testing

15.1 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing?

The Department revised wording in items a and b of this section, and included three additional fatal flaws as items f–h, to reflect fatal flaws for regulated donor specimens that have been identified by HHS-certified laboratories. These fatal flaws were addressed in NLCP guidance sent to all HHS-certified and applicant laboratories and IITFs on August 9, 2016. In addition, the Department revised this section to include an additional item i to allow a laboratory or IITF to reject a specimen when they identify a flaw that

prevents testing or affects the forensic defensibility of the drug test, and cannot be corrected. This general item enables laboratories and IITFs to reject specimens with fatal flaws that may be rare, but do occur. It is not possible to list all such flaws in the Guidelines.

15.3 What discrepancies are not sufficient to require an HHS-certified laboratory or an HHS-certified IITF to reject a urine specimen for testing or an MRO to cancel a test?

Two commenters indicated that inclusion of some items as insignificant discrepancies contradicts guidance provided to HHS-certified laboratories and IITFs in NLCP Notices, which required laboratories to attempt to recover missing information. One of these commenters suggested that if these items are important, they should be removed from the ''insignificant'' list. Two commenters disagreed with the Guidelines designating the listed omissions and discrepancies as ''insignificant only when they occur no more than once per month.'' The Department has evaluated the comments. The listed discrepancies would not result in rejection or cancellation. NLCP Notices requiring laboratory action are consistent with this section. However, the Department has reworded section 15.3 to not classify these errors as insignificant. While these types of errors do not warrant laboratory rejection of a specimen or MRO cancellation of a test, as noted in section 15.3(c), corrective action must be initiated when they occur more than once a month.

The commenters indicated that this section implies that the MRO must keep a log of insignificant errors by laboratory and by collection site in order to track frequency. The commenters noted that this is an unenforceable policy, that this should be a duty of inspectors of laboratories and collection sites, and that requiring MROs to keep these types of logs would create significant extra costs. One commenter suggested that item 15.3(c) be modified for the MRO to advise the collector or laboratory to retrain staff on relevant procedures to ensure that collections are completed correctly (rather than directing them to immediately take corrective action). The Department has evaluated the comments and has concluded that no change is needed. This section is the same as in the Guidelines effective October 1, 2010 (73 FR 71858).

One commenter suggested modifying 15.3(a)(5) to read ''donor identification number'' which would include a social security number or an employee identification number since many employers no longer use social security numbers for employee identification. The Department agrees and has revised Section 15.3(a)(5) to include ''employee identification number'' in addition to ''Social Security Number.''.

15.4 What discrepancies may require an MRO to cancel a test?

One commenter suggested adding the scenario where the donor did not sign the CCF because the collector forgot to ask the donor to sign, rather than the donor's refusal to sign. The Department has evaluated the comment and has concluded that no change is needed. As stated in Section 15.4, the MRO contacts the collector ''to obtain a statement to verify that the donor refused to sign the MRO copy.''

Regulatory Impact and Notices

Executive Orders 13563 and 12866

Executive Order 13563 of January 18, 2011 (Improving Regulation and Regulatory Review) states ''Our regulatory system must protect public health, welfare, safety, and our environment while promoting economic growth, innovation, competitiveness, and job creation.'' Consistent with this mandate, Executive Order 13563 requires agencies to tailor ''regulations to impose the least burden on society, consistent with obtaining regulatory objectives.'' Executive Order 13563 also requires agencies to ''identify and consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice'' while selecting ''those approaches that maximize net benefits.'' This notice presents a regulatory approach that will reduce burdens to providers and to consumers while continuing to provide adequate protections for public health and welfare.

The Secretary has examined the impact of the Guidelines under Executive Order 12866, which directs federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. The Guidelines do establish additional regulatory requirements and allow an activity that was otherwise prohibited. The Administrative Procedure Act (APA) delineates an exception to its rulemaking procedures for ''a matter relating to agency management or personnel'' 5 U.S.C. 553(a)(2). Because the Guidelines issued by the Secretary govern federal workplace drug testing programs, HHS has taken the position that the Guidelines are a ''matter relating to agency management or personnel'' and, thus, are not subject to the APA's requirements for notice and comment rulemaking. This position is consistent with Executive Order 12564 regarding Drug-Free Workplaces, which directs the Secretary to promulgate scientific and technical guidelines for executive agency drug testing programs. However, the statute under which the mandatory guidelines were created (Pub. L. 100–71, section 503(a)(3)) required notice and comment apart from the APA. This provision provides the following:

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

The Department included a Regulatory Impact and Notices section with cost and benefits analysis and burden estimates in the May 15, 2015 **Federal Register** Notice for the proposed UrMG (80 FR 28101), and requested public comment on all figures and assumptions. The Department's projections were developed using information from current HHS-certified urine testing laboratories, with input from DOT and the Nuclear Regulatory Commission (NRC), and cost analysis was based on information provided by multiple HHS-certified laboratories and MROs. The Department received no substantive data or evidence through public comments in favor of changing the estimated costs and benefits provided in the Department's May 2015 **Federal Register** Notice for the UrMG, and therefore, has retained the analysis and estimates provided in that notice below. Comments that related to the costs and benefits of this rule are summarized and discussed above in the Summary of Public Comments and

HHS's Response under the heading *Costs and Benefits.*

Need for Revisions to the Guidelines

The inclusion of oxycodone, oxymorphone, hydrocodone and hydromorphone in the URMG was recommended by the DTAB, reviewed by the Department's Prescription Drug Subcommittee of the Behavioral Health Coordinating Committee, and approved by the SAMHSA Administrator in January 2012. This action is supported by various data, described in this preamble.[1–4] In addition, in 2008, 12 percent of military personnel admitted to the illicit use of prescription medications. Prevalence testing by the Department of Defense (DoD) in 2009 indicated that prescription drug abuse exceeded illegal drug abuse. Because of this, hydrocodone and hydromorphone testing was added to the regular DoD drug testing panel in 2011.

Costs

Costs associated with the implementation of testing for oxycodone, oxymorphone, hydrocodone and hydromorphone will be minimal because the Department has determined that all HHS certified laboratories testing specimens from federal agencies are currently conducting tests for one or more of these analytes on non-regulated urine specimens. Likewise, there will be minimal costs associated with changing initial testing to include MDA since the current immunoassays can be adapted to test for this analyte. Laboratory personnel are currently trained and test methods have been implemented. However, there will be some administrative costs associated with adding these analytes. Prior to being allowed to test regulated specimens for these compounds, HHS certified laboratories will be required to demonstrate that their performance meets Guideline requirements by testing three (3) groups of PT samples. The Department will provide the PT samples through the National Laboratory Certification Program (NLCP) at no cost to the certified laboratories. Based on costs charged for specimen testing, laboratory costs to conduct the PT testing would range from $900 to $1,800 for each certified laboratory.

In Section 3.4, the Department included criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specified the cross-reactivity of the immunoassay to the other analytes(s) within the group. These Guidelines allow the use of methods other than immunoassay for initial testing. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance.

For the added opiate analytes, the two immunoassays currently used for oxycodone and oxymorphone meet the requirements, and two of the three existing opiate immunoassays used in certified laboratories meet the requirements for hydrocodone and hydromorphone analysis. The opiate immunoassay that does not have sufficient cross-reactivity would be acceptable as an initial test under these Guidelines when the lowest-reacting analyte, hydromorphone, is used to establish a decision point. Therefore, the Department assumes that all certified laboratories will elect to use existing immunoassays. Thus, the costs associated with implementing the initial tests for these analytes is expected to be *de minimis.*

For amphetamines, one of the three existing methylenedioxymethamphetamine (MDMA) immunoassays used in certified laboratories meets the requirements. The remaining two exhibit insufficient cross-reactivity for MDA. These two immunoassays would be acceptable as an initial test under these Guidelines when the lowest-reacting analyte, MDA, is used to establish a decision point. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance. Again, the Department assumes that certified laboratories will use the existing immunoassays and incur *de minimis* costs.

Once the testing has been implemented, the cost per specimen for initial testing for the added analytes will range from $.06 to $0.20 due to reagent costs. Current costs for each confirmatory test range from $5.00 to $10.00 for each specimen reported positive, due to sample preparation and analysis costs. Based on information from non-regulated workplace drug testing for these analytes and testing performed by the Department on de-identified federally regulated specimens in 2011, approximately 1% of the submitted specimens is expected to be confirmed as positive for the added analytes. Therefore, the added cost for confirmatory testing will be $0.05 to $0.10 per submitted specimen. This would indicate that the cost per specimen submitted for testing will increase by $0.11–$0.30. Annual recurring testing costs in the table below are based on an estimated number of 6,145,500 specimens.

The addition of the Schedule II prescription medications will require MRO review to verify legitimate drug use. Based on the positivity rates from non-regulated workplace drug testing for these analytes and the additional review of specimens confirmed positive for prescription medications, MRO costs are estimated to increase by approximately 3%. The burden of this 3% cost increase is expected to shift gradually from MROs to agencies as agencies' existing contracts expire and they renegotiate the terms of new contracts, with an increase to the total cost of a federal drug test over time to between $0.60–$1.35. This cost would indicate a total cost of $3,687,300 to $8,296,425 in the urine testing program. A federal agency may also incur additional costs (*e.g.,* additional managerial effort to arrange substitute workers) when an employee tests positive for a prescription medication and is removed from duties during the MRO verification process.

The additional costs for testing and MRO review will be incorporated into the overall cost for the federal agency submitting the specimen to the laboratory. The estimation of costs incurred is based upon overall cost to the federal agency because the review of positive specimens is usually based on all specimens submitted from an agency, rather than individual specimen testing costs or MRO review of positive specimens. Agencies may also incur some costs for training of federal employees such as drug program coordinators due to implementation of the revised Guidelines. Based on current training modules offered to drug program coordinators, and other associated costs including travel for 90% of drug program coordinators, the estimated total training cost for a one-day training session would be between $108,000 and $138,000 (*i.e.,* assuming 8 hours of time multiplied by a GS 12/13 wage including benefits and overhead adjustments). The Department will offer the choice of online or in-person training. This will eliminate travel costs for those federal agencies who choose to use online training.

RECURRING ANNUAL COSTS SUMMARY TABLE

	Lower bound	Upper bound
Reagent Costs	$368,730.00	$1,229,100.00
Additional Confirmatory tests	307,275.00	614,550.00
MRO Costs	3,687,300.00	8,296,425.00
Total annual costs	4,363,305.00	10,140,075.00

UPFRONT (ONE-TIME) COSTS SUMMARY TABLE

	Lower bound	Upper bound
Performance Testing	$27,900.00	$55,800.00
Training	108,000	138,000
Total	135,900.00	193,800.00

Benefits

The potential benefits of deterring use of oxycodone, oxymorphone, hydrocodone and hydromorphone are the prevention of their side effects (*e.g.,* anxiety, dizziness, drowsiness, fatigue, and other neurological effects), which will result in a healthier and more alert workforce as well as avoid the issues associated with addiction and rehabilitation. Since the personnel tested under this program are in positions that are safety sensitive, potential benefits include decreased risk of transportation accidents, decreased risk of low-probability high consequence events, more responsible workforce in positions of public trust, and potentially reducing individuals' dependence or addiction and the personal benefits associated with those conditions.

Considering the potential health and performance costs of narcotic abuse, the benefits to the federal workplace and the individuals within that workplace justify the inclusion of oxycodone, oxymorphone, hydrocodone and hydromorphone in Federal Workplace Drug Testing programs.

Regulatory Flexibility Analysis

For the reasons outlined above, the Secretary has determined that the Guidelines will not have a significant impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act [5 U.S.C. 605(b)]. The flexibility added by the UrMG will not require addition expenditures. Therefore, a final regulatory flexibility analysis is not required for this notice.

The Secretary has determined that the Guidelines are not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. This is not a major rule under the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.

Unfunded Mandates

The Secretary has examined the impact of the Guidelines under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This notice does not trigger the requirement for a written statement under section 202(a) of the UMRA because the Guidelines do not impose a mandate that results in an expenditure of $100 million (adjusted annually for inflation) or more by either state, local, and tribal governments in the aggregate or by the private sector in any one year.

Environmental Impact

The Secretary has considered the environmental effects of the UrMG. No information or comments have been received that would affect the agency's determination there would be a significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

Executive Order 13132: Federalism

The Secretary has analyzed the Guidelines in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt state law. As defined in the Order, ''policies that have federalism implications'' refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

In this notice, the Secretary revised the standards for certification of laboratories engaged in urine fluid drug testing for federal agencies and the use of urine testing in federal drug-free workplace programs. The Department of Health and Human Services, by authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in urine drug testing for federal agencies. Because the Mandatory Guidelines govern standards applicable to the management of federal agency personnel, there should be little, if any, direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Secretary has determined that the Guidelines do not contain policies that have federalism implications.

Paperwork Reduction Act of 1995

The Guidelines contain information collection requirements 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)]. Information collection and recordkeeping requirements which would be imposed on laboratories engaged in drug testing for federal agencies concern quality assurance and

quality control documentation, reports, performance testing, and inspections as set out in subparts H, I, K, L, M and N. Information collection and recordkeeping requirements which would be imposed on MROs engaged in drug testing services for federal agencies concern drug testing result review and reports as set out in subparts M and N. To facilitate ease of use and uniform reporting, a Federal CCF for each type of specimen collected will be developed as referenced in section 6.1. The Department will submit the information collection and recordkeeping requirements contained in the Guidelines to OMB for review and approval prior to the effective date of the final Guidelines. Information collections changed by these Guidelines are not effective until approved by OMB.

Privacy Act

The Secretary has determined that the Guidelines do not contain information collection requirements constituting a system of records under the Privacy Act. The **Federal Register** notice announcing the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine is not a system of records as noted in the information collection/recordkeeping requirements below. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** on April 11, 1988 [53 FR 11979]. SAMHSA subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008 [73 FR 75122]). The effective date of the Guidelines was further changed to October 1, 2010 on April 30, 2010 [75 FR 22809].

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 6, 2000) requires SAMHSA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' as defined in the Executive Order, include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the federal government and the Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.'' The Guidelines do not have tribal implications. The Guidelines will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175.

Information Collection/Record Keeping Requirements

The information collection requirements (*i.e.,* reporting and recordkeeping) in the current Guidelines (73 FR 71858) are approved by the Office of Management and Budget (OMB) under control number 0930–0158. The Federal Drug Testing Custody and Control Form used to document the collection and chain of custody of urine specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination, the National Laboratory Certification Program (NLCP) application, the NLCP Laboratory Information Checklist, and recordkeeping requirements in the current Guidelines, as approved under control number 0930–0158, will remain in effect until these final Guidelines are effective and OMB approves the revised information collection. OMB will assign a new control number to account for changes associated with the final Guidelines.

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: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine Specimens

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 No. 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.

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, 30 urine specimen testing laboratories, 1 IITF, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
9.2(a)(1)	Laboratory or IITF [1] required to submit application for certification.	10	1	3	30
9.12(a)(3)	Materials to submit to become an HHS inspector	10	1	2	20
11.3(a)	Laboratory submits qualifications of RP to HHS	10	1	2	20
11.4(c)	Laboratory submits information to HHS on new RP or alternate RP.	10	1	2	20
11.22	Specifications for laboratory semi-annual statistical report of test results to each federal agency.	10	5	0.5	25
12.3(a)	IITF[1] submits qualifications of RT to HHS	1	1	1	1
12.4(c)	IITF[1] submits information to HHS on new RT or alternate RT.	1	1	1	1
12.19	Specifications for IITF [1] semi-annual statistical report of test results to each federal agency.	1	1	1	1

ESTIMATE OF ANNUAL REPORTING BURDEN—Continued

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
13.9 and 14.7	Specifies that MRO must report all verified primary and split specimen test results to the federal agency.	100	14	0.05 (3 min)	70
16.1(b) & 16.5(a)	Specifies content of request for informal review of suspension/proposed revocation of certification.	1	1	3	3
16.4	Specifies information appellant provides in first written submission when laboratory suspension/revocation is proposed.	1	1	0.5	0.5
16.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period.	1	1	0.5	0.5
16.7(a)	Specifies contents of appellant submission for review.	1	1	50	50
16.9(a)	Specifies content of appellant request for expedited review of suspension or proposed revocation.	1	1	3	3
16.9(c)	Specifies contents of review file and briefs	1	1	50	50
Total		159			295

[1] Although IITFs are allowed under the Guidelines effective October 1, 2010 (73 FR 71858), SAMHSA has not received any IITF applications for certification to test federally regulated specimens. IITF numbers are provided in this analysis as placeholders for administrative purposes.

The following reporting requirements are also in the Guidelines, but have not been addressed in the above reporting burden table: Collector must report any unusual donor behavior or refusal to participate in the collection process on the Federal CCF [Sections 1.8, 8.9]; collector annotates the Federal CCF when a sample is a blind sample [Section 10.3(a)]; MRO notifies the federal agency and HHS when an error occurs on a blind sample [Section 10.4(c)]; Section 13.5 describes the actions an MRO takes to report a primary specimen result; Section 14.6 describes the actions an MRO takes to report a split specimen result; and Sections 13.6 and 13.7 describe the actions an MRO takes for the medical evaluation of a donor who cannot provide a urine specimen. 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	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3(a), 8.5(f)(2) (iii), 8.6(b)(2).	Collector must contact federal agency point of contact.	100	1	0.05 (3 min)	5
11.23, 11.24	Information on drug test that laboratory must provide to federal agency upon request or to donor through MRO.	50	10	3	1,500
12.20, 12.21	Information on drug test that IITF[1] must provide to federal agency upon request or to donor through MRO.	1	1	1	1
13.8(b)	MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported.	100	14	3	4,200
Total		211			5,706

[1] Although IITFs are allowed under the Guidelines effective October 1, 2010 (73 FR 71858), SAMHSA has not certified any IITFs to test federally regulated specimens. IITF numbers are provided in this analysis as placeholders for administrative purposes.

The following disclosure requirements are also included in the 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 8.3(e) and (g)]. SAMHSA believes having the collector explain the collection procedure to the donor and answer any questions is a standard business practice and not a disclosure burden.

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3, 8.5, 8.8	Collector completes Federal CCF for specimen collected.	100	380	0.07 (4 min)	2,534
8.8(d) & (f)	Donor initials specimen labels/seals and signs statement on the Federal CCF.	38,000	1	0.08 (5 min)	3,167

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN—Continued

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
11.8(a) & 11.19	Laboratory completes Federal CCF upon receipt of specimen and before reporting result.	10	3,800	0.05 (3 min)	1,900
12.8(a) & 12.15	IITF[1] completes Federal CCF upon receipt of specimen and before reporting result.	1	1	1	1
13.4(d)(4),13.9(c),14.7(c)	MRO completes Federal CCF before reporting the primary or split specimen result.	100	380	0.05 (3 min)	1,900
14.1(b)	MRO documents donor's request to have split specimen tested.	300	1	0.05 (3 min)	15
Total		38,511			9,517

[1] Although IITFs are allowed under the Guidelines effective October 1, 2010 (73 FR 71858), SAMHSA has not certified any IITFs to test federally regulated specimens. IITF numbers are provided in this analysis as placeholders for administrative purposes.

The 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)(3)] and the documentation must be maintained in the collector's training file [Section 4.3(c)]. Because this is required by the current Guidelines and is consistent with general forensic requirements, 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 8.4(c), 8.5(d)(2), 8.5(e)(1) and (2)] 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 are included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subpart K describes a number of recordkeeping requirements for laboratories associated with their testing procedures, maintaining chain of custody, and keeping records [*i.e.,* Sections 11.1(a) and (d); 11.2(b), (c), and (d); 11.6(b); 11.7(c); 11.8; 11.11(a); 11.14(a); 11.17; 11.21(a), (b), and (c); 11.22; 11.23(a) and 11.24. These recordkeeping requirements are necessary for any laboratory 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.

Thus the total annual response burden associated with the testing of urine specimens by the laboratories and IITFs is estimated to be 15,518 hours (that is, the sum of the total hours from the above tables). This is in addition to the 1,788,809 hours currently approved by OMB under control number 0930–0158 for urine testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary submitted a copy of these proposed Guidelines to OMB for its review. Comments on the information collection requirements were 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.

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Dated: January 11, 2017.

Kana Enomoto,

Acting Deputy Assistant Secretary for Mental Health and Substance Use, SAMHSA.

Dated: January 11, 2017.

Sylvia M. Burwell

Secretary.

The Mandatory Guidelines using Urine Specimens as revised are hereby adopted in accordance with section 503 of Public Law 100–71 and Executive Order 12564.

Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine Specimens

Subpart A—Applicability

Subpart A—Applicability

Section 1.1 To whom do these Guidelines apply?

(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 Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;

(5) Laboratories and instrumented initial test facilities (IITFs) that provide drug testing services to the federal agencies;

(6) Collectors who provide specimen collection services to the federal agencies; and

(7) Medical Review Officers (MROs) who provide drug testing review and interpretation of results services to the federal agencies.

(b) These 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]

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) To ensure the full reliability and accuracy of specimen 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 signs the Federal Drug Testing Custody and Control Form at the time of specimen receipt at the HHS-certified laboratory or (for urine) the HHS-certified IITF.

Adulterated Specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

Aliquot. A portion of a specimen used for testing.

Alternate Responsible Person. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fulfill these obligations.

Alternate Responsible Technician. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified IITF when the responsible technician is unable to fulfill these obligations.

Alternate Technology Initial Drug Test. An initial drug test using technology other than immunoassay to differentiate negative specimens from those requiring further testing.

Batch. A number of specimens or aliquots handled concurrently as a group.

Biomarker. An endogenous substance used to validate a biological specimen.

Blind Sample. A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

Calibrator. A sample of known content and analyte concentration prepared in the appropriate matrix used to define expected outcomes of a testing procedure. The test result of the calibrator is verified to be within established limits prior to use.

Cancelled Test. The result reported by the MRO to the federal agency when a specimen has been reported to the MRO as an invalid result (and the donor has no legitimate explanation) or rejected for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable flaw exists in the forensic records (as described in Sections 15.1 and 15.2).

Carryover. The effect that occurs when a sample result (*e.g.,* drug concentration) is affected by a preceding sample during the preparation or analysis of a sample.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of a test result reported by an HHS-certified laboratory.

Certifying Technician (CT). The individual responsible for verifying the chain of custody and scientific reliability of negative, rejected for testing, and (for urine) negative/dilute results reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF.

Chain of Custody (COC) Procedures. Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

Chain of Custody Documents. Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots and must include the name and signature of each individual who handled the specimen(s) or aliquot(s) and the date and purpose of the handling.

Collection Container. A receptacle used to collect a urine specimen.

Collection Site. The location where specimens are collected.

Collector. A person trained to instruct and assist a donor in providing a specimen.

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

Confirmatory Specimen Validity Test. A second test performed on a separate aliquot of a specimen to further support a specimen validity test result.

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

Cutoff. The analytical value (*e.g.,* drug or drug metabolite concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or, for urine, substituted) or the need for further testing.

Dilute Specimen. A urine specimen with creatinine and specific gravity values that are lower than expected but are still within the physiologically producible ranges of human urine.

Donor. The individual from whom a specimen is collected.

External Service Provider. An independent entity that performs services related to federal workplace drug testing on behalf of a federal agency, a collector/collection site, an

[1] The NRC-related information in this notice pertains to individuals subject to drug testing conducted pursuant to 10 CFR part 26, ''Fitness for Duty Programs'' (*i.e.,* employees of certain NRC-regulated entities).

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 scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines . . .'' See 49 U.S.C. 20140(c)(2). In carrying out its mandate, DOT requires by regulation at 49 CFR part 40 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 HHS Mandatory Guidelines.

HHS-certified laboratory, a Medical Review Officer (MRO), or, for urine, an HHS-certified Instrumented Initial Test Facility (IITF).

Failed to Reconfirm. The result reported for a split (B) specimen when a second HHS-certified laboratory is unable to corroborate the result reported for the primary (A) specimen.

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 and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (*i.e.,* HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic, or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

Gender Identity. Gender identity means an individual's internal sense of being male or female, which may be different from an individual's sex assigned at birth.

HHS. The Department of Health and Human Services.

Initial Drug Test. An analysis used to differentiate negative specimens from those requiring further testing.

Initial Specimen Validity Test. The first analysis used to determine if a specimen is invalid, adulterated, or (for urine) diluted or substituted.

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

Invalid Result. The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.9 when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

Laboratory. A permanent location where initial and confirmatory drug testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

Limit of Detection. The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

Limit of Quantification. For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

Lot. A number of units of an item (*e.g.,* reagents, quality control material) manufactured from the same starting materials within a specified period of time for which the manufacturer ensures that the items have essentially the same performance characteristics and expiration date.

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

Negative Result. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF to an MRO when a specimen contains no drug and/or drug metabolite; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class.

Oral Fluid Specimen. An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

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.

Performance Testing (PT) Sample. A program-generated sample sent to a laboratory or (for urine) to an IITF to evaluate performance.

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

Reconfirmed. The result reported for a split (B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (A) specimen.

Rejected for Testing. The result reported by an HHS-certified laboratory or (for urine) HHS-certified IITF when no tests are performed on a specimen because of a fatal flaw or an unrecovered correctable error (see Sections 15.1 and 15.2).

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

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

Sample. A performance testing sample, calibrator or control used during testing, or a representative portion of a donor's specimen.

Secretary. The Secretary of the U.S. Department of Health and Human Services.

Specimen. Fluid or material collected from a donor at the collection site for the purpose of a drug test.

Split Specimen Collection (for Urine). A collection in which the specimen collected is divided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

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

Substituted Specimen. A specimen that has been submitted in place of the donor's urine, as evidenced by creatinine and specific gravity values that are outside the physiologically producible ranges of human urine.

Section 1.6 What is an agency required to do to protect employee records?

Consistent with 5 U.S.C. 552a and 48 CFR 24.101–24.104, all agency contracts with laboratories, IITFs, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552a. In addition, the contracts must require compliance with employee access and confidentiality provisions of Section 503 of Public Law 100–71. Each federal 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.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR parts 160 and 164, Subparts A and E, may be applicable to certain health care providers with whom a federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding the HIPAA Privacy Rule, please visit *http://www.hhs.gov/ocr/hipaa.*

Section 1.7 What is a refusal to take a federally regulated drug test?

(a) As a donor for a federally regulated drug test, you have refused to take a federally regulated drug test if you:

(1) Fail to appear for any test (except a pre-employment test) within a

reasonable time, as determined by the federal agency, consistent with applicable agency regulations, after being directed to do so by the federal agency;

(2) Fail to remain at the collection site until the collection process is complete with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test as described in section 8.4(a);

(3) Fail to provide a specimen (*e.g.,* urine or another authorized specimen type) for any drug test required by these Guidelines or federal agency regulations with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test as described in section 8.4(a);

(4) In the case of a direct observed or monitored collection, fail to permit the observation or monitoring of your provision of a specimen when required as described in Sections 8.9 and 8.10;

(5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no legitimate medical explanation for the failure as determined by the process described in Section 13.6;

(6) Fail or decline to participate in an alternate specimen collection (*e.g.,* oral fluid) as directed by the federal agency or collector (*i.e.,* as described in Section 8.6);

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process (*i.e.,* Section 13.6) or as directed by the federal agency. In the case of a federal agency applicant/pre-employment drug test, the donor is deemed to have refused to test on this basis only if the federal agency applicant/pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(8) Fail to cooperate with any part of the testing process (*e.g.,* refuse to empty pockets when directed by the collector, disrupt the collection process, fail to wash hands after being directed to do so by the collector);

(9) For an observed collection, fail to follow the observer's instructions related to the collection process;

(10) Bring materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen;

(11) Attempt to adulterate, substitute, or dilute the specimen;

(12) Possess or wear a prosthetic or other device that could be used to interfere with the collection process; or

(13) Admit to the collector or MRO that you have adulterated or substituted the specimen.

Section 1.8 What are the potential consequences for refusing to take a federally regulated drug test?

(a) As a federal agency employee or applicant, a refusal to take a test may result in the initiation of disciplinary or adverse action, up to and including removal from, or non-selection for, federal employment.

(b) When a donor has refused to participate in a part of the collection process, including failing to appear in a reasonable time for any test except a pre-employment test as described in Section 1.7(a)(1), the collector must terminate the collection process and take action as described in Section 8.13. Required action includes immediately notifying the federal agency's designated representative by any means (*e.g.,* telephone or secure fax machine) that ensures that the refusal notification is immediately received and, if a Federal CCF has been initiated, documenting the refusal on the Federal CCF, signing and dating the Federal CCF, and sending all copies of the Federal CCF to the federal agency's designated representative.

(c) When documenting a refusal to test during the verification process as described in Sections 13.4, 13.5, and 13.6, the MRO must complete the MRO copy of the Federal CCF to include:

(1) Checking the refusal to test box;

(2) Providing a reason for the refusal in the remarks line; and

(3) Signing and dating the MRO copy of the Federal CCF.

Subpart B—Urine Specimens

Section 2.1 What type of specimen may be collected?

A federal agency may collect urine and/or an alternate specimen type for its workplace drug testing program. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected. An agency using urine must follow these Guidelines.

Section 2.2 Under what circumstances may a urine specimen be collected?

A federal agency may collect a urine specimen for the following reasons:

(a) Federal agency applicant/Pre-employment test;

(b) Random test;

(c) Reasonable suspicion/cause test;

(d) Post accident test;

(e) Return to duty test; or

(f) Follow-up test.

Section 2.3 How is each urine specimen collected?

Each urine specimen is collected as a split specimen as described in Section 2.5.

Section 2.4 What volume of urine is collected?

A donor is expected to provide at least 45 mL of urine for a specimen.

Section 2.5 How does the collector split the urine specimen?

The collector pours at least 30 mL into a specimen bottle that is designated as A (primary) and then pours at least 15 mL into a specimen bottle that is designated as B (split).

Section 2.6 When may an entity or individual release a urine specimen?

Entities and individuals subject to these Guidelines under Section 1.1 may not release specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable federal law. This section does not prohibit a donor's request to have a split (B) specimen tested in accordance with Section 13.8.

Subpart C—Urine Drug and Specimen Validity Tests

Section 3.1 Which tests are conducted on a urine specimen?

A federal agency:

(a) Must ensure that each specimen is tested for marijuana and cocaine metabolites as provided under Section 3.4;

(b) Is authorized to test each specimen for opioids, amphetamines, and phencyclidine, as provided under Section 3.4; and

(c) Must ensure that the following specimen validity tests are conducted on each urine specimen:

(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; and

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

(d) If a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color, semi-solid characteristics), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual

response), or contains an unidentified substance that interferes with the confirmatory analysis, then additional testing may be performed.

Section 3.2 May a specimen be tested for additional drugs?

(a) On a case-by-case basis, a specimen may be tested for additional drugs, if a federal agency is conducting the collection for reasonable suspicion or post accident testing. A specimen collected from a federal agency employee may be tested by the federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act. The federal agency must request the HHS-certified laboratory to test for the 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. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the federal agency can request an HHS-certified laboratory to test for the drug by analyzing two separate aliquots of the specimen in two separate testing batches using the confirmatory analytical method. Additionally, the split (B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

(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) 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 in accordance with Subpart C of these Guidelines. Use of specimens by donors, their designees, or any other entity, for other purposes (*e.g.,* deoxyribonucleic acid, DNA, testing) is prohibited unless authorized in accordance with applicable federal law.

(b) These Guidelines are not intended to prohibit federal agencies 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 drug test cutoff concentrations for urine?

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites (THCA) [2]	50 ng/mL [3]	THCA	15 ng/mL.
Cocaine metabolite (Benzoylecgonine).	150 ng/mL [3]	Benzoylecgonine	100 ng/mL.
Codeine/Morphine	2,000 ng/mL	Codeine	2,000 ng/mL.
		Morphine	2,000 ng/mL.
Hydrocodone/Hydromorphone	300 ng/mL	Hydrocodone	100 ng/mL.
		Hydromorphone	100 ng/mL.
Oxycodone/Oxymorphone	100 ng/mL	Oxycodone	100 ng/mL.
		Oxymorphone	100 ng/mL.
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL.
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL.
Amphetamine/Methamphetamine	500 ng/mL	Amphetamine	250 ng/mL.
		Methamphetamine	250 ng/mL.
MDMA [4]/MDA [5]	500 ng/mL	MDMA	250 ng/mL.
		MDA	250 ng/mL.

[1] For grouped analytes (*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff):
Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.
Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (*i.e.,* equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.
[2] An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA).
[3] *Alternate technology (THCA and benzoylecgonine):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (*i.e.,* 15 ng/mL for THCA, 100 ng/mL for benzoylecgonine).
[4] Methylenedioxymethamphetamine (MDMA).
[5] Methylenedioxyamphetamine (MDA).

Section 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

An HHS-certified laboratory is authorized to perform additional drug and/or specimen validity tests on a case-by-case basis as necessary to provide information that the MRO would use to report a verified drug test result (*e.g.,* tetrahydrocannabivarin, specimen validity tests using biomarkers). An HHS-certified laboratory is not authorized to routinely perform additional drug and/or specimen validity tests at the request of an MRO without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D,L stereoisomers of amphetamine and methamphetamine. All tests must meet appropriate validation and quality control requirements in accordance with these Guidelines.

Section 3.6 What criteria are used to report a urine specimen as adulterated?

An HHS-certified laboratory reports a primary (A) specimen as adulterated when:

(a) The pH is less than 4 or equal to or greater than 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 equal to or greater than 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 an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 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 equal to or greater than the limit of quantitation (LOQ) 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 an equal to or great than 200 mcg/mL nitrite-equivalent cutoff or an equal to or great than 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration equal to or greater than the LOQ) 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 equal to or greater than the LOQ 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 a different confirmatory test (*e.g.,* GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

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

(g) The presence of a surfactant is verified by using a surfactant colorimetric test with an equal to or greater than 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 an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(h) The presence of any other adulterant not specified in paragraphs (b) 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 3.7 What criteria are used to report a urine specimen as substituted?

An HHS-certified laboratory reports a primary (A) specimen as substituted when the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests on two separate aliquots (*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 equal to or greater than 1.0200 on both the initial and confirmatory specific gravity tests on two separate aliquots (*i.e.,* a refractometer is used to test both aliquots).

Section 3.8 What criteria are used to report a urine specimen as dilute?

A dilute result may be reported only in conjunction with the positive or negative drug test results for a specimen.

(a) An HHS-certified laboratory or an HHS-certified IITF reports a primary (A) specimen as dilute when the creatinine concentration is greater than 5 mg/dL but less than 20 mg/dL and the specific gravity is equal to or greater than 1.002 but less than 1.003 on a single aliquot.

(b) In addition, an HHS-certified laboratory reports a primary (A) specimen as dilute when the creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030.

Section 3.9 What criteria are used to report an invalid result for a urine specimen?

An HHS-certified laboratory reports a primary (A) specimen 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 equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(b) The pH is equal to or greater than 4 and less than 4.5 or equal to or greater than 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 equal to or greater than 200 mcg/mL using a nitrite colorimetric test or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial (first) test and the second test or using either initial test and the nitrite concentration is equal to or greater than 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 equal to or greater than 50 mcg/mL chromium (VI) for both the initial (first) test and the second 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 equal to or greater than the LOQ for both the initial (first) test and the second 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 (first) test and the second test on two separate aliquots;

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

(h) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with an equal to greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial (first) test and

the second test on two separate aliquots or a foam/shake test for the initial test;

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

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

(k) The physical appearance of the specimen (*e.g.,* viscosity) is such that testing the specimen may damage the laboratory's instruments; or

(l) The specimen has been tested and the appearances of the primary (A) and the split (B) specimens (*e.g.,* color) are clearly different; or

(m) The concentration of a biomarker is not consistent with that established for human urine for both the initial (first) test and the second test on two separate aliquots.

Subpart D—Collectors

Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect urine specimens in accordance with these Guidelines.

(b) The immediate supervisor of a federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a federal agency applicant may only collect that federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

Section 4.2 Who may not collect a specimen?

(a) A federal agency employee who is in a testing designated position and subject to the federal agency drug testing rules must not be a collector for co-workers in the same testing pool or who work together with that employee on a daily basis.

(b) A federal agency applicant or employee must not collect their own drug testing specimen.

(c) An employee working for an HHS-certified laboratory or IITF must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (*e.g.,* spouse, ex-spouse, relative) or a close personal friend (*e.g.,* fiancée).

Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector if they fulfill the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to these Guidelines;

(3) Is trained and qualified to collect a urine specimen. Training must include the following:

(i) All steps necessary to complete a urine collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include one uneventful collection scenario, one insufficient specimen quantity scenario, one temperature out of range scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen bottle tamper-evident seal.

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

(b) A trained collector must complete refresher training at least every five years that includes the requirements in paragraph (a) of this section.

(c) The collector must maintain the documentation of their training and provide that documentation to a federal agency when requested.

(d) An individual may not collect specimens for a federal agency until the individual's training as a collector has been properly documented.

Section 4.4 What are the requirements to be an observer for a direct observed collection?

(a) An individual may serve as an observer for a direct observed collection when the individual has satisfied the requirements:

(1) Is knowledgeable about the direct observed collection procedure described in Section 8.9 of these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program or additional information provided by the Secretary relating to the direct observed collection procedure described in these Guidelines;

(3) Has received training on the following subjects:

(i) All steps necessary to perform a direct observed collection; and

(ii) The observer's responsibility for maintaining the integrity of the collection process, ensuring the privacy of individuals being tested, ensuring that the observation is done in a professional manner that minimizes the discomfort to the employee so observed, ensuring the security of the specimen by maintaining visual contact with the collection container until it is delivered to the collector, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(b) The gender of the observer must be the same as the donor's gender, which is determined by the donor's gender identity. The observer selection process is described in Section 8.10(b).

(c) The observer is not required to be a trained collector.

Section 4.5 What are the requirements to be a trainer for collectors?

(a) Individuals are considered qualified trainers for collectors and may train others to collect urine specimens when they have completed the following:

(1) Qualified as a trained collector and regularly conducted urine drug test collections for a period of at least one year or

(2) Completed a ''train the trainer'' course given by an organization (*e.g.,* manufacturer, private entity, contractor, federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of the trainer's training and provide that documentation to a federal agency when requested.

Section 4.6 What must a federal agency do before a collector is permitted to collect a specimen?

A federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) The collector, who may be self-employed, or an organization (*e.g.,* third party administrator that provides a collection service, collector training company, federal agency that employs its own collectors) maintains a copy of the training record(s); and

(c) The collector has been provided the name and telephone number of the federal agency representative.

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) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect a urine specimen (*e.g.,* an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.12.

Section 5.2 What are the requirements for a collection site?

The facility used as a collection site must have the following:

(a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);

(b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;

(c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory or IITF;

(d) A restricted access area where only authorized personnel may be present during the collection;

(e) A restricted access area for the storage of collection supplies;

(f) The ability to store records securely; and

(g) The ability to restrict the donor access to potential diluents in accordance with Section 8.2.

Section 5.3 Where must collection site records be stored?

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

Section 5.4 How long must collection site records be stored?

Collection site records (*e.g.,* collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?

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

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

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

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

(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;

(6) Ensure that the Federal CCF is completed and distributed as required; and

(7) Ensure that specimens transported to an HHS-certified laboratory or IITF are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (*e.g.,* specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering;

(b) Couriers, express carriers, and postal service personnel are not required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory or IITF.

Section 5.6 What are the privacy requirements when collecting a urine specimen?

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

Subpart F—Federal Drug Testing Custody and Control Form

Section 6.1 What federal form is used to document custody and control?

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

(a) The use of a non-federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory or IITF to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector does not use the correct OMB-approved Federal CCF, the collector must document that it is a federal agency specimen collection and provide the reason that the incorrect form was used. Based on the information provided by the collector, the HHS-certified laboratory or IITF must handle and test the specimen as a federal agency specimen.

(c) If the HHS-certified laboratory, HHS-certified IITF, or MRO discovers that the collector used an incorrect form, the laboratory, IITF, or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form was used. If a memorandum for the record cannot be obtained, the laboratory or IITF reports a rejected for testing result to the MRO and the MRO cancels the test. The HHS-certified laboratory or IITF must wait at least 5 business days while attempting to obtain the memorandum before reporting a rejected for testing result to the MRO.

Subpart G—Urine Specimen Collection Containers and Bottles

Section 7.1 What is used to collect a urine specimen?

A single-use collection container with a means (*i.e.,* thermometer) to measure urine temperature and two specimen bottles must be used.

Section 7.2 What are the requirements for a urine collection container and specimen bottles?

(a) The collection container, the thermometer, and the specimen bottles must not substantially affect the composition of drugs and/or metabolites in the urine specimen.

(b) The two specimen bottles must be sealable and non-leaking, and must maintain the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory or IITF for the presence of drugs or their metabolites.

(c) The two specimen bottles must be sufficiently transparent to enable an objective assessment of specimen appearance and identification of abnormal physical characteristics without opening the bottle.

Section 7.3 What are the minimum performance requirements for a urine collection container and specimen bottles?

(a) The collection container must be capable of holding at least 55 mL and have a volume marking clearly noting a level of 45 mL.

(b) One of the two specimen bottles must be capable of holding at least 35 mL and the other at least 20 mL, and each must have a volume marking clearly noting the appropriate level (30 mL for the primary specimen and 15 mL for the split specimen).

(c) The thermometer may be affixed to or built into the collection container and must provide graduated temperature readings from 32–38 °C/90–100 °F. Alternatively, the collector may use another technology to measure specimen temperature (*e.g.,* thermal radiation scanning), providing the thermometer does not come into contact with the specimen.

Subpart H—Urine Specimen Collection Procedure

Section 8.1 What privacy must the donor be given when providing a urine specimen?

The following privacy requirements apply when a donor is providing a urine specimen:

(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

(b) The collector is not required to be the same gender as the donor. The gender of the observer for purposes of a direct observed collection (*i.e.,* as described in Section 8.10) must be the same as the donor's gender, which is determined by the donor's gender identity. The gender of the monitor for a monitored collection (*i.e.,* as described in Section 8.12) must be the same as the donor's gender, unless the monitor is a medical professional (*e.g.,* nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place).

(c) The collector must give the donor visual privacy while providing the specimen. The donor is allowed to provide a urine specimen in an enclosed stall within a multi-stall restroom or in a single person restroom during a monitored collection.

Section 8.2 What must the collector ensure at the collection site before starting a urine specimen collection?

The collector must deter the dilution or substitution of a specimen at the collection site by:

(a) Placing a toilet bluing agent in a toilet bowl or toilet tank, so the reservoir of water in the toilet bowl always remains blue. If no bluing agent is available or if the toilet has an automatic flushing system, the collector shall turn the water supply off to the toilet and flush the toilet to remove the water in the toilet when possible.

(b) Secure other sources of water (*e.g.,* shower or sink) in the enclosure where urination occurs. If the enclosure has a source of water that cannot be disabled or secured, a monitored collection must be conducted in accordance with Section 8.11.

Section 8.3 What are the preliminary steps in the urine specimen collection procedure?

The collector must take the following steps before beginning a urine specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the federal agency policy or contact the federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because the donor states that they are unable to urinate or an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (*e.g.,* driver's license; employee badge issued by the employer; an alternative photo identification issued by a federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector must provide identification (*e.g.,* employee badge, employee list) if requested by the donor.

(e) The collector explains the basic collection procedure to the donor.

(f) The collector informs the donor that the instructions for completing the Federal Custody and Control Form are located on the back of the Federal CCF or available upon request.

(g) The collector answers any reasonable and appropriate questions the donor may have regarding the collection procedure.

(h) The collector asks the donor to remove any unnecessary outer garments (*e.g.,* coat, jacket) that might conceal items or substances that could be used to adulterate or substitute the urine specimen:

(1) The collector must ensure that all personal belongings (*e.g.,* purse or briefcase) remain with the outer garments; the donor may retain the donor's wallet.

(2) The collector asks the donor to empty the donor's pockets and display the contents to ensure no items are present that could be used to adulterate or substitute the specimen.

(3) If no items are present that can be used to adulterate or substitute the specimen, the donor can place the items back into the donor's pockets and continue the collection procedure.

(4) If an item is present that appears to have been brought to the collection site with the intent to adulterate, substitute, or dilute the specimen, this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.13. If the item appears to be inadvertently brought to the collection site, the collector must secure the item and continue the normal collection procedure.

(5) If the donor refuses to show the collector the items in the donor's pockets, this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.13.

(i) The collector shall instruct the donor to wash and dry the donor's hands prior to urination. After washing the donor's 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 or substitute the specimen.

(1) If the donor refuses to wash the donor's hands when instructed by the collector, this is considered a ''refusal to test.'' The collector must stop the collection and report the refusal to test as described in Section 8.13.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides a urine specimen?

(a) The collector will provide or the donor may select a specimen collection container that is clean, unused, wrapped/sealed in original packaging and compliant with Subpart G. The specimen collection container will be opened in view of the donor.

(b) The collector instructs the donor to provide the specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy. The collector directs the donor to provide a

specimen of at least 45 mL, to not flush the toilet, and to return with the specimen as soon as the donor has completed the void.

(1) Except in the case of a direct observed collection (*i.e.,* as described in Section 8.10) or a monitored collection (*i.e.,* as described in Section 8.12), neither the collector nor anyone else may go into the room with the donor.

(2) The collector may set a reasonable time limit for specimen collection.

(c) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute), the collector must report a refusal to test in accordance with Section 8.13.

Section 8.5 What steps does the collector take during and after the urine specimen collection procedure?

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the urine specimen:

(a) The collector must inform the donor that, once the collection procedure has begun, the donor must remain at the collection site (*i.e.,* in an area designated by the collector) until the collection is complete. This includes the wait period (*i.e.,* up to 3 hours) if needed to provide a sufficient specimen as described in step (f)(2) below and in Section 8.6.

(b) After providing the specimen, the donor gives the specimen collection container to the collector. Both the donor and the collector must keep the specimen container in view at all times until the collector seals the specimen bottles as described in Section 8.8.

(c) After the donor has given the specimen to the collector, whenever practical, the donor shall be allowed to wash the donor's hands and the donor may flush the toilet.

(d) The collector must measure the temperature of the specimen within 4 minutes of receiving the specimen from the donor. The collector records on the Federal CCF whether or not the temperature is in the acceptable range of 32 °–38 °C/90 °–100 °F.

(1) The temperature measuring device must accurately reflect the temperature of the specimen and not contaminate the specimen.

(2) 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 in accordance with Section 8.9. The collector must forward both specimens (*i.e.,* from the first and second collections) to an HHS-certified laboratory for testing and record a comment on the Federal CCF for each specimen.

(e) The collector must inspect the specimen to determine if there is any sign indicating that the specimen may not be a valid urine specimen (*e.g.,* unusual color, presence of foreign objects or material, unusual odor).

(1) The collector notes any unusual finding on the Federal CCF. A specimen suspected of not being a valid urine specimen must be forwarded to an HHS-certified laboratory for testing.

(2) 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 direct observation in accordance with Section 8.10. The collector must forward both specimens (*i.e.,* from the first and second collections) to an HHS-certified laboratory for testing and record a comment on the Federal CCF for each specimen.

(f) The collector must determine the volume of urine in the specimen container. The collector must never combine urine collected from separate voids to create a specimen.

(1) If the volume is at least 45 mL, the collector will proceed with steps described in Section 8.8.

(2) If the volume is less than 45 mL, the collector discards the specimen and immediately collects a second specimen using the same procedures as for the first specimen (including steps in paragraphs c and d of this section).

(i) The collector may give the donor 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 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). However, the donor is not required to drink any fluids during this waiting time.

(ii) If the donor provides a sufficient urine specimen (*i.e.,* at least 45 mL), the collector proceeds with steps described in Section 8.8.

(iii) If the employee has not provided a sufficient specimen (*i.e.,* at least 45 mL) within three hours of the first unsuccessful attempt to provide the specimen, the collector records the reason for not collecting a urine specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(g) If the donor fails to remain present through the completion of the collection, declines to have a direct observed collection as required in steps (d)(2) or (e)(2) above, refuses to provide a second specimen as required in step (f)(2) above, or refuses to provide an alternate specimen as authorized in step (f)(2)(iii) above, the collector stops the collection and reports the refusal to test in accordance with Section 8.13.

Section 8.6 What procedure is used when the donor states that they are unable to provide a urine specimen?

(a) If the donor states that they are unable to provide a urine specimen during the collection process, the collector requests that the donor enter the restroom (stall) and attempt to provide a urine specimen.

(b) The donor demonstrates their inability to provide a specimen when he or she comes out of the stall with an empty collection container.

(1) If the donor states that they could provide a specimen after drinking some fluids, the collector gives the donor 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 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). If the donor simply needs more time before attempting to provide a urine specimen, the donor is not required to drink any fluids during the 3 hour wait time.

(2) If the donor states that they are unable to provide a urine specimen, the collector records the reason for not collecting a urine specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's

designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

Section 8.7 If the donor is unable to provide a urine specimen, may another specimen type be collected for testing?

Yes, if the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the federal agency.

Section 8.8 How does the collector prepare the urine specimens?

(a) All federal agency collections are to be split specimen collections.

(b) The collector, in the presence of the donor, pours the urine from the collection container into two specimen bottles to be labeled ''A'' and ''B''. The collector pours at least 30 mL of urine into Bottle A and at least 15 mL into Bottle B, and caps each bottle.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over each specimen bottle cap. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen bottle. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

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

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from the donor. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints their name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Bottle A and Bottle B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory or IITF that will be testing the Bottle A urine specimen.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory or IITF, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

(j) The collector must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: The collector may use excess urine to conduct clinical tests (*e.g.,* protein, glucose) if the collection was conducted in conjunction with a physical examination required by federal agency regulation. Neither the collector nor anyone else may conduct further testing (such as specimen validity testing) on the excess urine.

Section 8.9 When is a direct observed collection conducted?

A direct observed collection procedure must be conducted when:

(a) The agency has authorized a direct observed collection because:

(1) The donor's previous drug test result was reported by an MRO as positive, adulterated, or substituted; or

(2) The HHS-certified laboratory reports to the MRO that a specimen is invalid, and the MRO reported to the agency that there was not a legitimate medical explanation for the result; or

(3) The MRO reported to the agency that the primary bottle (A) specimen was positive, adulterated, or substituted result had to be cancelled because the test of the split specimen could not be tested and/or the split specimen bottle (B) failed to reconfirm; or

(b) At the collection site, an immediate collection of a second urine specimen is required because:

(1) The temperature of the specimen collected during a routine collection is outside the acceptable temperature range; or

(2) The collector suspects that the donor has tampered with the specimen during a routine collection (*e.g.,* abnormal physical characteristic such as unusual color and/or odor, and/or excessive foaming when shaken).

(c) The collector must contact a collection site supervisor to review and concur in advance with any decision by the collector to obtain a specimen under direct observation.

(d) If the donor declines to have a direct observed collection, the collector reports a refusal to test (*i.e.,* as described in Section 8.13).

Section 8.10 How is a direct observed collection conducted?

(a) A direct observed collection procedure is the same as that for a routine collection, except an observer watches the donor urinate into the collection container. The observer's gender must be the same as the donor's gender, which is determined by the donor's gender identity, with no exception to this requirement.

(b) Before an observer is selected, the collector informs the donor that the gender of the observer will match the donor's gender, which is determined by the donor's gender identity (as defined in Section 1.5). The collector then selects the observer to conduct the observation:

(i) The collector asks the donor to identify the donor's gender on the Federal CCF and initial it.

(ii) The donor will then be provided an observer whose gender matches the donor's gender.

(iii) The collector documents the observer's name and gender on the Federal CCF.

(c) If there is no collector available of the same gender as the donor's gender, the collector or collection site supervisor shall select an observer trained in direct observed specimen collection as described in Section 4.4. The observer may be an individual that is not a trained collector.

(d) At the point in a routine collection where the donor enters the restroom with the collection container, a direct observed collection includes the following additional steps:

(1) The observer enters the restroom with the donor;

(2) The observer must directly watch the urine go from the donor's body into the collection container (the use of mirrors or video cameras is not permitted);

(3) The observer must not touch or handle the collection container unless the observer is also serving as the collector;

(4) After the donor has completed urinating into the collection container:

(i) If the same person serves as the observer and collector, that person may receive the collection container from the donor while they are both in the restroom;

(ii) If the observer is not serving as the collector, the donor and observer leave the restroom and the donor hands the collection container directly to the collector. The observer must maintain visual contact of the collection container until the donor hands the container to the collector.

(5) The collector checks the box for an observed collection on the Federal CCF and writes the name of the observer and the reason for an observed collection on the Federal CCF; and

(6) The collector then continues with the routine collection procedure in Section 8.3.

Section 8.11 When is a monitored collection conducted?

(a) In the event that an agency-designated collection site is not available and there is an immediate requirement to collect a specimen (*e.g.,* an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.12.

(b) If the enclosure used by the donor to provide a specimen has a source of water that cannot be disabled or secured, a monitored collection must be conducted.

(c) If the donor declines to permit a collection to be monitored when required, the collector reports a refusal to test (*i.e.,* as described in Section 8.13).

Section 8.12 How is a monitored collection conducted?

A monitored collection is the same as that for a routine collection, except that a monitor accompanies the donor into the restroom to check for signs that the donor may be tampering with the specimen. The monitor remains in the restroom, but outside the stall, while the donor is providing the specimen. A person of the same gender as the donor shall serve as the monitor, unless the monitor is a medical professional (*e.g.,* nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The same procedures used for selecting an observer of the appropriate gender in Section 8.10(b) must be used to select the monitor for the purposes of Section 8.12, unless the monitor is a medical professional as described above. The monitor may be an individual other than the collector and need not be a qualified collector.

(a) The collector secures the restroom being used for the monitored collection so that no one except the employee and the monitor can enter the restroom until after the collection has been completed.

(b) The monitor enters the restroom with the donor.

(c) The monitor must not watch the employee urinate into the collection container. If the monitor hears sounds or makes other observations indicating an attempt by the donor to tamper with a specimen, there must be an additional collection under direct observation in accordance with Section 8.9.

(d) The monitor must not touch or handle the collection container unless the monitor is also the collector.

(e) After the donor has completed urinating into the collection container:

(1) If the same person serves as the monitor and collector, that person may receive the collection container from the donor while they are both in the restroom;

(2) If the monitor is not serving as the collector, the donor and monitor leave the restroom and the donor hands the collection container directly to the collector. The monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.

(f) If the monitor is not serving as the collector, the collector writes the name of the monitor on the Federal CCF.

(g) The collector then continues with the routine collection procedure in Section 8.3.

Section 8.13 How does the collector report a donor's refusal to test?

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any urine collected and reports the refusal to test by:

(a) Notifying the federal agency by means (*e.g.,* telephone, email, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test on the Federal CCF, and

(c) Sending all copies of the Federal CCF to the federal agency's designated representative.

Section 8.14 What are a federal agency's responsibilities for 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.

(b) A federal agency (or only one federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (*e.g.,* virtual, onsite, or self-evaluation).

(c) A federal agency must investigate reported collection site deficiencies (*e.g.,* specimens reported ''rejected for testing'' by an HHS-certified laboratory or IITF) and take appropriate action which may include a collection site self-assessment (*i.e.,* using the Collection Site Checklist for the Collection of Urine Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

Subpart I—HHS Certification of Laboratories and IITFs

Section 9.1 Who has the authority to certify laboratories and IITFs to test urine 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 HHS-certified laboratory or IITF including suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any HHS-certified laboratory or IITF to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any HHS-certified laboratory or IITF to send specimens or specimen aliquots to another HHS-certified 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 urine specimens for federal agencies unless it holds such certification.

Section 9.2 What is the process for a laboratory or IITF to become HHS-certified?

(a) A laboratory or IITF seeking HHS certification must:

(1) Submit a completed OMB-approved application form (*i.e.,* the applicant laboratory or IITF provides detailed information on both the administrative and analytical procedures to be used for federally regulated specimens);

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

(3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;

(4) Satisfy all the requirements for an initial inspection; and

(5) Receive notification of certification from the Secretary before testing specimens for federal agencies.

Section 9.3 What is the process for a laboratory or IITF to maintain HHS certification?

(a) To maintain HHS certification, a laboratory or IITF must:

(1) 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 at a minimum of every 6 months thereafter);

(2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and

(3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

Section 9.4 What is the process when a laboratory or IITF does not maintain its HHS certification?

(a) A laboratory or IITF that does not maintain its HHS certification must:

(1) Stop testing federally regulated specimens;

(2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.20, 11.21, 12.18, and 14.8;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.23, 11.24, 12.20, 12.21, and Subpart P; and

(4) Follow the HHS suspension and revocation procedures when imposed by the Secretary, follow the HHS procedures in Subpart P that will be used for all actions associated with the suspension and/or revocation of HHS-certification.

Section 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

(a) PT samples used to evaluate drug tests will be prepared using the following specifications:

(1) PT samples may contain one or more of the drugs and drug metabolites in the drug classes listed in Section 3.4 and must satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff concentration for the drug or drug metabolite;

(ii) The concentration of a drug or metabolite may be as low as 40 percent of the confirmatory test cutoff concentration when the PT sample is designated as a retest sample; or

(iii) The concentration of drug or metabolite may differ from 9.5(a)(1)(i) and 9.5(a)(1)(ii) for a special purpose.

(2) A PT sample may contain an interfering substance, an adulterant, or satisfy the criteria for a substituted specimen, dilute specimen, or invalid result.

(3) A negative PT sample will not contain a measurable amount of a target analyte.

(b) PT samples used to evaluate specimen validity tests 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 between 1.5 and 5.0 or between 8.5 and 12.5;

(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; or

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

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

(d) 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?

(a) An applicant laboratory that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the three sets of PT samples;

(4) For the confirmatory drug tests, correctly determine the concentrations [*i.e.,* no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 80 percent of the total drug challenges over the three sets of PT samples;

(5) For the confirmatory drug tests, must not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations [*i.e.,* no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over the three sets of PT samples;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over the three sets of PT samples that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean; and

(ii) pH values are no more than ±0.3 pH units from the appropriate reference or peer group mean using a pH meter; and

(iii) Specific gravity values are no more than ±0.0003 specific gravity units from the appropriate reference or peer group mean when the mean is less than 1.0100 and specific gravity values are no more than ±0.0004 specific gravity units from the appropriate reference or peer group mean when the mean is equal to or greater than 1.0100;

(10) Must not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for nitrite and creatinine concentrations, ±0.8 pH units using a pH meter, ±0.0006 specific gravity units when the mean is less than 1.0100, or ±0.0007 specific gravity units when the mean is equal to or greater than 1.0100; 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 appropriate reference or peer group mean is within the acceptable pH range, or substituted when the appropriate reference or peer group means for both creatinine and specific gravity are within the acceptable range.

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.7 What are the PT requirements for an HHS-certified urine laboratory?

(a) A laboratory certified under these Guidelines must satisfy the following criteria on the maintenance PT samples:

(1) Have no false positive results;

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

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over two consecutive PT cycles;

(4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(5) For the confirmatory drug tests, obtain no more than one drug concentration on a PT sample that differs by more than ±50 percent from the appropriate reference or peer group mean over two consecutive PT cycles;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over two consecutive PT cycles;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two consecutive PT cycles;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over two consecutive PT cycles that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than ±20 percent or ±2 standard deviations from the appropriate reference or peer group mean;

(ii) pH values are no more than ±0.3 pH units from the appropriate reference or peer group mean using a pH meter; and

(iii) Specific gravity values are no more than ±0.0003 specific gravity units from the appropriate reference or peer group mean when the mean is less than 1.0100 and specific gravity values are no more than ±0.0004 specific gravity units from the appropriate reference or peer group mean when the mean is equal to or greater than 1.0100;

(10) Obtain no more than one quantitative value over 2 consecutive PT cycles on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for nitrite and creatinine concentrations, ±0.8 pH units using a pH meter, ±0.0006 specific gravity units when the mean is less than 1.0100, or ±0.0007 specific gravity units when the mean is equal to or greater than 1.0100; and

(11) Do not report any PT sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the appropriate reference or peer group mean is within the acceptable pH range, or substituted when the appropriate reference or peer group means for both creatinine and specific gravity are within the acceptable range.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

Section 9.8 What are the PT requirements for an applicant IITF?

(a) An applicant IITF that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Correctly identify at least 90 percent of the total drug challenges over the three sets of PT samples;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over the three sets of PT samples;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(5) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total specimen validity test challenges over the three sets of PT samples that satisfy the following criteria:

(i) Creatinine concentrations are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than ±0.001 specific gravity units from the appropriate reference or peer group mean; and

(6) Must not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for creatinine concentration, or ±0.002 specific gravity units for specific gravity.

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.9 What are the PT requirements for an HHS-certified IITF?

(a) An IITF certified under these Guidelines must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Correctly identify at least 90 percent of the total drug challenges over two consecutive PT cycles;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over two consecutive PT cycles;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over two consecutive PT cycles;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two consecutive PT cycles;

(5) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total specimen validity test challenges over two consecutive PT cycles that satisfy the following criteria:

(i) Creatinine concentrations are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than ±0.001 specific gravity units from the appropriate reference or peer group mean; and

(6) Obtain no more than one quantitative value over 2 consecutive PT cycles on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than ±50 percent for creatinine concentration, or ±0.002 specific gravity units for specific gravity.

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified IITF's certification.

Section 9.10 What are the inspection requirements for an applicant laboratory or IITF?

(a) An applicant laboratory or IITF is inspected by a team of 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.

Section 9.11 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 at least every 6 months thereafter.

(b) An HHS-certified laboratory or IITF is inspected by one or more inspectors. The number of inspectors is determined according to the number of specimens reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's or IITF's procedures, records, 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.

Section 9.12 Who can inspect an HHS-certified laboratory or IITF and when may the inspection be conducted?

(a) An individual may be selected as an inspector for the Secretary if they satisfy the following criteria:

(1) Has experience and an educational background similar to that required for either a responsible person or a certifying scientist for an HHS-certified laboratory as described in Subpart K or as a responsible technician for an HHS-certified IITF as described in Subpart L;

(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) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory or IITF.

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

Section 9.13 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 laboratory or IITF must start the certification process from the beginning.

Section 9.14 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 deficiency) to provide any explanation for its performance and evidence that all deficiencies have been corrected.

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

(c) An HHS-certified laboratory or IITF may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

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

Section 9.15 What factors are considered in determining whether revocation of a laboratory's or IITF's HHS certification is necessary?

(a) The Secretary shall revoke certification of an HHS-certified laboratory or IITF in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug and specimen validity test results and reports.

(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 specimen validity tests (*e.g.,* an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

(3) A material violation of a certification standard, contract term, or other condition imposed on the HHS-certified 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 HHS-certified laboratory or IITF; or

(5) Any other cause that materially affects the ability of the HHS-certified laboratory or IITF to ensure fully reliable and accurate drug test results and reports.

(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 testing.

Section 9.16 What factors are considered in determining whether to suspend a laboratory's or IITF's HHS certification?

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's or IITF's HHS certification to conduct drug testing for federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

Section 9.17 How does the Secretary notify an HHS-certified laboratory or IITF that action is being taken against the laboratory or IITF?

(a) When laboratory's or IITF's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified 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 P 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 HHS-certified laboratory or IITF that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any HHS-certified 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 HHS 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 P.

Section 9.18 May a laboratory or IITF that had its HHS 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 9.17 or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory or IITF which has had its certification revoked may reapply for HHS certification as an applicant laboratory or IITF.

Section 9.19 Where is the list of HHS-certified laboratories and IITFs published?

(a) The list of HHS-certified laboratories and IITFs is published monthly in the **Federal Register**. This notice is also available on the Internet at *http://www.samhsa.gov/workplace.*

(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 submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory or IITF that the collector sends employee specimens.

(b) Each federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency must be negative, 15 percent must be positive for one or more drugs, and 10 percent must either be adulterated or substituted.

Section 10.2 What are the requirements for blind samples?

(a) Drug positive blind samples must be validated by the supplier as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must be fortified with one or more of the drugs or metabolites listed in Section 3.4.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff concentration.

(b) Drug negative blind samples (*i.e.,* certified to contain no drugs) must be validated by the supplier as negative using appropriate initial and confirmatory tests.

(c) A blind sample that is adulterated must be validated using appropriate initial and confirmatory specimen validity tests, and have the characteristics to clearly show that it is an adulterated sample at the time of validation.

(d) A blind sample that is substituted must be validated using appropriate initial and confirmatory specimen validity tests, and have the characteristics to clearly show that it is a substituted sample at the time of validation.

(e) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory or IITF, and must provide the information upon request to the MRO, the federal agency for which the blind sample was submitted, or the Secretary.

Section 10.3 How is a blind sample submitted to an HHS-certified laboratory or IITF?

(a) A blind sample must be submitted as a split specimen (specimens A and B) with the current Federal CCF that the HHS-certified laboratory or IITF uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

Section 10.4 What happens if an inconsistent result is reported for a blind sample?

If an HHS-certified laboratory or IITF reports a result for a blind sample that is inconsistent with the expected result (*e.g.,* a laboratory or IITF reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory or IITF and attempt to determine if the laboratory or IITF made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory or IITF;

(d) 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

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the federal agency. The Secretary shall ensure notification of the finding as appropriate to other federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

Subpart K—Laboratory

Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, 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, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

Section 11.2 What are the responsibilities of the responsible person (RP)?

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: Quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 11.3 What scientific qualifications must the RP have?

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or 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) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (*e.g.,* publications, court testimony, conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated 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 RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated 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.

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: The candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as required prior to conducting federally regulated 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) A certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?

(a) All HHS-certified laboratory staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(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, including training in forensic procedures related to their job duties) before they are permitted to work independently with federally regulated specimens. All training must be documented.

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 (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 11.9 What test(s) does an HHS-certified laboratory conduct on a urine specimen received from an IITF?

An HHS-certified laboratory must test the specimen in the same manner as a specimen that had not been previously tested.

Section 11.10 What are the requirements for an initial drug test?

(a) An initial drug test may be:

(1) An immunoassay or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified laboratory must validate an initial drug test before testing specimens.

(c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.

(d) An HHS-certified laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.12.

Section 11.11 What must an HHS-certified laboratory do to validate an initial drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff concentration, using samples at several concentrations between 0 and 150 percent of the cutoff concentration;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 11.12 What are the batch quality control requirements when conducting an initial drug test?

(a) Each batch of specimens must contain the following controls:

(1) At least one control certified to contain no drug or drug metabolite;

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

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

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.13 What are the requirements for a confirmatory drug test?

(a) The analytical method must use mass spectrometric identification [*e.g.,* gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS] or equivalent.

(b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.

(c) Confirmatory drug tests must be accurate and reliable for the testing of a urine specimen when identifying and quantifying drugs or their metabolites.

Section 11.14 What must an HHS-certified laboratory do to validate a confirmatory drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each confirmatory drug test:

(1) The linear range of the analysis;

(2) The limit of detection;

(3) The limit of quantification;

(4) The accuracy and precision at the cutoff concentration;

(5) The accuracy (bias) and precision at 40 percent of the cutoff concentration;

(6) The potential for interfering substances;

(7) The potential for carryover; and

(8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

Section 11.15 What are the batch quality control requirements when conducting a confirmatory drug test?

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

(1) A calibrator at the cutoff concentration;

(2) At least one control certified to contain no drug or drug metabolite;

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

(4) At least one control targeted at or less than 40 percent of the cutoff.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.16 What are the analytical and quality control requirements for conducting specimen validity tests?

(a) Each invalid, adulterated, or substituted specimen validity test result must be based on an initial specimen validity test on one aliquot and a confirmatory specimen validity test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results (required specimen validity tests are addressed in Section 11.18); and

(c) Controls must be analyzed concurrently with specimens.

Section 11.17 What must an HHS-certified laboratory do to validate a specimen validity test?

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 11.18 What are the requirements for conducting each specimen validity test?

(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 the following calibrators and controls:

(i) A calibrator at 2 mg/dL;

(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL;

(iii) A control in the range of 3 mg/dL to 20 mg/dL; and

(iv) A control in the range of 21 mg/dL to 25 mg/dL.

(3) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must have the following calibrators and controls:

(i) A calibrator at 2 mg/dL;

(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL; and

(iii) A control in the range of 3 mg/dL to 4 mg/dL.

(b) The requirements for measuring specific gravity are as follows:

(1) For specimens with initial creatinine test results greater than 5 mg/dL and less than 20 mg/dL, laboratories may perform a screening test using a refractometer that measures urine specific gravity to at least three decimal places to identify specific gravity values that are acceptable (equal to or greater than 1.003) or dilute (equal to or greater than 1.002 and less than 1.003). Specimens must be subjected to an initial specific gravity test using a four decimal place refractometer when the initial creatinine test result is less than or equal to 5 mg/dL or when the screening specific gravity test result using a three decimal place refractometer is less than 1.002.

(2) The screening specific gravity test must have the following calibrators and controls:

(i) A calibrator or control at 1.000;

(ii) One control targeted at 1.002;

(iii) One control in the range of 1.004 to 1.018.

(3) For the initial and confirmatory specific gravity tests, 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 paper copy of the digital electronic display to document the numerical values of the specific gravity test results;

(4) The initial and confirmatory specific gravity tests must have the following calibrators and controls:

(i) A calibrator or control at 1.0000;

(ii) One control targeted at 1.0020;

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

(iv) One control equal to or greater than 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 3 to 12 to support the 4 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Colorimetric pH tests, dipsticks, and pH paper (*i.e.,* screening tests) that have a narrow dynamic range and do not support the cutoffs may be used only to determine if an initial pH specimen validity test must be performed;

(2) For the initial and confirmatory pH tests, the pH meter must report and display pH to at least one decimal place. The pH meter must be interfaced with a LIMS, computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the pH test results;

(3) 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;

(4) An initial colorimetric pH test must have the following calibrators and controls:

(i) One calibrator at 4;

(ii) One calibrator at 11;

(iii) One control in the range of 3 to 3.8;

(iv) One control in the range 4.2 to 5;

(v) One control in the range of 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;

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

(i) One calibrator at 3;

(ii) One calibrator at 7;

(iii) One calibrator at 10;

(iv) One control in the range of 3 to 3.8;

(v) One control in the range 4.2 to 5;

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

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

(6) An initial pH meter test (if a pH screening test is used) or confirmatory pH meter test must have the following calibrators and controls when the result of the preceding pH test 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 3 to 3.8; and

(iv) One control in the range 4.2 to 5; and

(7) An initial pH meter test (if a pH screening test is used) or confirmatory pH meter test must have the following calibrators and controls when the result of the preceding pH test 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 11.19(d)(2), (3), or (4) 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 250 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL.

Section 11.19 What are the requirements for an HHS-certified laboratory to report a test result?

(a) Laboratories must report a test result to the agency's MRO within an average of 5 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or if the specimen is negative upon confirmatory drug testing, and the specimen does not meet invalid criteria as described in items (h)(1) through (h)(12) below.

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with Section 3.4.

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

(1) The pH is less than 4 or equal to or greater than 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 equal to or greater than 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 an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 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 equal to or greater than the LOQ 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 an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration equal to or greater than the LOQ) 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 equal to or greater than the LOQ 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 a different confirmatory method (*e.g.,* GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

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

(7) The presence of a surfactant is verified by using a surfactant colorimetric test with an equal to or greater than 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 an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(8) The presence of any other adulterant not specified in paragraphs d(2) through d(7) 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 (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 equal to or greater than 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 (A) urine specimen is reported dilute when the creatinine concentration is equal to or greater than 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) For a specimen that has an invalid result for one of the reasons stated in items (h)(4) through (h)(12) below, the HHS-certified laboratory shall contact the MRO and both will decide if testing by another HHS-certified laboratory would be useful in being able to report a positive or adulterated result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

(h) A primary (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 equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(2) The pH is equal to or greater than 4 and less than 4.5 or equal to or greater than 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 equal to or greater than 200 mcg/mL using a nitrite colorimetric test or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial (first) test and the second test or using

either initial test and the nitrite concentration is equal to or greater than 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 equal to or greater than 50 mcg/mL chromium (VI) for both the initial (first) test and the second 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 equal to or greater than the LOQ for both the initial (first) test and the second 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 (first) test and the second test on two separate aliquots;

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

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

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

(10) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the HHS-certified laboratory is unable to identify the interfering substance;

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

(12) The physical appearances of the A and B specimens are clearly different (note: A is tested).

(i) An HHS-certified laboratory shall reject a primary (A) specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified 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.

(j) An HHS-certified laboratory must report all positive, adulterated, substituted, and invalid test results for a urine specimen. For example, a specimen can be positive for a specific drug and adulterated.

(k) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported for a positive result.

(l) An HHS-certified laboratory must report numerical values of the specimen validity test results that support a specimen that is reported adulterated, substituted, or invalid (as appropriate).

(m) When the concentration of a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than ''insert the actual value for the upper limit of the linear range,'' or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method's linear range and multiplying the result by the appropriate dilution factor.

(n) HHS-certified laboratories may transmit test results to the MRO by various electronic means (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(o) HHS-certified laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(p) For positive, adulterated, substituted, invalid, and rejected specimens, laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 11.20 How long must an HHS-certified laboratory retain specimens?

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, substituted, or as an invalid result for a minimum of 1 year.

(b) Retained specimens must be kept in secured frozen storage (− 20 °C or less) to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the 1-year period.

Section 11.21 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. The laboratory may convert hardcopy records to electronic records for storage and then discard the hardcopy records after 6 months.

(b) A federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.23) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal 2-year period of time.

Section 11.22 What statistical summary reports must an HHS-certified laboratory provide for urine testing?

(a) HHS-certified laboratories must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, facsimile, or email within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified laboratory name and address;

(3) Federal agency name;

(4) Number of specimen results reported;
(5) Number of specimens collected by reason for test;
(6) Number of specimens reported negative and the number reported negative/dilute;
(7) Number of specimens rejected for testing because of a fatal flaw;
(8) Number of specimens rejected for testing because of an uncorrected flaw;
(9) Number of specimens tested positive by each initial drug test;
(10) Number of specimens reported positive;
(11) Number of specimens reported positive for each drug and drug metabolite;
(12) Number of specimens reported adulterated;
(13) Number of specimens reported substituted; and
(14) Number of specimens reported as invalid result.
(b) An HHS-certified laboratory must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the laboratory is performing drug-testing services.
(c) An HHS-certified laboratory must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the laboratory.

Section 11.23 What HHS-certified laboratory information is available to a federal agency?

(a) Following a federal agency's receipt of a positive, adulterated, or substituted drug test report, the federal agency may submit a written request for copies of the records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.
(b) Standard documentation packages provided by an HHS-certified laboratory must contain the following items:
(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;
(2) A table of contents that lists all documents and materials in the package by page number;
(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified laboratory, and a copy of the electronic report (if any) generated by the HHS-certified laboratory;
(4) A brief description of the HHS-certified laboratory's initial drug and specimen validity testing procedures, instrumentation, and batch quality control requirements;
(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the initial tests;
(6) A brief description of the HHS-certified laboratory's confirmatory drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;
(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the confirmatory tests; and
(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

Section 11.24 What HHS-certified laboratory information is available to a federal employee?

A federal employee who is the subject of a workplace drug test may submit a written request through the MRO and/or the federal agency requesting copies of any records relating to the employee's drug test results or a documentation package as described in Section 11.23(b) and any relevant certification, review, or revocation of certification records. Federal employees, or their designees, are not permitted access to their specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines.

Section 11.25 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

An HHS-certified laboratory must not enter into any relationship with a federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a federal agency use a specific MRO.

This means 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 HHS-certified 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 HHS-certified laboratory or have any agreement with an HHS-certified laboratory that may be construed as a potential conflict of interest.

Section 11.26 What type of relationship can exist between an HHS-certified laboratory and an HHS-certified IITF?

An HHS-certified laboratory can enter into any relationship with an HHS-certified IITF.

Subpart L—Instrumented Initial Test Facility (IITF)

Section 12.1 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 HHS-certified IITF operations. When followed, the SOP manual ensures that all specimens are tested consistently using the same procedures.
(b) The SOP manual must include at a minimum, 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, and laboratory information management systems.
(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.
(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for two years.

Section 12.2 What are the responsibilities of the responsible technician (RT)?

(a) Manage the day-to-day operations of the HHS-certified IITF even if another individual has overall responsibility for alternate areas of a multi-specialty facility.
(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified IITF. The RT must ensure the continued competency of IITF personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.
(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified IITF, and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RT when procedures are

first placed into use or changed or when a new individual assumes responsibility for the management of the HHS-certified IITF. The SOP must be reviewed and documented by the RT annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) *Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified IITF in response to the following:* Quality control systems not within performance specifications, errors in result reporting or in analysis of performance testing samples, and inspection deficiencies. The RT must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 12.3 What qualifications must the RT have?

An RT must:

(a) Have at least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(b) Have training and experience in the analytical methods and forensic procedures used by the HHS-certified IITF;

(c) Have training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise;

(d) Be found to fulfill RT responsibilities and qualifications, as demonstrated by the HHS-certified IITF's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying technician.

Section 12.4 What happens when the RT is absent or leaves an HHS-certified IITF?

(a) HHS-certified IITFs must have an RT and an alternate RT. When an RT is absent, an alternate RT must be present and qualified to fulfill the responsibilities of the RT.

(1) If an HHS-certified IITF is without the RT and alternate RT for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, business trip), the HHS-certified IITF may continue operations and testing of federal agency specimens under the direction of a certifying technician.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's HHS certification for all specimens if the IITF does not have an RT or alternate RT for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RT or alternate RT.

(b) If the RT leaves an HHS-certified IITF:

(1) The HHS-certified IITF may maintain certification and continue testing federally regulated 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 RT's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend an IITF's HHS certification for all federally regulated specimens if the IITF does not have a permanent RT within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RT.

(c) *To nominate an individual as the RT or alternate RT, the HHS-certified IITF must submit the following documents to the Secretary:* The candidate's current résumé or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RT qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified IITF.

(d) The HHS-certified IITF must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RT.

Section 12.5 What qualifications must an individual have to certify a result reported by an HHS-certified IITF?

A certifying technician must have:

(a) Training and experience in the analytical methods and forensic procedures used by the HHS-certified IITF relevant to the results that the individual certifies; and

(b) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 12.6 What qualifications and training must other personnel of an HHS-certified IITF have?

(a) All HHS-certified IITF staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified IITF must be properly trained (*i.e.,* receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before they are permitted to work independently with federally regulated specimens. All training must be documented.

Section 12.7 What security measures must an HHS-certified IITF maintain?

(a) An HHS-certified IITF 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 (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified IITF must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for the access to the secured area.

Section 12.8 What are the IITF chain of custody requirements for specimens and aliquots?

(a) HHS-certified IITFs must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the IITF through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified IITFs must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 12.9 What are the requirements for an initial drug test?

(a) An initial drug test may be:
(1) An immunoassay or
(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).
(b) An HHS-certified IITF must validate an initial drug test before testing specimens;
(c) Initial drug tests must be accurate and reliable for the testing of urine specimens when identifying drugs or their metabolites.
(d) An HHS-certified IITF may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 12.11.

Section 12.10 What must an HHS-certified IITF do to validate an initial drug test?

(a) An HHS-certified IITF must demonstrate and document the following for each initial drug test:
(1) The ability to differentiate negative specimens from those requiring further testing;
(2) The performance of the test around the cutoff concentration, using samples at several concentrations between 0 and 150 percent of the cutoff concentration;
(3) The effective concentration range of the test (linearity);
(4) The potential for carryover;
(5) The potential for interfering substances; and
(6) The potential matrix effects if using an alternate technology.
(b) Each new lot of reagent must be verified prior to being placed into service.
(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 12.11 What are the batch quality control requirements when conducting an initial drug test?

(a) Each batch of specimens must contain the following calibrators and controls:
(1) At least one control certified to contain no drug or drug metabolite;
(2) At least one positive control with the drug or drug metabolite targeted at a concentration 25 percent above the cutoff;
(3) At least one control with the drug or drug metabolite targeted at a concentration 75 percent of the cutoff; and
(4) At least one control that appears as a donor specimen to the analysts.
(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 12.12 What are the analytical and quality control requirements for conducting specimen validity tests?

(a) Each specimen validity test result must be based on performing a single test on one aliquot;
(b) The HHS-certified IITF must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results in accordance with Section 12.14; and
(c) Controls must be analyzed concurrently with specimens.

Section 12.13 What must an HHS-certified IITF do to validate a specimen validity test?

An HHS-certified IITF must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 12.14 What are the requirements for conducting each specimen validity test?

(a) The requirements for measuring creatinine concentration are as follows:
(1) The creatinine concentration must be measured to one decimal place on the test;
(2) The creatinine test must have the following calibrators and controls:
(i) A calibrator at 2 mg/dL;
(ii) A control in the range of 1.0 mg/dL to 1.5 mg/dL;
(iii) A control in the range of 3 mg/dL to 20 mg/dL; and
(iv) A control in the range of 21 mg/dL to 25 mg/dL.
(b) The requirements for measuring specific gravity are as follows:
(1) For specimens with creatinine test results greater than 5 mg/dL and less than 20 mg/dL, an IITF must perform a screening test using a refractometer to identify specific gravity values that are acceptable (equal to or greater than1.003) or dilute (equal to or greater than1.002 and less than1.003). Specimens must be forwarded to an HHS-certified laboratory when the creatinine test result is less than or equal to 5 mg/dL or when the screening specific gravity test result is less than 1.002.
(2) The screening specific gravity test must have the following calibrators and controls:
(i) A calibrator or control at 1.000;
(ii) One control targeted at 1.002; and
(iii) One control in the range of 1.004 to 1.018.
(c) The requirements for measuring pH are as follows:
(1) The IITF may perform the pH test using a pH meter, colorimetric pH test, dipsticks, or pH paper. Specimens must be forwarded to an HHS-certified laboratory when the pH is less than 4.5 or equal to or greater than 9.0.
(2) The pH test must have, at a minimum, the following calibrators and controls:
(i) One control below 4.5;
(ii) One control between 4.5 and 9.0;
(iii) One control above 9.0; and
(iv) One or more calibrators as appropriate for the test. For a pH meter: calibrators at 4, 7, and 10.
(d) The requirements for measuring the nitrite concentration are that the nitrite test must have a calibrator at 200 mcg/mL nitrite, a control without nitrite (*i.e.,* certified negative urine), one control in the range of 200 mcg/mL to 250 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL. Specimens with a nitrite concentration equal to or greater than 200 mcg/mL must be forwarded to an HHS-certified laboratory; and,
(e) Requirements for performing oxidizing adulterant tests are that the test must include an appropriate calibrator at the cutoff specified in Sections 11.19(d)(3), (4), or (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. Specimens with an oxidizing adulterant result equal to or greater than the cutoff must be forwarded to an HHS-certified laboratory.

Section 12.15 What are the requirements for an HHS-certified IITF to report a test result?

(a) An HHS-certified IITF must report a test result to the agency's MRO within an average of 3 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying technician.
(b) A primary (A) specimen is reported negative when each drug test is negative and each specimen validity test result indicates that the specimen is a valid urine specimen.
(c) A primary (A) urine specimen is reported dilute when the creatinine concentration is greater than 5 mg/dL but less than 20 mg/dL and the specific gravity is equal to or greater than 1.002 but less than 1.003.
(d) An HHS-certified IITF shall reject a urine specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described

in Section 15.2 is not recovered. The HHS-certified IITF will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(e) HHS-certified IITFs may transmit test results to the MRO by various electronic means (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. IITFs and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(f) HHS-certified IITFs must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(g) For rejected specimens, IITFs must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 12.16 How does an HHS-certified IITF handle a specimen that tested positive, adulterated, substituted, or invalid at the IITF?

(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; and

(c) The resealed specimen and split specimen and the Federal CCF are sealed in a leak-proof plastic bag, and are sent to an HHS-certified laboratory under chain of custody within one day after completing the drug and specimen validity tests.

Section 12.17 How long must an HHS-certified IITF retain a specimen?

A specimen that is negative, negative/dilute, or rejected for testing is discarded.

Section 12.18 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. The IITF may convert hardcopy records to electronic records for storage and then discard the hardcopy records after six months.

(b) A federal agency may request the HHS-certified IITF to maintain a documentation package (as described in Section 12.20) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the IITF must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified IITF may retain records other than those included in the documentation package beyond the normal two-year period of time.

Section 12.19 What statistical summary reports must an HHS-certified IITF provide?

(a) HHS-certified IITFs must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, facsimile, or email within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified IITF name and address;

(3) Federal agency name;

(4) Total number of specimens tested;

(5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative and the number reported negative/dilute;

(7) Number of specimens rejected for testing because of a fatal flaw;

(8) Number of specimens rejected for testing because of an uncorrected flaw;

(9) Number of specimens tested positive by each initial drug test; and

(10) Number of specimens forwarded to an HHS-certified laboratory for testing.

(b) An HHS-certified IITF must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the IITF is performing drug-testing services.

(c) An HHS-certified IITF must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the IITF.

Section 12.20 What HHS-certified IITF information is available to a federal agency?

(a) Following a federal agency's receipt of a positive, adulterated, or substituted drug test report from a laboratory, the federal agency may submit a written request for copies of the IITF records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified IITF must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified IITF, and a copy of the electronic report (if any) generated by the HHS-certified IITF;

(4) A brief description of the HHS-certified IITF's drug and specimen validity testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of all test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the tests; and

(6) Copies of the résumé or curriculum vitae for the RT and for the certifying technician of record.

Section 12.21 What HHS-certified IITF information is available to a federal employee?

A federal employee who is the subject of a drug test may provide a written request through the MRO and/or the federal agency requesting access to any records relating to the employee's drug test results or a documentation package (as described in Section 12.20) and any relevant certification, review, or revocation of certification records.

Section 12.22 What types of relationships are prohibited between an HHS-certified IITF and an MRO?

An HHS-certified IITF must not enter into any relationship with a federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a federal agency use a specific MRO.

This means 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 HHS-certified IITF 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 HHS-certified IITF or have any agreement with an HHS-certified IITF that may be construed as a potential conflict of interest.

Section 12.23 What type of relationship can exist between an HHS-certified IITF and an HHS-certified laboratory?

An HHS-certified IITF can enter into any relationship with an HHS-certified laboratory.

Subpart M—Medical Review Officer (MRO)

Section 13.1 Who may serve as an MRO?

(a) A currently licensed physician who has:

(1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;

(2) Knowledge regarding the pharmacology and toxicology of illicit drugs;

(3) The training necessary to serve as an MRO as set out in Section 13.3;

(4) Satisfactorily passed an initial examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs; and

(5) At least every five years from initial certification, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

Section 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (*e.g.,* answers, previous examination statistics or other background examination information, if requested). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and content of the examination. Each approved MRO certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notice in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notice is also available on the Internet at *http://www.samhsa.gov/workplace/drug-testing.*

Section 13.3 What training is required before a physician may serve as an MRO?

(a) A physician must receive training that includes a thorough review of the following:

(1) The collection procedures used to collect federal agency specimens;

(2) How to interpret test results reported by HHS-certified IITFs and laboratories (*e.g.,* negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);

(3) Chain of custody, reporting, and recordkeeping requirements for federal agency specimens;

(4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types; and

(5) Procedures for interpretation, review (*e.g.,* donor interview for legitimate medical explanations, review of documentation provided by the donor to support a legitimate medical explanation), and reporting of results specified by any federal agency for which the individual may serve as an MRO;

(b) Certified MROs must complete training on any revisions to these Guidelines prior to their effective date, to continue serving as an MRO for federal agency specimens.

Section 13.4 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and (for urine) substituted test results.

(b) Staff under the direct, personal supervision of the MRO may review and report negative and (for urine) negative/dilute test results to the agency's designated representative. The MRO must review at least 5 percent of all negative results reported by the MRO staff to ensure that the MRO staff are properly performing the review process.

(c) The MRO must discuss potential invalid results with the HHS-certified laboratory, as addressed in Section 11.19(g) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) HHS-certified IITF, 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 or HHS-certified IITF;

(2) Interview the donor when required;

(3) Make a determination regarding the test result; and

(4) Report the verified result to the federal agency.

(e) The MRO must maintain records for a minimum of two years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records for storage and discard the hardcopy records after six months.

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen, as addressed in Section 8.6.

Section 13.5 What must an MRO do when reviewing a urine specimen's test results?

(a) When the HHS-certified laboratory or HHS-certified IITF reports a negative result for the primary (A) specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory or HHS-certified IITF reports a negative/dilute result for the primary (A) urine specimen, the MRO reports a negative/dilute result to the agency and directs the agency to immediately collect another specimen from the donor.

(1) If the recollected specimen provides a negative or negative/dilute result, the MRO reports a negative result to the agency, with no further action required.

(2) If the recollected specimen provides a result other than negative or negative/dilute, the MRO follows the procedures in 13.5(c) through (f) for the recollected specimen.

(c) When the HHS-certified laboratory reports multiple results for the primary (A) urine specimen, as the MRO, you must follow the verification procedures described in 13.5(c) through (f) and:

(1) Report all verified positive and/or refusal to test results to the federal agency.

(2) If an invalid result was reported in conjunction with a positive, adulterated, or substituted result, do not report the verified invalid result to the federal agency at this time. The MRO reports the verified invalid result(s) for the primary (A) urine specimen only if the split specimen is tested and reported as a failure to reconfirm as described in Section 14.6(l).

(d) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor provides documentation (*e.g.,* a valid

prescription) to support a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency. If the laboratory also reports that the urine specimen is dilute, the MRO reports a negative/dilute result to the agency and directs the agency to immediately collect another specimen from the donor. The MRO follows the procedures in 13.5(b)(1) or (2) for the recollected specimen.

(i) Passive exposure to marijuana smoke is not a legitimate medical explanation for a positive THCA result.

(ii) Ingestion of food products containing marijuana is not a legitimate medical explanation for a positive THCA result.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a positive result to the agency for all drugs except codeine and/or morphine (see below). If the laboratory also reports that the urine specimen is dilute, the MRO may choose not to report the dilute result.

(i) For codeine and/or morphine less than 15,000 ng/mL and no legitimate medical explanation: the MRO must determine if there is clinical evidence of illegal use (in addition to the test result) to report a positive result to the agency. If there is no clinical evidence of illegal use, the MRO reports a negative result to the agency. 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).

(ii) For codeine and/or morphine equal to or greater than 15,000 ng/mL and no legitimate medical explanation: the MRO reports a positive result to the agency. 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 the HHS-certified laboratory reports an adulterated or substituted result for the primary (A) urine specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated or substituted result.

(1) If the donor provides a legitimate medical explanation, the MRO reports a negative result to the federal agency.

(2) If the donor is unable to provide a legitimate explanation, the MRO reports a refusal to test to the federal agency because the urine specimen was adulterated or substituted.

(f) When the HHS-certified laboratory reports an invalid result for the primary (A) urine specimen, the MRO must contact the donor to determine if there is a legitimate explanation for the invalid result. In the case of an invalid result based on pH of 9.0 to 9.5, when an employee has no other medical explanation for the pH in this range, the MRO must consider whether there is evidence of elapsed time and high temperature that could account for the pH value. The MRO may contact the collection site, HHS-certified IITF, and/or HHS-certified laboratory to discuss time and temperature issues (*e.g.,* time elapsed from collection to receipt at the testing facility, likely temperature conditions between the time of the collection and transportation to the testing facility, specimen storage conditions).

(1) If the donor provides a legitimate explanation (*e.g.,* a prescription medication) or if the MRO determines that time and temperature account for the pH in the 9.0 to 9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and informs the federal agency that a recollection is not required because there is a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate explanation or if the MRO determines that time and temperature fail to account for the pH in the 9.0—9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and directs the federal agency to immediately collect another urine specimen from the donor using a direct observed collection.

(i) If the specimen collected under direct observation provides a valid result, the MRO follows the procedures in 13.5(a) through (e).

(ii) If the specimen collected under direct observation provides an invalid result, the MRO reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (*e.g.,* oral fluid).

(g) When two separate specimens collected during the same testing event were sent to the HHS-certified laboratory for testing (*e.g.,* the collector sent a urine specimen out of temperature range and the subsequently collected specimen—urine or another authorized specimen type), as the MRO, you must follow the verification procedures described in Sections 13.4, 13.5, and 13.6, and:

(1) If both specimens were verified negative, report the result as negative.

(2) If one specimen was verified negative and the other was not (*i.e.,* the specimen was verified as negative/dilute or as positive, adulterated, substituted, and/or invalid), report only the verified result(s) other than negative. For example, if you verified one specimen as negative and the other as a refusal to test because the specimen was substituted, report only the refusal to the federal agency.

(3) If both specimens were verified as positive, adulterated, and/or substituted, report all results. For example, if you verified one specimen as positive and the other as a refusal to test because the specimen was adulterated, report the positive and the refusal results to the federal agency.

(4) If one specimen has been verified and the HHS-certified laboratory has not reported the result(s) of the other specimen,

(i) Report verified result(s) of positive, adulterated, or substituted immediately and do not wait to receive the result(s) of the other specimen.

(ii) Do not report a verified result of negative, negative/dilute, or invalid for the first specimen to the federal agency. Hold the report until results of both specimens have been received and verified.

(5) When the HHS-certified laboratory reports an invalid result for one or both specimens, follow the procedures in paragraph c above.

(h) When the HHS-certified laboratory or HHS-certified IITF reports a rejected for testing result for the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor. The recollected specimen must be the same type (*i.e.,* urine).

Section 13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of urine for a drug test?

(a) When another specimen type (*e.g.,* oral fluid) was collected as authorized by the federal agency, the MRO reviews and reports the test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(b) When the federal agency did not authorize the collection of an alternative specimen, the MRO consults with the federal agency. The federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. The MRO may perform this evaluation if the MRO has appropriate expertise.

(1) For purposes of this section, a medical condition includes an ascertainable physiological condition (*e.g.,* a urinary system dysfunction) or a medically documented pre-existing

psychological disorder, but does not include unsupported assertions of ''situational anxiety'' or dehydration. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time. Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on genitourinary matters. Acute or temporary medical conditions, such as cystitis, urethritis or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in the previous sentence.

(2) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of urine to complete the test;

(ii) The consequences of the appropriate federal agency regulation for refusing to take the required drug test;

(iii) That, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in paragraph (b)(3) of this section and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the federal agency in writing:

(i) A medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the federal agency.

(ii) A permanent or long-term medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine and is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the federal agency and recommend that the agency authorize collection of an alternative specimen type (*e.g.,* oral fluid) for any subsequent drug tests for the donor.

(iii) There is not an adequate basis for determining that a medical condition has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, you must report a refusal to test to the federal agency.

(4) When a federal agency receives a report from the MRO indicating that a test is cancelled as provided in paragraph (b)(3)(i) of this section, the agency takes no further action with respect to the donor. When a test is canceled as provided in paragraph (b)(3)(ii) of this section, the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (*i.e.,* authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the federal agency plan. The donor remains in the random testing pool.

13.7 What happens when an individual is unable to provide a sufficient amount of urine for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which the donor has a medical condition that precludes the donor from providing a sufficient specimen for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test and the condition involves a permanent or long-term disability and the federal agency does not authorize collection of an alternative specimen. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.6.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and for the determination that no signs and symptoms of drug use exist. The MRO recommends that the agency authorize collection of an alternate specimen type (*e.g.,* oral fluid) for any subsequent collections.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state that a permanent or long-term medical condition [as defined in Section 13.6(b)(1)] exists, making provision of a sufficient urine specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*e.g.,* the federal agency is not authorized to allow the donor to begin or resume performing official functions, because a negative test is needed for that purpose).

Section 13.8 Who may request a test of a split (B) specimen?

(a) For a positive, adulterated, or substituted result reported on a primary (A) specimen, a donor may request through the MRO that the split (B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that the donor's specimen was reported positive, adulterated, or (for urine) substituted to request a test of the split (B) specimen. The MRO must inform the donor that the donor has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or (for urine) substituted result is being reported to the federal agency on the primary (A) specimen.

Section 13.9 How does an MRO report a primary (A) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(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 copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and (for urine) substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

Section 13.10 What types of relationships are prohibited between an MRO and an HHS-certified laboratory or an HHS-certified IITF?

An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory or an HHS-certified IITF for which the MRO is reviewing drug test results.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory or HHS-certified IITF, or have any agreement with the HHS-certified laboratory or the HHS-certified IITF that may be construed as a potential conflict of interest.

Subpart N—Split Specimen Tests

Section 14.1 When may a split (B) specimen be tested?

(a) The donor may request, verbally or in writing, through the MRO that the split (B) specimen be tested at a different (*i.e.,* second) HHS-certified laboratory when the primary (A) specimen was determined by the MRO to be positive, adulterated, or (for urine) substituted.

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The MRO must document in the MRO's records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) urine specimen cannot be tested by a second HHS-certified laboratory (*e.g.,* insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory available to perform the test), the MRO reports to the federal agency that the test must be cancelled and the reason for the cancellation. The MRO directs the federal agency to ensure the immediate recollection of another urine specimen from the donor under direct observation, with no notice given to the donor of this collection requirement until immediately before the collection.

(d) If a donor chooses not to have the split (B) specimen tested by a second HHS-certified laboratory, a federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or (for urine) substituted result.

Section 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoff concentrations established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (A) specimen.

(c) For a split (B) urine specimen, if the second HHS-certified laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first HHS-certified laboratory, the second laboratory must conduct specimen 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 specimen validity tests as it would conduct on a primary (A) urine specimen and reports those results to the MRO.

Section 14.3 How does an HHS-certified laboratory test a split (B) urine specimen when the primary (A) specimen was reported adulterated?

(a) An HHS-certified laboratory must use one of the following criteria to reconfirm an adulterated result when testing a split (B) urine specimen:

(1) pH must be measured using the laboratory's confirmatory pH test with the appropriate cutoff (*i.e.,* either less than 4 or equal to or greater than 11);

(2) Nitrite must be measured using the laboratory's confirmatory nitrite test with a cutoff concentration of equal to or greater than 500 mcg/mL;

(3) Surfactant must be measured using the laboratory's confirmatory surfactant test with a cutoff concentration of equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff; or

(4) For adulterants without a specified cutoff (*e.g.,* glutaraldehyde, chromium (VI), pyridine, halogens (such as, bleach, iodine), peroxidase, peroxide, other oxidizing agents), the laboratory must use its confirmatory specimen validity test at an established limit of quantification (LOQ) to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

Section 14.4 How does an HHS-certified laboratory test a split (B) urine specimen when the primary (A) specimen was reported substituted?

(a) An HHS-certified laboratory must use the following criteria to reconfirm a substituted result when testing a split (B) urine 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 or equal to 1.0010 or equal to or greater than 1.0200.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the substituted result reported by the first HHS-certified laboratory.

Section 14.5 Who receives the split (B) specimen result?

The second HHS-certified laboratory must report the result to the MRO.

Section 14.6 What action(s) does an MRO take after receiving the split (B) urine specimen result from the second HHS-certified laboratory?

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split (B) 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 specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (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.

(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 (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 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 give 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 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 14.7 How does an MRO report a split (B) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(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 copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

Section 14.8 How long must an HHS-certified laboratory retain a split (B) specimen?

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for the primary (A) specimen.

Subpart O—Criteria for Rejecting a Specimen for Testing

Section 15.1 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing?

The following discrepancies are considered to be fatal flaws. The HHS-certified 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 when:

(a) The specimen ID number on the primary (A) or split (B) 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 either specimen label/seal;

(b) The primary (A) specimen label/seal is missing, misapplied, broken, or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;

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

(d) There is an insufficient amount of specimen for analysis in the primary (A) specimen unless the split (B) specimen can be re-designated as the primary (A) specimen;

(e) The accessioner failed to document the primary (A) specimen seal condition on the Federal CCF at the time of accessioning, and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(f) The specimen was received at the HHS-certified laboratory or IITF without a CCF;

(g) The CCF was received at the HHS-certified laboratory or IITF without a specimen;

(h) The collector performed two separate collections using one CCF; or

(i) The HHS-certified laboratory or IITF identifies a flaw (other than those specified above) that prevents testing or affects the forensic defensibility of the drug test and cannot be corrected.

Section 15.2 What discrepancies require an HHS-certified laboratory or an HHS-certified IITF to report a specimen as rejected for testing unless the discrepancy is corrected?

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified 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 HHS-certified laboratory or IITF may report the test result for the specimen. If, after holding the specimen for at least 5 business days, the HHS-certified 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 HHS-certified 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, after holding the specimen for at least 5 business days, the HHS-certified 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 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory or an HHS-certified IITF to reject a urine specimen for testing or an MRO to cancel a test?

(a) The following omissions and discrepancies on the Federal CCF that are received by the HHS-certified laboratory or IITF should not cause an HHS-certified laboratory or IITF to reject a urine specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appearing 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 Social Security Number or employee identification number;

(6) A telephone 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 HHS-certified laboratory or IITF copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(19) 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, after at least 5 business days, the collector cannot provide a memorandum for record to attest to the fact that the collector did measure the specimen temperature, the HHS-certified laboratory or IITF may report the test result for the specimen but indicates that the collector could not provide a memorandum to recover the omission.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory or IITF 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 their name;

(3) The certifying scientist or certifying technician fails to print their name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies should occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory or 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, HHS-certified laboratory, or HHS-certified IITF (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

Section 15.4 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 Federal CCF for a specimen being reported drug positive, adulterated, invalid, or (for urine) substituted; or

(3) The electronic report provided by the HHS-certified laboratory or HHS-certified IITF does not contain all the data elements required for the HHS standard laboratory or IITF electronic report for a specimen being reported drug positive, adulterated, invalid result, or (for urine) substituted.

(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, after at least 5 business days, 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 certifying scientist that they inadvertently forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 5 business days, the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory or HHS-certified IITF. If, after at least 5 business days, the laboratory or IITF does not retransmit a corrected electronic report, the MRO must cancel the test.

Subpart P—Laboratory or IITF Suspension/Revocation Procedures

Section 16.1 When may the HHS certification of a 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 16.2 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 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 the official's 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 16.3 Are there any limitations 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 relevant 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 16.4 Who represents the parties?

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

Section 16.5 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 16.6 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 16.7 What procedures are 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 testing, which is 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 16.8 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 their 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 the Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date the 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 the official's 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 Federal 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 their 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 16.9 Are there expedited procedures for review of immediate suspension?

(a) *Applicability.* When the Secretary notifies an HHS-certified laboratory or IITF in writing that its certification to perform drug 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 HHS-certified 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, which is 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 16.8(c) and will conduct the oral presentation in accordance with the procedures of Sections 16.8(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 16.14 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, secured electronic transmissions, or overnight mail.

Section 16.10 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 16.11 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, secured electronic transmissions, 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 federal 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 16.12 What are 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 16.13 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 16.14 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 therefore 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 their 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 16.15 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 16.9(e) or 16.14(a) constitutes final agency action and is ripe for judicial review as of the date of the decision.

[FR Doc. 2017–00979 Filed 1–19–17; 8:45 am]

BILLING CODE 4162–20–P

APPENDIX E

Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid [OFMG]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Chapter I

[SAMHSA—4162–20–P]

RIN 0930–AA24

Mandatory Guidelines for Federal Workplace Drug Testing Programs—Oral/Fluid

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

ACTION: Issuance of guidelines.

SUMMARY: The Department of Health and Human Services (''HHS'' or ''Department'') has established scientific and technical guidelines for the inclusion of oral fluid specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines).

DATES: *Effective* January 1, 2020.

FOR FURTHER INFORMATION CONTACT: Charles LoDico, M.S., F–ABFT, Division of Workplace Programs, Center for Substance Abuse Prevention (CSAP), SAMHSA, 5600 Fishers Lane, Room 16N03A, Rockville, MD 20857, telephone (240) 276–2600 or email at *charles.lodico@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) will allow federal executive branch agencies to collect and test an oral fluid specimen as part of their drug testing programs. In addition, some agencies, such as the Department of Transportation, are required to follow the Guidelines in developing drug testing programs for their regulated industries, whereas others, such as the Nuclear Regulatory Commission (NRC), use the Guidelines as part of the regulatory basis for their drug testing programs for their regulated industries. The OFMG establish standards and technical requirements for oral fluid collection devices, initial oral fluid drug test analytes and methods, confirmatory oral fluid drug test analytes and methods, processes for review by a Medical Review Officer (MRO), and requirements for federal agency actions.

The OFMG provide flexibility for federal agency workplace drug testing programs to address testing needs and revise the requirement to collect only a urine specimen, which has existed since the Guidelines were first published in 1988. Since 1988, several products have appeared on the market making it easier for individuals to adulterate their urine specimens. The scientific basis for the use of oral fluid as an alternative specimen for drug testing has now been broadly established and the advances in the use of oral fluid in detecting drugs have made it possible for this alternative specimen to be used in federal programs with the same level of confidence that has been applied to the use of urine. For example, oral fluid collection devices and procedures have been developed that protect against biohazards, maintain the stability of analytes, and provide sufficient oral fluid for testing. Additionally, specimen volume is also much lower, saving time in collection and transport cost. Developments in analytical technologies have provided efficient and cost-effective methods with the analytical sensitivity and accuracy required for testing oral fluid specimens.

Federal agencies, MROs, and regulated industries using the OFMG will continue to adhere to all other federal standards established for workplace drug testing programs. The OFMG provide the same scientific and forensic supportability of drug test results as the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG).

Background

The Department of Health and Human Services, by authority of Section 503 of Public Law 100–71, 5 U.S.C. Section 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in drug testing for federal agencies. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** [FR] on April 11, 1988 [53 FR 11979]. The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858]. The revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) were published on January 23, 2017 [82 FR 7920] with an effective date of October 1, 2017.

The Department published the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) in the May 15, 2015 **Federal Register** (80 FR 28054). There was a 60-day public comment period, during which 120 commenters submitted comments on the OFMG. These commenters were comprised of individuals, organizations, and private sector companies. The comments are available for public view at *http://www.regulations.gov/.* All comments were reviewed and taken into consideration in the preparation of the Guidelines. The issues and concerns raised in the public comments for the OFMG are set forth below. Similar comments are considered together in the discussion.

Summary of Public Comments and HHS's Response

The following comments were directed to the information and questions in the preamble.

Requirements for Specimen Validity Testing

The Department requested comments on requirements for federal agencies to test all oral fluid specimens for either albumin or immunoglobulin G (IgG) to determine specimen validity. Four commenters agreed with the proposed requirements. Twelve commenters disagreed with the Guidelines as written, suggesting that specimen validity testing is not needed because all oral fluid collections are observed, collection procedures require visual inspection of the mouth by the collector and a 10-minute wait period, collection devices contain a volume indicator, and there is a limited volume of oral fluid collected and this volume is needed to complete confirmatory drug tests. One commenter expressed concern over the consequences of erroneous validity test results in relation to inappropriate cutoffs being set. One commenter questioned the proposed specimen validity testing analytes and cutoffs, and proposed that volume sufficiency be determined upon receipt at the laboratory. One commenter disagreed with the proposed IgG cutoff. One commenter disagreed that specimen validity testing should be performed on all specimens, and recommended performing specimen validity testing on a randomly chosen subset. This commenter also stated that specimen validity testing must be subjected to oversight by proficiency testing and blind sample testing programs. The Department has evaluated the comments and has revised the Guidelines to allow, but not require, specimen validity testing. The Department agrees that the OFMG collection procedures greatly minimize the risks of donor attempts to tamper with the specimen, and the volume indicator requirement for oral fluid collection devices should prevent collection of insufficient volume. To avoid prohibiting use of albumin and

IgG tests, as well as other scientifically supportable oral fluid biomarker or adulterant tests that may become available, the Department is authorizing specimen validity testing upon request of the Medical Review Officer as described in Sections 3.1 and 3.5. All tests must be properly validated and include appropriate quality control samples in accordance with these Guidelines. In response to commenters' concerns about expending the limited volume of oral fluid collected, it should be noted that HHS-certified laboratories currently performing specimen validity tests for non-regulated oral fluid testing use low volumes (*i.e.,* 25 mcL for albumin tests, 15 mcL for IgG tests) that would not be expected to have a significant impact on a laboratory's ability to complete testing.

Proposed Cutoff Concentrations

Nineteen commenters submitted comments on the proposed drug test cutoffs. Some were general comments, while others concerned specific drug analytes. Cutoffs for marijuana tests are discussed in the following section, *Testing for Marijuana Use.* The comments and the Department's responses concerning cutoffs for other drug tests are described below.

Two commenters agreed with all proposed analytes and cutoffs. Two deferred setting cutoffs to HHS-certified laboratories. Three disagreed with all proposed cutoffs. Two of these commenters recommended retaining the cutoffs in the proposed Guidelines of April 13, 2004 (69 FR 19673). One of these commenters believes that the technology to detect analytes at these low levels is questionable and that these cutoffs will identify employees on prescribed medications. One commenter requested the basis for changing the cutoffs from those proposed in 2004. As described in the preamble to the proposed OFMG (80 FR 28054), the Department based the proposed cutoffs for each drug on information in public comments from the April 2004 proposed Guidelines, public responses to the June 2011 Request for Information (76 FR 34086), and the recommendations of a technical workgroup consisting of subject matter experts and representatives from various stakeholder groups (*e.g.,* collection device and test kit manufacturers, oral fluid drug testing laboratories). The Department provided the recommended cutoffs with supporting scientific information to the SAMHSA Drug Testing Advisory Board (DTAB) for review and discussion and, in the preamble to the proposed OFMG of May 15, 2015 (80 FR 28054, pages 28061–28065), included reasons for the proposed cutoffs for each drug, with references to supporting scientific studies. The Department has raised the cutoffs for some drug tests to address specific comments as described below. The Department concluded that no change is needed for other analytes. The cutoffs in Section 3.4 are supported by scientific studies, and are consistent with the goals of the federal workplace drug testing programs. The National Laboratory Certification Program (NLCP) Pilot Performance Testing (PT) Program has documented that laboratories are able to meet the Guidelines requirements using the cutoffs in Section 3.4.

One commenter agreed with the proposed initial test cutoff for cocaine, and recommended that a slightly lower cutoff be used for the confirmatory test. The Department did not find scientific evidence to warrant a change to the proposed confirmatory cutoff, which is the same as that proposed in 2004.

Five commenters disagreed with the proposed codeine and morphine cutoffs. Two commenters stated that the cutoffs are too low: One expressed concern over the technology to detect analytes at the proposed low levels and both noted that the change from currently used cutoffs will increase the number of initial test positives, thereby increasing costs. Two commenters stated that the Department has not supported changing from the cutoffs proposed in 2004 (*i.e.,* 40 ng/mL for both the initial and confirmatory tests), which are currently used by the industry. One commenter indicated that their test data support a cutoff of 30 ng/mL for both the initial and confirmatory tests. In the preamble to the proposed OFMG of May 15, 2015 (80 FR 28054, page 28063), the Department included reasons for the selected test cutoffs for each drug, with references supporting those cutoffs. The Department is retaining the proposed cutoffs (*i.e.,* 30 ng/mL for the initial test and 15 ng/mL for the confirmatory test) and is providing further explanation below to address the comments.

Reports in the literature provide information supporting lowering the morphine initial test cutoff from 40 to 30 ng/mL. In one dosing study with doses of 20 and 10 mg of morphine sulfate, morphine concentrations in saliva peaked at 0.5 hours at 37.8 ng/mL and 10.8 ng/mL, respectively, with detection times of 24 hours using a limit of detection (LOD) of 0.6 ng/mL.[1] In another report, morphine concentrations in oral fluid of treatment patients (n=4,575) were reported to range from 2 to 3,026 ng/mL with a median concentration of 49.8 ng/mL.[2] It was also found that 25% of the specimens contained morphine less than 13.5 ng/mL. These reports of short detection times and low concentrations of morphine in oral fluid also justify lowering the confirmatory cutoff for morphine to 15 ng/mL. The NLCP Pilot PT program has demonstrated oral fluid testing laboratories' abilities to meet codeine and morphine confirmatory cutoffs of 15 ng/mL using current testing technologies.

One commenter agreed with the proposed initial test cutoffs for oxycodone, oxymorphone, hydrocodone, and hydromorphone, but recommended that the same cutoffs be used for confirmatory testing. One commenter disagreed with all proposed cutoffs for these drugs, stating that the cutoffs are too low and will identify legitimate prescription users. The Department will retain the cutoffs as proposed. In the preamble to the proposed OFMG of May 15, 2015 (80 FR 28054, pages 28064–28065), the Department included reasons for the selected test cutoffs for each drug, with references supporting those cutoffs. Considerable research and discussion were conducted regarding the complex issues surrounding the specification of each cutoff concentration. The Department solicited input from laboratories, reagent and device manufacturers, subject matter experts, and the Food and Drug Administration (FDA). The cutoff concentrations are the outcome of the lengthy discussion process and represent the best approach currently available. Furthermore, the OFMG include the same requirements as the UrMG for Medical Review Officers to interview donors to determine whether there is a legitimate medical explanation for a positive test result, and to review documentation provided by the donor to support a legitimate medical explanation.

One commenter disagreed with the proposed 3 ng/mL initial test cutoff for 6-acetylmorphine (6–AM), stating that the proposed cutoff is higher than that currently used. As suggested by the commenter, and based on current 6–AM test methods and laboratory results from the NLCP Pilot PT Program, the Department has raised the proposed 6–AM initial test cutoff in Section 3.4 to 4 ng/mL (*i.e.,* the same as proposed in 2004). The same commenter recommended a higher confirmatory test cutoff (3 ng/mL vs. the proposed 2 ng/mL), and noted that their data show that using an opiates cutoff of 30 ng/mL and a 6–AM confirmatory cutoff of 3 ng/mL identifies more positive 6–AM specimens than urine testing. The comparison of 6–AM positivity rates in urine and oral fluid does not support a

change to the proposed confirmatory test cutoff. Studies have shown that 6–AM is statistically more likely to be detected in oral fluid than urine, regardless of the cutoff. [3 4 5] The Department has retained the 2 ng/mL 6–AM confirmatory test cutoff proposed in 2015, primarily for enhanced sensitivity. Studies have shown that 6–AM concentrations between 1 and 3 ng/mL are detected in the study populations. [2 3 6 7]

One commenter agreed with the proposed test cutoffs for phencyclidine (PCP). Three others disagreed, recommending that the Department use the 2004 proposed cutoffs (*i.e.,* 10 ng/mL for both the initial and confirmatory tests). The Department has evaluated the comments and agrees with commenters that there is an insufficient scientific basis to warrant changes from the PCP test cutoffs in the April 13, 2004 proposed Guidelines (69 FR 19673), which are currently used by many test manufacturers and laboratories. Therefore, the Department has raised the proposed cutoffs in Section 3.4 as follows: PCP cutoffs are 10 ng/mL for both the initial and confirmatory tests.

Six commenters disagreed with the proposed test cutoffs for amphetamines. Two of these commenters recommended that the Department use the 2004 proposed cutoffs (*i.e.,* 50 ng/ml for both the initial and confirmatory tests). One recommended that the 2004 cutoff be used for the initial test; another recommended using the 2004 cutoff for the initial test and half of that concentration (25 ng/mL) as the confirmatory test cutoff. One commenter suggested cutoffs of 150 ng/mL or 120 ng/mL. One suggested setting cutoffs at 120 ng/mL or above to reduce the number of unverified positive initial tests. One commenter requested the basis for using different initial and confirmatory test cutoffs for methylenedioxymethamphetamine (MDMA).

The Department has evaluated the comments and agrees with commenters that, for amphetamines, there is an insufficient scientific basis to warrant changes from the initial test cutoffs in the April 13, 2004 proposed Guidelines (69 FR 19673), which are currently used by many test manufacturers and laboratories. Therefore, the Department has raised the proposed initial and confirmatory test cutoffs in Section 3.4 as follows: The initial test cutoff for amphetamines (*i.e.,* amphetamine, methamphetamine, MDMA, and MDA) is 50 ng/mL, and the confirmatory test cutoff for each amphetamine analyte is 25 ng/mL.

Testing for Marijuana Use

The Department requested comments on several topics related to testing for marijuana use. Public comments and the Department's responses are described below. After reviewing the comments, as well as the results of scientific studies published after the development of the proposed OFMG, the Department has decided to test for one marijuana analyte, delta-9-tetrahydrocannabinol (THC). THC is the primary psychoactive constituent (or cannabinoid) of the cannabis plant and is the primary intoxicant in marijuana. After careful consideration of all available evidence for THC in oral fluid, the Department has decided to retain the proposed 4 ng/mL initial test cutoff for THC in the final OFMG. Details regarding this decision are described below.

The Capability of Laboratories To Test Delta-9-Tetrahydrocannabinol-9-Carboxylic Acid (THCA) Analyte Using a Cutoff of 50 pg/mL

One commenter agreed and four commenters disagreed that laboratories were currently capable of testing THCA in oral fluid using this cutoff. One commenter stated that laboratory instrumentation required for the analysis of THCA in oral fluid is widely available and can be added to routine laboratory testing. The commenter listed examples: Two-dimensional gas chromatography/mass spectrometry (GC/MS), GC/MS/MS, and liquid chromatography (LC)/MS/MS. Three commenters disagreed, stating that it would require significant investment in more sensitive instrumentation. One commenter disagreed, stating they doubt the capabilities of the laboratories to consistently test for THCA with accuracy, sensitivity and validity. One commenter disagreed, stating that the number of laboratories with the experience in testing for THCA is limited. The Department has evaluated the comments and agrees that there is a limited number of laboratories currently testing for THCA in oral fluid. Only one commercial drug testing laboratory participating in the Oral Fluid Pilot PT program performed THCA testing. Furthermore, due to the concentration differences between THC (*i.e.,* nanogram/milliliter or ng/mL levels) and THCA (*i.e.,* picogram/milliliter or pg/mL levels), immunoassays do not have sufficient cross-reactivity to enable use of a single assay for both analytes. Initial testing for both THC and THCA would require two separate immunoassay kits or use of alternative technology. No current immunoassay has been identified that is selective for THCA only. Laboratories planning to become HHS-certified to test federal agency oral fluid specimens may already have instrumentation for confirmatory testing that could be used as an alternate technology for initial testing, but may incur additional costs to develop and validate these new initial drug tests.

The Validity of Whether THCA Can Be Established as an Accurate, Sensitive and Valid Marker for Oral Fluid Testing To Detect Marijuana Use and Whether THCA Should Be Used To Extend the Window of Detection for Marijuana Use

Four commenters agreed with THCA as a test analyte. These commenters believe that analysis of THCA may prevent or minimize the risk of positive results due to ''passive exposure'' (*i.e.,* a nonsmoker's exposure to secondhand marijuana smoke). One commenter stated that if both THC and THCA analytes are required to be present to constitute a rule or policy violation, this would also eliminate protracted detection of THCA. The commenter suggested that if only one of the marijuana analytes is reported, it could be addressed as a safety concern. This commenter also opposed MROs requesting THCA testing as needed and, as an alternative, suggested requiring disclosure from the donor at the time of collection (*i.e.,* the collector would ask the donor whether the donor had been exposed to marijuana recently and testing for THCA would be performed based on the donor's answer). If the donor indicated no recent exposure, the donor has waived the right to a passive inhalation defense. One commenter recommended an agency or employer should have the option to choose either test (THC or THCA), providing flexibility for employers' testing goals. One commenter noted that THCA testing, if included in the Guidelines, would be in conjunction with THC testing and expressed concerns including how to handle two test results (THC and THCA) that do not agree, additional costs, longer turnaround time, and handling of retests.

Six commenters disagreed with THCA as a test analyte. One commenter disagreed, suggesting solely testing for the active parent drug is one of the defining characteristics of oral fluid testing. Two commenters disagreed, suggesting THCA is not a reliable metabolite to be an appropriate marker for marijuana use. One commenter disagreed, stating that THCA is only present in oral fluid at very low levels. One commenter disagreed, suggesting that under realistic conditions of casual passive exposure and specimen

collection where the collection occurs outside the exposure area, a donor would not test positive for THC at the currently used initial test (3 ng/mL) and confirmatory test (1.5 ng/mL) cutoffs. One commenter disagreed, stating that more research is needed before adding THCA to the Guidelines. One commenter disagreed, indicating that, for the majority of the time, no significant THC positives are reported for samples containing THCA alone. The commenter also stated that for THCA alone (in the absence of THC) to be detected as positive in the immunoassay, the level must be at least 1,000 pg/ml, and that specimen volume is limited and should not be wasted for unnecessary tests.

The Department has evaluated the comments and decided to use THC as the sole initial and confirmatory test analyte for marijuana, with a 4 ng/mL initial test cutoff and a 2 ng/mL confirmatory test cutoff. This decision is supported by the reasons detailed below.

First, the Department is not aware of any scientific evidence to suggest that individuals would test positive for THC under the standards in these Guidelines as the result of incidental exposure to secondhand marijuana smoke. The preamble to the proposed OFMG, published on May 15, 2015, provided information on THC and THCA results from studies of subjects who were passively exposed to marijuana smoke under a variety of exposure conditions.[8–11] These studies, detailed below, were conducted under conditions of extreme marijuana smoke exposure for several hours in enclosed spaces (*i.e.,* heavy smoke in unventilated and ventilated conditions). The study data indicate that transient amounts of THC may be present in nonsmokers' oral fluid for a few hours (*i.e.,* one to three), but only under those extreme conditions, meaning exposure to smoke from multiple cannabis cigarettes in an enclosed space for an extended time period.

One 2011 study tested nonsmokers in two Dutch coffeehouses where marijuana was being smoked.[10] While some positive tests were obtained from the subjects, those samples were taken during a time of ongoing exposure to marijuana smoke in the coffeehouses, no subjects tested positive after returning for a final collection 12 to 24 hours after exposure. It should be noted that at the time of this notice's publishing, recreational and/or medical marijuana use is not permitted in places of public accommodation under either state or federal law. While this study demonstrated the types of THC oral fluid concentrations that could be obtained during exposure to secondhand marijuana smoke, the study is not directly applicable to Federal drug testing because the positive specimens collected in this study were collected during ongoing exposure to secondhand marijuana smoke, which does not approximate federal drug testing collection conditions.

A more recent study exposed nonsmokers to extreme levels of marijuana smoke under controlled conditions.[12 13] The extreme exposure in this 2015 study consisted of three different one-hour sessions in which nonsmokers were enclosed in a sealed room with six smokers who smoked cannabis cigarettes almost continually through each session. The room was a specially constructed sealed Plexiglas chamber (10 ft. by 13 ft. with a 7-ft. ceiling). Nonsmokers and smokers were seated around a table in alternating seats and the nonsmokers were continually exposed to heavy amounts of marijuana smoke. In two sessions, there was no air flow (*i.e.,* air conditioning was turned off) and in one session, the air conditioning was turned on. Heavy marijuana smoke was present in each session and the smoke caused eye irritation in the two non-ventilated sessions. Because of the extreme smoke conditions, most participants elected to wear eye goggles to reduce eye irritation. In this study, 3 of the 6 nonsmokers were negative directly after the exposure concluded (0 hours) and 4 of 6 were negative at 0.5 hours.

Some of these subjects (nonsmokers) also reported drug effects that were approximately 25% of the smokers' responses (*i.e.,* self-reported effects on a visual analog scale). The nonsmokers also exhibited detectable levels of performance impairment on some behavioral/cognitive assessments. Therefore, a reasonable donor in a safety sensitive position who is aware that he or she is in an enclosed environment with heavy levels of secondhand marijuana smoke should understand that he or she is very likely to experience the effects of inhaled marijuana smoke if he or she remains in this type of environment. Importantly, it is worth noting that exposure to the extreme levels of marijuana smoke in all three study sessions (*i.e.,* non-ventilated and ventilated) does not represent a real-world situation and, therefore, is an unlikely passive exposure situation for donors in a federal agency testing program.

The marijuana studies described above indicate that transient amounts of THC may be present in nonsmokers' oral fluid between one to three hours after prolonged, extreme exposure. Conversely, however, in two similar passive exposure studies from 2001 and 2005, none of the nonsmoking subjects tested positive using cutoffs that were lower than the OFMG THC cutoffs (*i.e.,* 4 ng/mL for initial tests and 2 ng/mL for confirmatory tests).[8 9] While the exposure in the 2005 study was ''extreme,'' both the 2001 and 2005 studies represent more likely ''real world'' situations than the 2015 study.

In the 2005 study of nonsmoking individuals exposed to marijuana smoke in an unventilated passenger van, none of the passively exposed individuals tested positive using a 3 ng/mL initial test cutoff when the oral fluid collection device was protected from exposure to contaminated surfaces.[9] In this two-part study, four non-smoking subjects sat beside four active cannabis smokers who each smoked a single cannabis cigarette containing either a low dose of THC (Study 1) or high dose of THC (Study 2). In Study 1, oral fluid was collected inside the THC-contaminated van. Maximum oral fluid THC concentrations in non-smoking subjects were 7.5 ng/mL but declined to negative levels within 45 minutes of exposure. In Study 2, oral fluid was collected outside the van. Even though the dose of THC was more than twice the dose in Study 1, the maximum concentration detected in the passively exposed subjects was 1.2 ng/mL, which is well below the initial and confirmatory THC cutoffs in these Guidelines. When potential contamination during collection was eliminated in Study 2, all non-smoking subjects were negative at both initial and confirmatory cutoff concentrations throughout the study.

In the 2001 study, subjects were administered a single dose of marijuana by smoked and oral routes, and their oral fluid and urine THC test results were compared.[8] The study used a 1 ng/mL THC initial test cutoff and a 0.5 ng/mL THC confirmatory test cutoff, both lower than the THC cutoffs in these Guidelines (*i.e.,* 4 ng/mL initial test cutoff and 2 ng/mL confirmatory test cutoff). Two nonsmoking subjects were included to simulate passive exposure scenarios (*e.g.,* sitting in an unventilated room where marijuana is smoked). These subjects were positive by immunoassay using the 1 ng/mL initial test cutoff at 1- and 4-hours post-exposure but negative by the confirmatory test using a 0.5 ng/mL cutoff.

These carefully executed studies on passive exposure are considered strong evidence that exposure to secondhand marijuana smoke under normal ventilation conditions presents no risk

that an individual will have a passive exposure related positive test result under the standards used in these Guidelines.

Another reason for the Department's decision to test only for THC is that THCA cannot be reliably detected in all individuals who use marijuana. Two recent studies investigated the presence of THC and THCA in oral fluid after various routes of administration.[15] [16] One study characterized marijuana analytes including THC and THCA in oral fluid of nine occasional and 11 frequent marijuana smokers after smoked, vaporized, and oral administration (*i.e.,* ingestion of a brownie containing marijuana).[15] THC was present in oral fluid specimens in all individuals from both groups, after all routes of administration, immediately after use. THC was detected above the OFMG confirmatory cutoff (*i.e.,* 2 ng/mL) for 32 hours with the occasional users and 72 hours with the frequent users. Of the nine occasional users, all tested positive for THC using the OFMG confirmatory cutoff after all administration routes. However, only three occasional users tested positive for THCA (*i.e.,* at or above 15 pg/mL) after all administration routes. In a second study, drug-free subjects ate brownies containing marijuana in three separate dosing sessions, with THC concentrations of 10 mg, 25 mg, and 50 mg.[16] The appearance of THCA in oral fluid in this study was highly variable, and THCA was not present in all subjects. Within the first eight hours after marijuana ingestion, 116 oral fluid specimens were positive for either THC or THCA. Of those specimens, 23 specimens were positive for both THC and THCA, 75 were positive for THC only, and 18 were positive for THCA only. Therefore, THC was detected in approximately 84.5% of the positive oral fluid tests, while THCA was only detected in approximately 35.3%. These studies support the Department's decision to test for THC by showing that THCA cannot be as reliably detected as THC in all marijuana users.

The Department's decision to use THC as the initial and confirmatory test analyte is also supported by the differences between the detection patterns of the two analytes in occasional smokers versus chronic frequent smokers. For example, one study showed that, although THCA was detected in frequent cannabis smokers almost 100% of the time studied, occasional smokers did not consistently test positive for THCA using the previously considered confirmatory test cutoff concentration of 0.05 ng/mL.[17] Some individuals tested negative for THCA after smoking cannabis. Consequently, confirmatory testing for THCA without performing an initial test for THCA would be biased toward detecting chronic frequent cannabis smokers and would be ineffective in detecting occasional users. Such an outcome would diminish the reliability of marijuana testing using oral fluid. It is also important to note that occasional users may exhibit greater acute impairment than chronic frequent users due to the lack of tolerance to cannabis effects.[18] This consideration suggests that an oral fluid drug testing system that relies upon testing for THCA to detect marijuana use may fail to identify occasional users who could pose a safety risk to a federal agency's enterprise.

The Department believes that an immunoassay initial test with the appropriate sensitivity for testing for both THCA and THC could allow oral fluid marijuana tests to take advantage of THCA's extended detection window. The preamble to the proposed OFMG, published on May 15, 2015, noted the lack of scientific data on the time course of excretion or the detection window of THC, THCA, and conjugated THCA in oral fluid following marijuana use, especially for occasional users. It was noted that studies of daily marijuana smokers indicated that THC is detectable for up to two days, but THCA continued to be excreted in oral fluid during abstinence for several weeks in daily users.[19] Two other studies evaluated oral fluid results following cannabis smoking (*i.e.,* one cannabis cigarette containing 6.8% THC).[17] [20] In a 2013 study, oral fluid was collected from 10 participants using the Quantisal™ (Immunalysis) oral fluid collection device over a 22-hour period.[17] The authors used a 0.5 ng/mL cutoff for THC and a 7.5 pg/mL cutoff for THCA. The mean time to last concentration and the mean last concentration was 12.3 hours and 5.1 ng/mL for THC and 14.6 hours and 42.3 pg/mL for THCA, thus providing evidence of a longer detection window for THCA. A 2012 study evaluated cannabinoid concentrations in oral fluid of chronic and occasional smokers.[20] Oral fluid was collected 19 hours before smoking to 30 hours after smoking, using the Statsure Saliva Sampler™ (Statsure Diagnostic Systems). The authors concluded that: (1) All specimens were THC positive for up to 13.5 hours post-smoking without significant differences between chronic and occasional smokers, (2) THCA provided longer detection times than THC in the 13.5 to 30 hour post-smoking period in all chronic smokers, and (3) THCA windows of detection for chronic cannabis smokers extended beyond 30 hours.

However, the Department has not identified immunoassay technology that is feasible as an initial test for both THC and THCA in a high-throughput laboratory environment. Such technology is necessary for the implementation of THCA testing in the federal drug testing program because: (1) THCA-only testing is not a viable option for the federal drug testing program (as discussed previously), and (2) even though THCA and THC can be tested during the confirmation phase of drug testing, the theoretical advantages of THCA's longer detection window will not be achieved unless THCA can be detected in the initial test. In other words, in the absence of a viable initial test to detect THCA, specimens positive for THCA only would not advance to confirmation testing. Therefore, until a suitable immunoassay initial test that is capable of screening for both THC and THCA is available, the Department believes that its decision to test for THC using the cutoffs established in these Guidelines provides federal agencies with an efficient, cost-effective and reliable means to detect marijuana use.

As such, it is the conclusion of the Department that a 4 ng/mL initial test cutoff for THC is supported by scientific studies and is consistent with the Department's objective of detecting the use of illicit drugs while, to the extent practicable, eliminating the risk of positive test results caused solely by the drug use of others and not caused by the drug use of the individual being tested, as directed by the SUPPORT for Patients and Communities Act, Public Law 115–271, section 8107(b).[14]

Lowering the Initial Test Cutoff Concentration for THC to Either 2 or 3 ng/mL and Lowering the Confirmation Test Cutoff Concentration for THC to 1 ng/mL To Extend the Window of Detection for Marijuana Use

Three commenters recommended lowering the THC initial test and confirmatory cutoffs to extend the window of detection; one commenter recommended lowering the initial test cutoff for this reason, but keeping the proposed confirmatory cutoff. One commenter recommended a slightly lower confirmatory cutoff (*i.e.,* 1.5 ng/mL). Two commenters agreed with the proposed THC cutoffs.

Two other commenters recommended increasing the initial and confirmatory THC cutoffs, so claims of positive

results due to passive exposure will not be justified.

The Department's decision on initial and confirmatory cutoffs is discussed above, but to reiterate, the Department concluded after careful review of all available scientific evidence that: (1) Credible claims of positive THC tests resulting from second-hand smoke/passive exposure are extremely unlikely, and (2) the only scenario in which there is a theoretical possibility of testing positive for THC as the result of second-hand smoke/passive exposure under these Guidelines involves sustained exposure to extreme levels of marijuana smoke. The Department is confident that under these Guidelines, only a donor's marijuana use would be identified.

Performance Requirements for an Oral Fluid Collection Device

One commenter agreed and one commenter disagreed with requiring the use of only collection devices that have been cleared by the Food and Drug Administration (FDA). One commenter suggested the requirements for collection devices should be developed by appropriate professionals after suitable scientific and stakeholder review, while another suggested the requirements be determined by laboratories and manufacturers. One commenter disagreed with the Guidelines, and suggested that only devices using ''the swab technique'' be required.

The Department has evaluated these comments, and maintained the requirement in Section 7.1 for oral fluid collection devices to be FDA-cleared.

Five commenters addressed proposed volume specifications. Three commenters suggested that the Department specify oral fluid collection and/or diluent volume as a percentage and not a specific volume, due to variability in commercially available devices. One commenter encouraged increasing the allowed specimen and diluent volume variance to +/− 20%. One commenter believes that the proposed 0.05 mL diluent variance is too small and not realistic. One commenter suggested that the Guidelines not specify a required volume, but emphasize that laboratories choose devices that would ensure sufficient volume is collected for initial and confirmatory testing. One commenter disagreed with the proposed variance in specimen collected and suggested that the device must collect a known volume (similar to the ''European Guidelines for Workplace in Oral Fluid''). This commenter also disagreed with the 1 mL collection requirement, stating that LC/MS/MS methods use approximately 200 mcL of oral fluid and that reducing the volume will reduce the time required for collection.

The Department has evaluated these comments, and revised Section 7.3(b) to specify oral fluid collection and diluent volumes as percentages (rather than specific volumes as proposed). The Department agreed with commenters that specifying allowable diluent variance as a percentage rather than volume would allow different manufacturers to produce their oral fluid collection devices with an optimized volume of diluent while ensuring reliability across systems. The Department also changed the specimen volume variance to a percentage for consistency. Section 7.3 specifies variances of 2.5% for diluent volume and 10% for specimen volume, based on information obtained from device manufacturers. The Department also maintained the requirement to collect at least 1 mL of oral fluid. This is a reasonable collection volume that will enable sufficient specimen for testing (*e.g.,* when repeat testing or confirmatory tests for multiple drugs are required).

Four commenters addressed the proposed device requirements for recovery of ≥90% (but no more than 120%) of drug and/or drug metabolite at (or near) the initial test cutoff. The commenters disagreed with the proposed requirement of ≥90%, and suggested recovery between 80% and 120%. One commenter noted that 80% to 120% recovery is consistent with current FDA-cleared systems. One commenter cited adherence of THC to surfaces as a problem in achieving 90% recovery, and recommended either requiring ≥80% for all drugs or requiring ≥80% recovery for THC and ≥90% recovery for other drugs. One commenter agreed with specifying minimum and maximum recovery, and recommended additional emphasis on the consistency of recovery performance of the device and confirmatory methods.

The Department has evaluated these comments, and revised Section 7.3(b) to change the lower limit for drug recovery from ≥90% to ≥80%.

Two commenters addressed stability at room temperature. One commenter agreed with the requirement for stability at room temperature for at least one week, and one commenter disagreed. This commenter indicated that in-house studies found cocaine and 6–AM were unstable for that length of time and also indicated that specimens are typically received at the laboratory one to two days after collection.

The Department has evaluated these comments, and changed the stability requirement in Section 7.3(b) from one week at room temperature to five days at room temperature. Because oral fluid is collected with either a preservative buffer (*i.e.,* collection device with diluent) or preservative dry reagents (*i.e.,* neat oral fluid collection), normal transport conditions are not expected to affect stability of the drugs and/or drug metabolites. The Department will include guidance to collectors concerning proper collection and transport of oral fluid specimens in the Oral Fluid Specimen Collection Handbook.

Medical Review Officer (MRO) Reporting Procedures for Positive Morphine/Codeine Results

In Section 13.5, the Department proposed a concentration of 150 ng/mL for codeine and morphine to be used by the MRO to report a positive result in the absence of a legitimate medical explanation (*i.e.,* prescription), without requiring clinical evidence of illegal use, and to rule out the possibility of a positive result due to consumption of food products. The Department requested comments on the appropriateness of this concentration. One commenter agreed. Six commenters disagreed: One commenter recommended 100–120 ng/mL, one commenter recommended 50–100 ng/mL, one commenter recommended 120 ng/mL, and one commenter recommended 40 ng/mL. One commenter suggested that no additional decision point is needed because, based on scientific studies including in-house studies, positive opiate results using a 40 ng/mL cutoff are not typical and are difficult to achieve, thus there is no justification for an MRO reversal of a codeine or morphine result less than 150 ng/mL. One commenter expressed concern that the 150 ng/mL decision point would not rule out positive codeine/morphine results due to food products and suggested that the Department use a much higher decision point or require clinical evidence of illegal drug use before an MRO verifies any opiate results as positive. Based on evaluation of these comments and examination of the data from scientific studies, the Department has concluded that no change is needed.[21–24] The 150 ng/mL concentration is higher than the highest concentration seen in study subjects at one hour and later after consumption of raw poppy seeds and products containing poppy seeds.

HHS List of FDA-Cleared Oral Fluid Collection Devices

The Department requested comments on whether HHS should publish a list of FDA-cleared oral fluid collection devices. Seven commenters agreed. One commenter disagreed, stating that it is sufficient to provide regulation on requirements and noting that the Department does not publish a list of FDA-cleared urine specimen containers. After further review, the Department has decided not to publish a list. The list might not reflect all current FDA-cleared oral fluid collection devices, and could be misconstrued as a list of SAMHSA-approved devices. Also, FDA clearance does not mean that the collection device meets OFMG requirements. The federal agency and/or the HHS-certified laboratory must ensure that the FDA-cleared device meets the device requirements in Sections 7.2 and 7.3. FDA has a searchable database on its website that can be used to identify FDA-cleared oral fluid collection devices. The Department will include a link to this database on the SAMHSA website *http://www.samhsa.gov/workplace.*

Medical Review Officer (MRO) Requalification—Continuing Education Units (CEUs)

The Department requested comments on requiring MRO requalification continuing education units (CEUs) and on the optimum number of credits and the appropriate CEU accreditation bodies should CEUs be required as part of MRO requalification. Three commenters agreed with requiring MRO recertification, but disagreed with the addition of CEU requirements to the Guidelines. Two commenters disagreed with specifying the number of CEUs required. Two commenters indicated that certification entities already enforce training requirements and recommended that acceptance of CEUs be handled by MRO certification boards, not the Department. Two commenters recommended a requirement of annual CEUs: One suggested 16 CEUs and the other recommended three CEUs. One commenter recommended 12 CEUs prior to initial certification, eight CEUs every five years, and also recommended two CEUs related to the new requirements/topics within two years of implementation of the revised Guidelines. The Department has evaluated the comments and has concluded that requirements for continuing education units will remain with the MRO certification entities and will not be included in the Guidelines. The Department has removed references to MRO training entities in Sections 13.2 and 13.3, because training documentation is maintained by MRO certification entities. The Department agrees with the comment that MROs should receive training on revisions to the Guidelines and has added item Section 13.3(b) to require such training prior to the effective date of revised Guidelines, to ensure that all MROs are trained in program requirements before performing MRO duties for federal agency specimens.

Split Specimen Collection Methods

All federal agency collections are to be split specimen collections. The donor's primary (A) specimen is tested and the split (B) specimen is available for testing if the donor requests a retest at another HHS-certified laboratory. For urine, one specimen is collected from the donor, then the collector pours the collected specimen into two bottles that are then labelled as A and B specimens. Most current oral fluid collection devices collect a single specimen that cannot be divided into A and B specimens. Therefore, the Department requested comments on whether serial or simultaneous collection using two collection devices constitutes a split oral fluid collection, and recommendations for any other oral fluid collection processes that enable subdividing the collected specimen. Three commenters agreed with the proposed guidelines as written. Two cited problems with collecting expectorated oral fluid (*i.e.,* difficult to obtain a sufficient specimen, distasteful to donor and collector), and stated that collection with a device provides analyte stability, a homogenous specimen, and facilitates processing in the laboratory. The commenters noted that the split specimen requirement to identify the presence of the drug addresses any concentration differences between first and second specimens. They also noted that split collections with two devices are currently used for non-regulated testing without issue and that scientific studies support these methods. Five commenters disagreed. Some raised concerns over possible insufficient specimen volume and non-homogenous specimens leading to possible discrepant primary and split specimen results. One commenter disagreed stating that the use of two devices for each collection increases costs. One commenter believes that serial collections using two devices may increase the likelihood of collection problems (*e.g.,* collector forgets to perform the second collection; the donor may leave the collection site or be out of collector's line-of-sight between collections; the two-minute period may be exceeded). The Department has evaluated the comments and has concluded that no change is needed. Either serial or simultaneous collection using two collection devices constitutes a split oral fluid collection for federal workplace drug testing programs. These split collection procedures are described in Section 8.8. The Department revised the split specimen collection definition in Section 1.5 and revised Section 8.8(a) to clarify that the OFMG do not prohibit collection of a single specimen and subdividing the collected specimen into primary (A) and split (B) specimens. In Section 2.5, the Department clarified that the split oral fluid specimen may be collected using two devices or using one device and subdividing the specimen.

Discussion of Sections

The Department has not included a discussion in the preamble of any sections for which public comments were not submitted or where minor typographical or grammatical changes were made.

Subpart A—Applicability

1.5 What do the terms used in these Guidelines mean?

One commenter requested that ''external service provider'' be defined, because this is a new term included in the proposed Guidelines. The Department agrees and has added the definition ''An independent entity that performs services related to federal workplace drug testing on behalf of a federal agency, a collector/collection site, an HHS-certified laboratory, a Medical Review Officer (MRO), or, for urine, an HHS-certified Instrumented Initial Test Facility (IITF).''

Two commenters disagreed with the proposed definition for ''invalid result'' which indicated that an invalid result was reported only when an HHS-certified laboratory could not complete testing or obtain a valid drug test result. The Department agrees and has reinstituted wording from the definition in the Guidelines effective October 1, 2010 (73 FR 71858). The definition in Section 1.5 is ''The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.7 when a positive or negative result cannot be established for a specific drug or specimen validity test.''

To address comments described in this preamble under Section 13.1, the Department deleted the definition for ''non-medical use of a drug.''

Two commenters found the definition of ''specimen'' confusing, because the term ''sample'' used in the definition

was also defined as a representative portion of a donor's specimen. The Department agrees and has reinstituted some wording for the definition of ''specimen'' from the Guidelines effective October 1, 2010 (73 FR 71858) for clarity. The definition in Section 1.5 is ''Fluid or material collected from a donor at the collection site for the purpose of a drug test.''

The Department revised the definition of ''split specimen collection (for oral fluid)'' to clarify that the OFMG allow collection of a single specimen and subdividing the collected specimen into primary (A) and split (B) specimens. This is consistent with the change described in this preamble under Section 8.8(a).

For clarity, the Department added a definition for the term ''undiluted (neat) oral fluid'' which is used throughout the OFMG. The definition in Section 1.5 is ''An oral fluid specimen to which no other solid or liquid has been added. For example, see Section 2.4: a collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.''

1.6 What is an agency required to do to protect employee records?

One commenter suggested that the non-applicability of the Health Insurance Portability and Accountability Act (HIPAA) and the Health Information Technology for Economic and Clinical Health Act (HITECH) should be clearly stated in the Guidelines. The Department has evaluated the comment and has concluded that the applicability of HIPAA and other relevant privacy laws is clearly stated in Section 1.6. Accordingly, except for minor rewording for clarity, no further revisions are necessary.

1.7 What is a refusal to take a federally regulated drug test?

The Department proposed within Section 1.7 what is a refusal to take a federally regulated drug test. Two commenters noted that this section does not include the same requirements as Section 1.7(a)(10) of the UrMG defining a refusal to test when a collector finds a device intended for the purpose of adulteration or substitution and recommended adding similar language to the OFMG. The Department has evaluated the comments, and agrees that the collector must report a refusal to test when a donor brings materials for adulterating, substituting, or diluting the specimen to the collection site, or when the collector observes a donor's clear attempt to tamper with a specimen. The Department has revised Sections 1.7, 8.3(d), and 8.4(c) accordingly. Collectors will inspect the donor's oral cavity to ensure it is free of items that may impede or interfere with the drug test as described in Section 8.3.

One commenter recommended that OFMG Section 1.7 include the same requirements as UrMG Section 1.7(a)(5) defining a refusal to test when the donor failed to provide a sufficient amount of specimen when directed, ''and the required medical evaluation did not identify a legitimate medical explanation for the failure.'' The Department agrees with this comment and has added a new item 4 to Section 1.7(a) consistent with the UrMG requirement.

One commenter recommended clarification that a donor's refusal to provide a split specimen will also qualify as a refusal to test. The Department has evaluated the comment and has added this as a refusal to test in Sections 1.7(a)(7) and Section 8.5(b). If the donor refuses to provide a split specimen, the collector will report this as a refusal to test.

Also in regard to Section 1.7, one commenter suggested expanding the section to include specific actions that would be classified as a refusal to test. The commenter suggested wording under the current example ''disrupt the collection process'' describing actions specific to OF collections ''(*e.g.,* disrupt the collection process including: biting on the collection device, sucking the fluid back out of the device, failure to open mouth when directed for inspection, failure to rinse mouth when directed, failure to remove foreign object from mouth when instructed, failure to permit the observation or monitoring of the specimen collection, avoiding swabbing in-between teeth and the gum line when instructed, failure to follow the collector's instructions on swab location in the mouth, attempting to conceal chemicals or mints in the mouth, attempting to use a mouth wash immediately prior to or during the collection, attempting to chew ice during the collection, behave in a confrontational way that disrupts the collection process, fail to wash hands after being directed to do so by the collector, possess or wear a prosthetic or other device that could be used to interfere with the collection process, other failures to comply with the collector's instructions or attempt to defraud the drug test)''.

The Department has evaluated the comment and has added the failure to rinse the mouth when directed by the collector as an example of donor actions classified as a refusal to test in Sections 1.7(a)(7) and in Section 8.3(d)(2). It should be noted that Section 1.7(a)(7) lists some examples. In practice, the trained collector determines whether the donor's action is a refusal to test. Many of the commenter's described actions would disrupt the collection process and thus constitute a refusal to test under Section 1.7(a)(7). The Department will consider the commenter's suggestions during preparation of guidance which will be provided in the HHS Oral Fluid Specimen Collection Handbook.

One commenter noted that the collector does not report a refusal to test when a donor leaves the collection site before the collection process begins for a pre-employment test. The commenter recommended defining the beginning of the pre-employment collection process as the point at which the donor is asked to present photo identification. The Department agrees with the suggestion to define the beginning of the collection process specifically for this situation. However, the Department has designated the beginning as the step described in Section 8.4(a), when the collector provides or the donor selects a specimen collection device. The Department has revised Sections 1.7(a)(2) and (3) to include a reference to this section. All subsequent items in Section 1.7(a) (*i.e.,* items 4—10) apply once the donor has arrived for the pre-employment test collection.

1.8 What are the potential consequences for refusing to take a federally regulated drug test?

The Department reworded Section 1.8(b) to clarify that the requirements in this section apply to donors who fail to appear at the collection site in a reasonable time for any test (except a pre-employment test), as described in Section 1.7(a)(1).

Subpart B—Oral Fluid Specimens

2.1 What type of specimen may be collected?

Ten commenters agreed with adding oral fluid and three commenters disagreed with adding oral fluid and alternate matrices. One commenter raised questions regarding the accuracy of oral fluid testing, MRO interpretation of detection of the parent compound of a prohibited drug, and the cost of oral fluid testing. The Department has evaluated the comments, and believes the concerns raised by the commenters are not sufficient to remove oral fluid testing from the Guidelines. The Department believes that collecting and testing oral fluid specimens according to

the requirements in these Guidelines is an efficient means to detect illicit drug use and ensures that the oral fluid test results are forensically and scientifically supportable.

Numerous commenters expressed concern with the Department's urine collection policy, stating that 7 to 10% of Americans have a condition (''paruresis''), described as a social anxiety disorder which prevents a person from producing urine on demand or in the presence of other people. These commenters stated that if the government wants to seek the largest group of qualified applicants, the Guidelines should specify that a diagnosis of paruresis means non-urine (*i.e.,* oral fluid) testing will automatically be provided, and that donors should not have to attempt to provide a urine specimen first. These comments are not relevant to the OFMG. The OFMG establish the standards and technical requirements for oral fluid testing in federal workplace drug testing programs. Each federal agency will decide whether to collect urine, oral fluid, or both specimen types in their workplace testing programs.

2.2 Under what circumstances may an oral fluid specimen be collected?

One commenter recommended that oral fluid be restricted based on the reason for the test due to the short window of detection compared to urine (and hair), the benefits of observed collection, and the ability to identify the parent or active drug that was used. One commenter recognized the benefit of oral fluid with respect to fewer adulterated, substituted, and/or invalid specimens, but raised concern over the shorter window of detection in oral fluid, especially with respect to pre-employment testing. Two commenters suggested that oral fluid and hair testing be performed for pre-employment and random tests. The Department has evaluated the comments and has concluded that no change is needed. Each federal agency will decide which of the authorized specimen types it will collect and the reasons for collecting each type of specimen.

2.3 How is each oral fluid specimen collected?

One commenter noted that this section does not clearly describe a split specimen ''collected either simultaneously or serially.'' The Department has evaluated the comment and has revised this section to include a reference to Section 8.8, which provides clear descriptions of these split specimen collection methods.

2.4 What volume of oral fluid is collected?

2.5 How is the split oral fluid specimen collected?

Comments on these two sections (*i.e.,* Section 2.4 and Section 2.5) are addressed here. One commenter noted that Sections 2.4 and 2.5 require collection of ''a known volume'' of at least 1 mL undiluted oral fluid, and stated that an absorbent pad device will not meet this requirement. The commenter recommended that these sections be clarified and address all types of oral fluid collection devices. The Department has evaluated the comment and has revised Sections 2.4 and 2.5 to ensure consistent requirements for collection devices with and without a diluent (or other component, process, or method that modifies the volume of the testable specimen). The Department revised Section 2.4 to require A and B tubes to have a volume marking clearly noting a level of 1 mL if the device does not include a diluent (or other component, process, or method that modifies the volume of the testable specimen). This is consistent with requirements in Section 7.3 for devices that modify the volume of the testable specimen to have a volume indicator, to ensure that at least 1 mL of oral fluid is collected. In Section 2.5, in addition to referencing Section 8.8, the Department clarified that the split oral fluid specimen may be collected using two devices or using one device and subdividing the specimen.

Subpart C—Oral Fluid Specimen Tests

3.1 Which tests are conducted on an oral fluid specimen?

One commenter suggested changing the term ''opiates'' to ''opioids'' in the Guidelines. ''Opiates'' is the term used to describe naturally occurring substances known as alkaloids derived from the opium poppy plant (*e.g.,* codeine; morphine; and heroin, which is produced by the acetylation of morphine) that bind to specific receptors in the central nervous system. The broadly used term ''opioids'' includes opiates (*e.g.,* codeine, morphine, and heroin); semi-synthetic compounds (*e.g.,* hydrocodone, hydromorphone, methadone, oxycodone, and oxymorphone); and synthetic compounds (*e.g.,* fentanyl). The Department agrees with the commenter and has changed the term ''opiates'' to ''opioids'' where appropriate to refer to oxycodone, oxymorphone, hydrocodone, and hydromorphone in addition to codeine, morphine, and 6-acetylmorphine (6–AM).

In addition, as described under *Requirements for specimen validity testing* in this preamble, the Department revised Section 3.1 to allow, but not require, oral fluid specimen validity testing.

3.2 May a specimen be tested for additional drugs?

The Department reworded Section 3.2(a) to clarify the additional drug tests that may be performed on federal employee specimens.

3.3 May any of the specimens be used for other purposes?

It should be noted that, consistent with the Urine Mandatory Guidelines, Section 3.3 specifically prohibits conducting, among other types of testing, deoxyribonucleic acid (DNA) testing, on oral fluid specimens unless authorized in accordance with applicable federal law.

3.4 What are the drug test cutoff concentrations for undiluted (neat) oral fluid?

Comments concerning marijuana test cutoffs are addressed under the *Testing for Marijuana Use* section above. Comments on other drug test cutoffs are addressed under *Proposed cutoff concentrations.* To summarize, the Department revised Section 3.4 to use higher cutoffs for some drugs (*i.e.,* initial test cutoffs for 6–AM, PCP, and amphetamines; confirmatory test cutoffs for PCP and amphetamines) than in the proposed OFMG. Other comments related to Section 3.4 are addressed below.

Three commenters disagreed with testing for cocaine in oral fluid, stating that cocaine is not stable in oral fluid, especially at the pH of human oral fluid. The commenters noted that cocaine has a short half-life and hydrolyzes to benzoylecgonine, and that benzoylecgonine is present longer and at higher levels. Two of these commenters further noted that the current industry standard is to test for benzoylecgonine only in oral fluid. One stated that their in-house studies found that testing cocaine did not increase the positivity rate compared to testing only benzoylecgonine. The other commenter refuted the study cited in the preamble to the proposed OFMG that supported the inclusion of cocaine as a test analyte. The Department based the proposed analytes for each drug on the recommendations of a technical workgroup consisting of subject matter experts and representatives from various stakeholder groups (*e.g.,* collection

device and test kit manufacturers, oral fluid drug testing laboratories). In the preamble to the proposed OFMG of May 15, 2015 (80 FR 28054, page 28063), the Department included the scientific basis for including both analytes. The inclusion of both cocaine and benzoylecgonine as test analytes will increase the number of specimens that are identified as containing these cocaine analytes and, thereby, will increase the deterrent effect of the program and improve identification of employees using this drug.

One commenter disagreed with testing for hydromorphone and oxymorphone in oral fluid due to extremely low incidence and recommended testing for more prevalent metabolites. The Department has evaluated the comment and decided that no change is needed. Information provided by initial test manufacturers indicates that the proposed analytes (*i.e.,* parent drugs) are present in higher concentrations and in the absence of their metabolites.

One commenter recommended specifying D-isomers as the initial test analytes for amphetamines. The Department agrees that an antibody that is directed toward D-enantiomers in an immunoassay method should be preferred over an antibody that is non-stereoselective, but concluded that no change is needed. The wording in this section is consistent with the UrMG, and the selection of an immunoassay kit or methodology will remain the testing laboratory's choice.

An HHS-certified laboratory may group analytes for initial testing. For clarity, the Department has defined the term ''grouped analytes'' where used in footnote 1 of the table in Section 3.4: ''(*i.e.,* two or more analytes that are in the same drug class and have the same initial test cutoff).''

The Department proposed criteria for calibrating initial tests for grouped analytes such as opioids and amphetamines, specifying the minimum cross-reactivity to the other analyte(s) within the group. The Department also proposed including methylenedioxyamphetamine (MDA) and methylenedioxyethylamphetamine (MDEA) as initial test analytes. Four commenters stated that 80% cross-reactivity may not be possible with current immunoassay technology, so may require independent analyses (*e.g.,* hydrocodone and hydromorphone for an opiate assay; MDEA for an amphetamines assay). Two of these commenters noted concerns with additional oral fluid specimen volume needed for the independent assays. Another commenter stated that cross-reactivity specifications for hydromorphone are not necessary, based on their non-regulated testing results (*i.e.,* confirmatory test concentrations detected after using an immunoassay with 60% cross-reactivity for hydromorphone).

The Department has evaluated these comments and concluded that no change is needed for immunoassay cross-reactivity requirements. The cross-reactivity requirements in Section 3.4 are necessary to ensure consistency in testing among laboratories using different immunoassay kits, as well as those using different test methods for initial drug testing. Cross-reactivity must be demonstrated and documented by the manufacturer (*e.g.,* package insert) and by the HHS-certified laboratory (*i.e.,* assay validation studies, reagent lot verification, and batch quality control for any analyte that exhibits less than 100% cross-reactivity).

One commenter stated that the low prevalence of MDA and MDEA does not warrant the burden placed on immunoassay manufacturers and laboratories. The Department has evaluated the comment and has removed MDEA from the Guidelines (*i.e.,* MDEA is no longer included as an authorized drug in Section 3.4). The number of positive MDEA specimens reported by HHS-certified urine laboratories (*i.e.,* information provided to the Department through the NLCP) does not support testing all specimens for MDEA in federal workplace drug testing programs. Because MDEA is a Schedule I drug, a federal agency may test specimens for MDEA in accordance with Section 3.2 (*i.e.,* on a case-by-case basis for reasonable suspicion or post-accident testing, routinely with a waiver from the Secretary). The Department understands that some other analytes have a low incidence, but believes that continued testing for these analytes is warranted in a deterrent program. In particular, inclusion of MDA as an initial and confirmatory test analyte is warranted because, in addition to being a drug of abuse, it is a metabolite of MDEA and MDMA.

Also in Section 3.4, the Department did not specify the target analyte to be used to calibrate an initial test for grouped analytes such as amphetamines or opioids. Three commenters noted that when an immunoassay is calibrated with a low-reacting drug, other analytes may exhibit high cross-reactivity, leading to false initial test positives. Two of these commenters also noted that this may result in possibly different cross-reactivity profiles for some structurally unrelated and concomitantly used prescription and/or over the counter drugs. It was not the Department's intent for the laboratory to calibrate an immunoassay test using an analyte other than that specified by the manufacturer. In the preamble to the proposed OFMG, the Department described using a control containing the lowest reacting analyte at its cutoff concentration to establish the decision point (*i.e.,* when an immunoassay for grouped analytes did not demonstrate at least 80% cross-reactivity to each analyte). The Department has determined that this approach is not necessary, and will not be permitted. There are current immunoassays that meet the requirements of this section for two or more analytes in a group (*i.e.,* analytes in the same drug class that have the same initial test cutoff). As indicated in Section 3.4, the laboratory may use multiple test kits or a single kit to meet the requirements.

However, the Department has revised Section 3.4 regarding the use of alternate technology initial tests for THC and 6-AM. To ensure consistent treatment of specimens, depending on the technology, the confirmatory test cutoff (*i.e.,* 2 ng/mL) must be used for THC and 6-AM. For example, because immunoassays cross-react with various marijuana constituents and metabolites, a specimen that is positive using a cutoff of 4 ng/mL for an immunoassay may not test positive using an alternate technology initial test with a 4 ng/mL cutoff for THC. When using an alternate technology initial test (*e.g.,* LC/MS/MS) that is specific for the target analyte, THC, must be tested using the confirmatory test cutoff.

3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

One commenter recommended that HHS maintain a list of allowable additional tests and reporting criteria (*e.g.,* threshold for reporting as positive, adulterated, substituted, and/or invalid, and a limit of detection as appropriate), to ensure consistency among laboratories and within the testing program. The Department has evaluated the comment and has concluded that no change is needed. The Department does not want to limit the analytes that may be tested, and will provide guidance to laboratories as necessary. It is also noted that the section requires all tests to meet appropriate validation and quality control requirements. The procedures and specimen records for such tests will be reviewed at NLCP inspections. The Department will continue to maintain a

list of HHS-certified laboratories that choose to perform additional tests for regulated specimens. The Department has reworded Section 3.5 in concert with revisions to Section 3.1 removing the requirement for albumin or IgG testing, as described under *Requirements for specimen validity testing* in this preamble.

One commenter asked whether an MRO could submit a blanket request to perform additional testing (*e.g.,* additional opioid metabolites) for all confirmatory specimens (*i.e.,* would laboratories be permitted to monitor the additional compounds in all confirmatory test assays?). The Department believes that testing all specimens for additional analytes may not be appropriate for some tests, especially hydrocodone, hydromorphone, oxycodone and oxymorphone. Recent studies show that testing for norhydrocodone and/or noroxycodone is not necessary for the interpretation of all results.[26 27] Norhydrocodone and noroxycodone metabolites may be helpful for the MRO to interpret test results only when a donor's prescription does not support the test results. The presence of norhydrocodone metabolite would support the use of hydrocodone and validate the donor's prescription. The same could be said for interpreting test results following an oxycodone dose. The presence of noroxycodone metabolite would support the use of oxycodone and validate the donor's prescription. The Department will provide guidance on these and other additional tests that may provide useful information for the MRO in the Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs. The Department has revised Section 3.5 to clarify that HHS-certified laboratories are authorized to perform additional tests upon MRO request on a case-by-case basis, but are not authorized to routinely perform such tests without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D,L stereoisomers of amphetamine and methamphetamine. The Department will continue to allow HHS-certified laboratories to test for D,L amphetamine and methamphetamine routinely or upon MRO request. The Department will provide guidance on these and other additional tests that may provide useful information for the MRO (*e.g.,* tetrahydrocannabivarin) in the Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs.

Additional drug and specimen validity testing under Section 3.5 does not include DNA testing.

3.7 What criteria are used to report an invalid result for an oral fluid specimen?

One commenter disagreed and recommended deleting Sections 3.7(a-c) and 3.7(g) from the Guidelines due to observed collections by trained collectors. As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. Section 3.7 has been revised accordingly.

Subpart D—Collectors

4.1 Who may collect a specimen?

One commenter questioned why the Department prohibits supervisors or hiring officials from collecting oral fluid specimens (unless no other collector is available). The commenter cited fewer privacy concerns in collecting oral fluid versus urine, and indicated that having supervisors collect specimens would be particularly useful in remote locations and/or for post-accident tests. The Department has evaluated the comments and has concluded that no change is needed. The Department will continue to prohibit routine collections by a supervisor, to avoid potential conflicts of interest due to the employee-supervisor relationship as much as possible. The Guidelines permit collections by a supervisor who has been trained as a collector when no other trained collector is available.

4.2 Who may not collect a specimen?

One commenter expressed concern that this section as written may unintentionally prevent the use of valid collection methods (*i.e.,* preventing the donor from collecting their own specimen may prohibit the donor from holding the collection device). The Department has evaluated the comments and has concluded that no change is needed to Section 4.2, which includes general language concerning the entire collection process. Section 8.4 describes steps the collector takes before the donor provides the oral fluid specimen, including reviewing with the donor the manufacturer's instructions for oral fluid collection using the specimen collection device. Section 8.5 describes the collection procedure, including the requirement for the donor to position the device for collection, and for the collector and donor to complete the collection in accordance with the manufacturer's instructions for the collection device. However, the Department has revised the wording in Section 8.5(a)(1) to address all types of oral fluid collection devices allowed by the OFMG (*i.e.,* including those that are not placed in the mouth).

Subpart E—Collection Sites

5.2 What are the requirements for a collection site?

One commenter suggested that the Department require restricted access only to be applicable during a collection period, and allow supplies and records to be stored in nearby secured areas. The Department has evaluated the comments and has concluded that no change is needed. The section clearly describes the requirements and addresses the commenter's concerns.

Subpart F—Federal Drug Testing Custody and Control Form (CCF)

6.1 What federal form is used to document custody and control?

6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

Comments on these two sections (Sections 6.1 and 6.2) are addressed here. Three commenters recommended that the Federal Custody and Control Form (CCF) be revised to address oral fluid specimens. The Department will revise the Federal CCF when Guidelines allowing oral fluid become effective.

The Department reworded items 6.2(b) and (c) for clarity.

Subpart G—Oral Fluid Specimen Collection Devices

7.3 What are the minimum performance requirements for a collection device?

The Department reworded Section 7.3(a) in reference to oral fluid collection volume, as described under Sections 2.4 and 2.5 above, and revised Section 7.3(b) in response to public comments, as described under *Performance requirements for an oral fluid collection device* above.

Subpart H—Oral Fluid Specimen Collection Procedure

8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?

One commenter stated that this section requires the collector to deter adulteration or substitution at the collection site, but does not provide any information on how this is to be done. The commenter recommended that Section 8.2 be deleted or, alternatively, that additional information be added to the section. The Department has

evaluated the comments and has concluded that no change is needed. The section provides the general requirement; the Department will provide more specific guidance as needed in the HHS Oral Fluid Specimen Collection Handbook, which will be issued after these Guidelines become effective.

8.3 What are the preliminary steps in the oral fluid specimen collection procedure?

In response to comments described under Sections 1.7 and 8.4 in this preamble, the Department revised Section 8.3(d) to require the collector to report a refusal to test when a donor brings materials for adulterating, substituting, or diluting a specimen to the collection site.

One commenter requested that the Guidelines clarify (possibly using a flowchart) the different waiting periods in Sections 8.3 and 8.6 (*i.e.,* if multiple waiting periods are required, do they run concurrently or consecutively?). The Department has evaluated the comments and has concluded that no change is needed. The Department will consider the commenter's suggestion during preparation of the HHS Oral Fluid Specimen Collection Handbook.

Several comments concerned Section 8.3 collection procedures regarding rinsing or drinking. One commenter disagreed with the requirement to have tobacco users rinse their mouth prior to an oral fluid collection, noting it is an inconvenience for the collector to provide a place for the donor to spit out the liquid. One commenter requested clarification on oral fluid collection procedures for tobacco users (*e.g.,* is the collector required to ask, is it a refusal if a tobacco user doesn't rinse their mouth, is the donor required to rinse with water, what if the donor uses more than 4 oz. of liquid to rinse?). The Department removed the reference to tobacco users in 8.3(d)(2) because there is no need for all tobacco users to rinse their mouths. The proposed procedure for tobacco users was due to the dark brown color of tobacco juice. The issue is that any discoloration may interfere with initial testing (*i.e.,* not just tobacco juice). The Department reworded this section to include abnormally colored saliva as a reason for the collector to give water to the donor for rinsing their mouth.

One commenter recommended that the Guidelines clarify that if the donor drinks water, the water must not be provided by the donor. For clarity, the Department revised Section 8.3(d)(2) to require the collector to give the donor water (for example, up to 4 oz.) to rinse the donor's mouth when the collector's inspection of the oral cavity identifies any items that could impede or interfere with the collection of an oral fluid specimen. If the donor refuses to rinse, this is a refusal to test. Rinsing with more than 4 oz. of water does not invalidate the collection, so this amount was given as an example rather than a requirement.

One commenter indicated that some collection devices specifically instruct against offering the donor anything to rinse with or drink. This commenter suggested modifying Section 8.3 to make offering of water conditionally allowed, depending on the collection device manufacturer's instructions. The Department has evaluated these comments and concluded that no change is needed. The Department believes that rinsing the oral cavity with water prior to a 10-minute wait period is a reasonable part of the oral fluid collection protocol. The wait period is sufficient to comply with the device instructions, and will not dilute the collected oral fluid.

Several comments concerned Section 8.3 collection procedures regarding inspection of the donor's mouth. One commenter requested clarification on what items need to be removed from a donor's mouth prior to an oral fluid collection (tobacco, food, gum, or mints versus retainers and piercings). One commenter requested clarification of whether ''dental retainer'' refers to a temporary or permanent device (or both), should the device be removed and, if so, where the device should be placed during the oral fluid collection. The Department has evaluated the comments and concluded that only one change is needed: Removal of ''dental retainer'' from the examples of items that must be removed based on a collector's inspection of the donor's mouth in Section 8.3(d). A donor is not required to remove dental appliances such as a retainer. The Department will provide additional information in the Oral Fluid Specimen Collection Handbook to clarify items that may impede or interfere with the collection.

One commenter recommended that the Guidelines address the situation where a donor may have a medical condition that prevents them from opening their mouth for the collector to inspect. The Department agrees with the commenter and has revised Section 8.3(d) to address this situation. The collector will proceed with the same steps as when a donor is unable to provide an oral fluid specimen, as described in Section 8.6(b)(2), and the MRO will follow the steps in Section 13.6(b) requiring a medical evaluation of the donor.

8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

Two commenters believe that if the collector finds an adulterant or substitution product, this should be a refusal to test. As noted under Sections 1.7 and 8.3 in this preamble, the Department agrees that the collector must report a refusal to test when a donor brings materials for adulterating, substituting, or diluting a specimen to the collection site, or when the collector observes a donor's clear attempt to tamper with a specimen. The Department has revised Section 8.4(c) accordingly.

The Department deleted Section 8.4(b)(1) for consistency with Section 8.6(b). The deleted item stated that the collector may set ''a reasonable time for a collection based on the device used, not to exceed 15 minutes.'' Section 8.6(b) states that the donor demonstrates their inability to provide a specimen when, after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device.

8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?

One commenter suggested that the section should state that the collector be present and maintain visual contact with the donor and collection device during the procedures outlined in this section. The Department has evaluated the comment and has concluded that no change is needed: Sections 8.4(a) and 8.5(a) clearly require the collector to keep the unwrapped collection devices and the donor in view at all times during the collection.

One commenter asked if there was a limit to the number of times a collection could be restarted due to collection device failures. The Department has evaluated the comment and has reworded Section 8.5 for clarity. Section 8.5(a)(1) was revised to indicate that a failure to provide a specimen (which may or may not be due to device failure) prompts recollection using a new device and that the collector documents the failed collection attempt on the Federal CCF. The Department also reworded Section 8.5(b) to clarify that a donor's refusal to begin the collection process after a failure to collect the specimen is a refusal to test. The Department did not set a limit for the number of attempts because there may be different reasons for failing to collect the specimen from the donor. However, the Department

revised the section to require the collector to follow the procedure in Section 8.6 ''after multiple attempts to collect the specimen.''

One commenter stated that HHS should clarify that a donor's refusal to provide a split specimen will also qualify as a refusal to test. The Department agrees with the comment and has revised Section 8.5(b) to include the refusal to provide a split oral fluid specimen as a refusal to test.

Additionally, as described under Section 4.2 above, the Department revised Section 8.5(a)(1) to address all types of collection devices allowed by the OFMG (including those that are not placed in the mouth).

8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?

Three commenters disagreed with the requirement for the collector to contact the agency representative for authorization to collect an alternate specimen each time a donor is unable to provide a sufficient volume. These commenters suggested that the Guidelines allow this to be addressed in established standard protocols for the agency. The Department agrees with the commenters. Each federal agency may decide whether to require notification in each case or whether to provide a standard protocol for collectors to follow. Section 8.6 has been revised accordingly.

Also in regard to Section 8.6, one commenter requested additional information on donor hydration during an oral fluid specimen collection (*i.e.,* asking if there is evidence that hydration improves the ability to provide a specimen and whether hydration dilutes the specimen). One commenter indicated that the volume of oral fluid collected does not appear to be directly related to fluid intake and suggested that, because some donors may not be able to provide a sufficient specimen even after the one hour wait time, a urine specimen should be collected immediately. One commenter disagreed with the one hour period allowed for an oral fluid collection, and indicated that there is no evidence provided that dry mouth is eliminated by waiting one hour. The commenter indicated that this extra time allotted costs the employer unnecessary time and money, and maintained that a waiting period of 10 minutes after consumption of 8 oz. of water is sufficient. The Department has evaluated the comments and concluded that no change is needed to Section 8.6. The proposed procedure sets a reasonable time limit within which most donors would be able to provide an acceptable specimen volume (*i.e.,* 10 minutes between attempts to provide the oral fluid specimen, up to one hour), and the section clearly states that the donor is not required to drink any fluids during the wait time. The Guidelines clearly describe the limited circumstances in which the collector offers the donor fluids. However, the Department has revised Section 8.8(a)(2) to expressly prohibit rinsing or drinking between the collection of the primary and split specimens when serially collected.

8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?

One commenter disagreed with the Guidelines as written and suggested that when a donor cannot provide the primary specimen type, an alternate specimen should be collected immediately. The commenter cited the additional time and cost as well as the fact that the collector may not know the agency's policy on alternate specimen types. The Department has concluded that no change is needed for Section 8.7 in response to this comment. The Guidelines will continue to require that the donor be allowed reasonable attempts to provide an oral fluid specimen as described in Sections 8.5 and 8.6. The Department has revised Section 8.6 to allow a federal agency to either require notification in each case or provide a standard protocol for collectors to follow when the donor is unable to provide an oral fluid specimen. The Department has reworded this section to state ''Yes, if. . .'' rather than ''No, unless. . .'' in response to a federal agency's comment and to enhance clarity. The meaning of this section remains the same.

8.8 How does the collector prepare the oral fluid specimens?

One commenter requested clarification of the ''simultaneous'' oral fluid collections. The Department has evaluated the comment and has concluded that no change is needed. Section 8.8(a)(1) describes ''Two specimens collected simultaneously with two separate collection devices.''

One commenter expressed concern that the requirement for a serial collection of a split specimen to begin within two minutes of the first collection may be difficult to monitor and may lead to differences between the two specimens. This commenter requested clarification on how this process will be monitored. One commenter agreed with the two-minute maximum time between serial collections of a split specimen. The Department has evaluated the comments and agrees with the second commenter that no change is needed. The proposed procedure in Section 8.8 sets a reasonable time within which the collector can take the first collection device from the donor and record the time on the Federal CCF, while the donor positions the second device for the collection. Because the collector works with one donor at a time, the collector should have no difficulty monitoring the time between primary and split collections. Furthermore, the Department believes this timing would not affect results of the primary and split oral fluid specimens.

One commenter disagreed with the proposed two-minute maximum time between serial collections of a split specimen and suggested that the time be increased to 10 minutes (so as not to rush the collector in completing chain of custody forms). This commenter suggested that a second specimen should only be collected after an initial test result is obtained (which the commenter indicates can usually be done in 10 minutes). The Department has evaluated the comments and has concluded that no change is needed. The collector is not required to complete the Federal CCF until both the primary and split specimens have been collected. Point of collection testing is not allowed under these Guidelines. That is, all testing must be performed at an HHS-certified test facility.

One commenter asked whether hydration would be allowed between serial split collections. The Department revised Section 8.8(a)(2) to expressly prohibit rinsing or drinking between the collection of the primary and split specimens when serially collected. Prohibiting rinsing or drinking will better ensure consistency of the primary and split specimens.

The Department added an additional item under Section 8.8(a) to clarify that the OFMG allow collection of a single specimen and subdividing the collected specimen into primary (A) and split (B) specimens. A similar change was made to the definition of ''split specimen collection (for oral fluid)'' in Section 1.5.

The Department also removed the word ''known'' in Section 8.8(b) in reference to oral fluid collection volume, as described under Sections 2.4 and 2.5 above.

In response to a federal agency comment, the Department deleted a sentence in item 8.8(h) that required the collector to send a copy of the Federal CCF to the HHS-certified laboratory. The Department agreed with the federal

agency that this instruction is redundant because item 8.8(g) instructs the collector to distribute copies of the Federal CCF as required.

Subpart I—HHS-Certification of Laboratories

9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

One commenter noted that, because proposed initial test requirements allow calibration with a low-reacting analyte, PT schemes would likely need to be designed based on the specific implementation at each laboratory. The commenter provided an example: When an immunoassay is calibrated with a drug/metabolite that exhibits 50% cross-reactivity, the intended target analyte (''calibrant'') at the cutoff concentration would elicit a response well in excess of the cutoff. This could result in inaccurate initial test results (*i.e.,* a positive initial test result for a specimen containing the calibrant at a concentration below the cutoff). The commenter stated that this result could be scored as a ''false positive'' PT result. The Department has evaluated the comment and has concluded that no change is needed. As noted above regarding Section 3.4, it was not the Department's intent for the laboratory to calibrate an immunoassay test using an analyte other than that specified by the manufacturer. NLCP PT schemes are designed based on known cross-reactivity profiles of the initial tests used by HHS-certified laboratories.

Also in regard to proposed Section 9.5, one commenter suggested that the Guidelines use the same wording as in the Guidelines effective October 1, 2010 (73 FR 71858) for retest PT sample specifications (*i.e.,* ''. . . may be as low as . . .'' rather than the proposed wording ''. . . may be less than . . .''). The Department agrees and has reinstituted wording from Section 9.3 of the Guidelines effective October 1, 2010 (73 FR 71858) into Section 9.5(a)(1)(ii).

As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. Section 9.5 has been revised accordingly.

9.6 What are the PT requirements for an applicant laboratory?

9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?

Comments on these two sections (Sections 9.6 and 9.7) are addressed here. As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. Sections 9.6 and 9.7 have been revised accordingly.

Subpart J—Blind Samples Submitted by an Agency

10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories?

Two commenters disagreed with the proposed limit to the number of blind samples required (*i.e.,* a maximum of 400 blind samples per year) in Section 10.1(b). The commenters indicated that for a large agency, there is a very large difference between 3% and 400 samples and suggested keeping only the 3% requirement. Another commenter disagreed with the 3% requirement for blind samples and requested that the amount to be lowered to 1% to lessen the burden on employers. The Department has evaluated the comments and has concluded that no change is needed. The 400 sample limit was added to reduce the burden on large agencies based on the Department's review of agencies' blind testing programs.

One commenter suggested that the wording be modified to clarify that employers are responsible for ensuring blind samples are sent to the laboratories, but that collectors are tasked with submitting the blind samples. The Department has evaluated the comment and has concluded that no change is needed. The wording in Section 10.1(a) clearly describes the responsibilities of the federal agency and the role of the collector in blind sample submission; however, the Department reworded Section 10.3(a) for clarity as described below.

10.3 How is a blind sample submitted to an HHS-certified laboratory?

The Department has reworded Section 10.3(a) to clarify that the collector sends a blind sample to a laboratory as a split specimen (*i.e.,* specimens A and B).

Subpart K—Laboratory

11.9 What are the requirements for an initial drug test?

One commenter noted that HHS previously required initial and confirmatory testing using different techniques, and asked whether this requirement had been removed with allowance of technologies other than immunoassay for initial testing. The commenter expressed concern that an error in the initial drug test could be repeated in the confirmatory drug test using the same method. The Department has evaluated the comment and has concluded that no change is needed. The Guidelines maintain the requirement for initial and confirmatory tests on two separate aliquots to report a result other than negative. The NLCP will review validation and quality control records, as well as specimen records, to ensure that the initial and confirmatory testing methods meet Guidelines requirements and provide scientifically and forensically supportable results.

11.10 What must an HHS-certified laboratory do to validate an initial drug test?

One commenter noted that Section 11.10 provides general information on validation requirements, and asked where detailed requirements can be found. The Department has evaluated the comment and has concluded that no change is needed. The Department will continue to provide details for applicant and certified test facilities through the NLCP.

One commenter asked whether the requirement in 11.10(c) for periodic verification of ''each initial drug test using an alternate technology'' applied to immunoassay tests used differently than originally cleared by the FDA or other laboratory developed tests. The Department has evaluated the comment and has concluded that no change is needed. This section clearly distinguishes initial tests using immunoassay from those using an alternate technology. Furthermore, Section 1.5 includes the definition for ''alternate technology initial drug test.''

11.11 What are the batch quality control requirements when conducting an initial drug test?

Seven commenters disagreed with the requirement for an initial test control targeted at 25% above the cutoff. The commenters noted that drug concentrations are much lower in oral fluid than in urine, and stated that assays are unlikely to perform robustly with current immunoassay technology. One commenter also noted that oral fluid is diluted three- to four-fold. One commenter suggested requiring a control targeted at 50% above the cutoff, consistent with current FDA-cleared assays. The Department has evaluated the comments and has concluded that no change is needed. Consistent with the urine program requirements, laboratories must have the ability to apply the program cutoffs to regulated specimens, and document that ability by analyzing a control targeted at 25% above the cutoff in each batch.

One commenter asked whether the inclusion of ''additional compounds as target analytes'' for amphetamine and

opioid assays affect quality control content requirements. The Department has evaluated the comment and has concluded that no change is needed. The initial drug test quality control requirements in the Guidelines apply to each analyte used to calibrate the test (*i.e.,* immunoassay or alternate technology initial drug test). When a single immunoassay test is used for two or more analytes in a drug class, the HHS-certified laboratory must include a control in accordance with item 11.11(a)(2) for each analyte that has less than 100% cross-reactivity with the assay, to demonstrate that the requirement for at least 80% cross-reactivity has been met.

11.14 What are the batch quality control requirements when conducting a confirmatory drug test?

One commenter stated that analyzing quality control samples with concentrations of a drug or metabolite targeted at less than 40% of the proposed cutoffs would be an analytical challenge for high volume laboratories utilizing GC/MS or LC/MS/MS. The Department has evaluated the comments and has concluded that no change is needed. The NLCP Pilot PT Program has documented the capability of laboratories to meet the proposed OFMG requirements.

Also in regard to the proposed quality control requirements for an initial drug test in Section 11.11 and for a confirmatory drug test in Section 11.14, one commenter requested clarification for the requirement for a drug-free control (*i.e.,* whether the control should contain no drug or whether the control should not contain the specific analyte for that test). The Department has evaluated the comment and has concluded that no change is needed. These Guidelines sections list the requirement for ''at least one control certified to contain no drug or drug metabolite,'' meaning that the control must contain no regulated drug analytes.

11.15 What are the analytical and quality control requirements for conducting specimen validity tests?

The Department has reworded Section 11.15(a) for clarity, to correctly reflect requirements.

11.17 What are the requirements for an HHS-certified laboratory to report a test result?

One commenter suggested that the Department remove the requirement for an executed CCF as the official report for ''non-negative'' specimens and permit the use of an electronic report with the required information. The Department has evaluated the comment and has concluded that no change is needed. The Federal CCF establishes the chain of custody for the specimen from the time of collection until receipt by the laboratory and also contains the certification statement signed by the certifying scientist. The Federal CCF may be paper or electronic.

As described under *Requirements for specimen validity testing* in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. Section 11.17 has been revised accordingly.

11.21 What HHS-certified laboratory information is available to a federal agency?

As described under *Requirements for specimen validity* testing in this preamble, the Department has revised the Guidelines to allow, but not require, specimen validity testing. The list of items provided in a standard documentation package for an oral fluid specimen has been revised accordingly [*i.e.,* Section 11.21(b)(4)].

11.22 What HHS-certified laboratory information is available to a federal employee?

One commenter asked why the proposed Guidelines include a requirement for a copy of the semiannual statistical summary report to be sent to the Secretary or designated HHS representative. The Department included the requirement to facilitate compilation of statistical information for the federal drug-free workplace program. This will not place an additional burden on the laboratory other than transmission of the report. The Department will continue to evaluate the effectiveness of this requirement.

Subpart L—Instrumented Initial Test Facility (IITF)

12.1 May an IITF test oral fluid specimens for a federal agency's workplace drug testing program?

One commenter disagreed with prohibiting IITFs for oral fluid. This commenter considers the current HHS-certified urine IITF to be a success in Canada and stated that prohibiting oral fluid IITFs would result in less enthusiasm for regulated procedures and impact workplace safety. At this time, as stated in the preamble to the proposed OFMG, IITFs are not practical and will not be allowed due primarily to the limited specimen volume of oral fluid collected from the donor. The Department will continue to monitor developments in oral fluid drug testing after this new specimen type has been implemented in federal workplace programs, and may reassess the feasibility of allowing IITFs for oral fluid in the future.

Subpart M—Medical Review Officer (MRO)

13.1 Who may serve as an MRO?

Three commenters disagreed with the term ''nonmedical use of a drug'' used in Section 13.1 (and defined in Section 1.5) and indicated that the term changes the role of an MRO from review, verify and ''report a non-negative result'' to review, verify and ''interpret before reporting a result as negative or nonmedical use of a drug.'' Two commenters disagreed with use of ''interpretation of results'' to supplant ''alternative medical explanation.'' One commenter noted that this perceived change in the MRO's role represents an unjustified shifting of risk to the MRO. One commenter believes the term presents a possible legal flaw to Guidelines, stating that this term is legally different from ''safety concern'' and places MROs in the position of being in conflict with the prescribing physician and subject to lawsuits. This commenter stated that even a lack of a finding of nonmedical use could be an issue if the donor subsequently had an accident after using the drug. The same commenter submitted five recommendations related to inclusion of prescription drugs in federal workplace drug testing programs, to address the commenter's concerns with the proposed Guidelines. These five specific recommendations pertain to matters that are outside the scope of these Guidelines, and therefore are not addressed in the Department's response below.

The responsibilities of an MRO to interpret results have largely remained the same between the Guidelines effective October 1, 2010 (73 FR 71858) and these Guidelines. As stated in Section 13.5(c) of these Guidelines, ''if the donor provides a legitimate medical explanation (*e.g.,* a valid prescription) for the positive result, the MRO reports the test result as negative to the agency.'' Accordingly, the intent of the Guidelines, in this context, is to confirm whether a positive drug test is the result of drug use under a valid prescription. Furthermore, the term ''alternate medical explanation'' has never been used in the Guidelines, but has been used in the HHS Medical Review Officer Manual for Federal Workplace Drug Testing Programs.

For the reasons above, the Department believes that the definition of ''nonmedical use of a drug'' and the requirement for a physician serving as an MRO to have knowledge of this topic do not fundamentally change the MRO's responsibilities. However, to address the commenters' concerns, the Department has removed this term from the Guidelines (*i.e.,* revised Sections 1.5 and 13.1).

One commenter requested clarification that it is the federal agency's burden to ensure that the MRO is certified. One commenter asked how the laboratory will be informed that an MRO has met requirements for re-qualification. The Department evaluated the comments and concluded that no change is needed. The MRO is an employee or a contractor of the agency. Therefore, it is the agency's responsibility to ensure that the MRO meets the Guidelines qualification requirements.

Two commenters disagreed with the requirement for MRO recertification every five years, and recommended that MROs complete training every three years. Five commenters stated support for five year requalification and examination requirements. The Department has evaluated the comments and has concluded that no change is needed. The Department will keep the five-year requalification requirement as proposed. This is consistent with the MRO requalification requirement in the UrMG.

13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

One commenter agreed with MRO certification/training entities submitting the delivery method and content of the MRO examination as applicable along with other required documents. One commenter agreed with extending time from one to two years for approved MRO certification/training entities' resubmission of qualifications for HHS approval. The commenter noted that they would support further extension to 3 years.

One commenter recommended that approval of MRO educational courses and content be at the discretion of the MRO certification entities, not HHS. Since the certification entities and their examinations are subject to HHS oversight and approval, the commenter noted that it may be burdensome for HHS to review and approve the courses and content, and be a disincentive to development of new courses. One commenter recommended that examinations be allowed to be in-person or online with appropriate security precautions for each delivery method. The Department has evaluated the comments and agrees that the submission of training materials to HHS would possibly discourage the development of new training courses. Therefore, the review of MRO educational courses and content will not be part of the approval process for MRO certification entities. As described under *Medical Review Officer (MRO) requalification—continuing education units (CEUs)* in this preamble, the Department has removed references to MRO training entities in Section 13.2, because training documentation is maintained by MRO certification entities. The Department will only require the MRO certification entities to submit their examination and any other necessary supporting examination materials (*e.g.,* answers, examination statistics or background information on questions) that will help in the Department's evaluation of the examination. The Department has revised Section 13.2 accordingly.

The Department will review and evaluate the examination delivery method (*e.g.,* in-person or online) when reviewing submitted materials to ensure that the delivery method employs appropriate security and identification procedures.

13.3 What training is required before a physician may serve as an MRO?

Five commenters disagreed and one commenter agreed with the added requirement for MRO training to include information about how to discuss substance misuse and abuse and how to access those services. The Department has evaluated the comments and has revised Section 13.3 to remove this requirement. Federal agencies may provide this information to employees and applicants to facilitate their access to effective treatment and support recovery. The Department provides information to the public on help and treatment for substance misuse and abuse, and how to access those services, on the SAMHSA website *http://www.samhsa.gov/*.

One commenter stated that the Department should add a requirement for MRO training on what constitutes a refusal to test. One commenter suggested that the Department should add a requirement for MRO training on when and how to report safety concerns to employers when prescription and/or over-the-counter medications may affect performance. The Department has evaluated the comments and has concluded that no change is needed. Criteria for reporting a refusal to test are covered under the topics listed in Section 13.3 such as items (a)(4) training on the Guidelines and (a)(5) procedures for interpretation, review, and reporting of results. When a donor provides a legitimate medical explanation for a positive drug test (*e.g.,* a valid prescription), the Guidelines do not require MROs to contact federal agency employers for the purpose of reporting a safety concern. Accordingly, MRO training related to reporting ''safety concerns'' does not relate to a mandatory function under the Guidelines and, therefore, is not an essential component of required MRO training. The Department will provide additional guidance in the HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs.

In addition, the Department revised Section 13.3 as described under *Medical Review Officer (MRO) requalification—continuing education units (CEUs)* in this preamble. The Department removed references to MRO training entities because training documentation is maintained by MRO certification entities, and added item 13.3(b) to require MRO training on revised Guidelines prior to their effective date.

13.4 What are the responsibilities of an MRO?

One commenter suggested creating a subset of medical professionals trained specifically to determine fitness for duty since an MRO cannot determine fitness for duty over the telephone. The Department has evaluated the comment and has concluded that no change is needed. Fitness for duty evaluations fall outside the purview of the Guidelines.

13.5 What must an MRO do when reviewing an oral fluid specimen's test results?

The Department has revised Section 13.5(c)(1) to include ''a valid prescription'' as an example of documentation to support a medical explanation for a positive drug test result.

As described under *Testing for Marijuana Use* in this preamble, the Department has revised Section 13.5(c)(1) to reflect the Department's policy that passive exposure to a drug (*e.g.,* exposure to secondhand marijuana smoke) and ingestion of food products containing marijuana are not legitimate medical explanations for a positive drug test result.

In Section 13.5(c)(2)(i), the Department clarified that the requirement for ''clinical evidence of illegal use'' does not apply if the laboratory confirms the presence of 6-

acetylmorphine (*i.e.,* the presence of this metabolite is proof of heroin use).

13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of oral fluid for a drug test?

One commenter requested definition of ''appropriate expertise'' in medical issues raised by a donor's failure to provide a specimen. The same commenter requested medical referral information on the employer's actions when a donor could not provide a urine specimen and then could not provide an oral fluid specimen. The Department has evaluated the comments and has concluded that no change is needed. A physician who is a trained MRO will have the knowledge necessary to identify another physician with appropriate expertise for the medical evaluation. The Department will provide additional guidance in the HHS Medical Review Officer Guidance Manual for Federal Workplace Drug Testing Programs as appropriate when oral fluid is allowed in federal workplace drug testing programs.

The Department clarified the definition of ''permanent or long-term medical conditions'' in Section 13.6(b)(1) based on a federal agency comment.

Subpart O—Criteria for Rejecting a Specimen for Testing

15.1 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing?

The Department revised wording in items a and b of this section, and included three additional fatal flaws as items f-h, to reflect fatal flaws for regulated donor specimens that have been identified by HHS-certified laboratories. These fatal flaws were addressed in NLCP guidance sent to all HHS-certified and applicant laboratories and IITFs on August 9, 2016. In addition, the Department revised this section to include an additional item i to allow a laboratory to reject a specimen when they identify a flaw that prevents testing or affects the forensic defensibility of the drug test, and cannot be corrected. This general item enables laboratories to reject specimens with fatal flaws that may be rare, but do occur. It is not possible to list all such flaws in the Guidelines.

15.3 What discrepancies are not sufficient to require an HHS-certified laboratory to reject an oral fluid specimen for testing or an MRO to cancel a test?

Two commenters indicated that inclusion of some items as insignificant discrepancies contradicts guidance provided to HHS-certified laboratories and IITFs in NLCP Notices, which required laboratories to attempt to recover missing information. One of these commenters suggested that if these items are important, they should be removed from the ''insignificant'' list. Two commenters disagreed with the Guidelines designating the listed omissions and discrepancies as ''insignificant only when they occur no more than once per month.'' The Department has evaluated the comments. The listed discrepancies would not result in rejection or cancellation. NLCP Notices requiring laboratory action are consistent with this section. However, the Department has reworded section 15.3 to not classify these errors as insignificant. While these types of errors do not warrant laboratory rejection of a specimen or MRO cancellation of a test, as noted in section 15.3(c), corrective action must be initiated when they occur more than once a month.

The commenters indicated that this section implies that the MRO must keep a log of insignificant errors by laboratory and by collection site in order to track frequency. The commenters noted that this is an unenforceable policy, that this should be a duty of inspectors of laboratories and collection sites, and that requiring MROs to keep these types of logs would create significant extra costs. One commenter suggested that item 15.3(c) be modified for the MRO to advise the collector or laboratory to retrain staff on relevant procedures to ensure that collections are completed correctly (rather than directing them to immediately take corrective action). The Department has evaluated the comments and has concluded that no change is needed. This section is the same as in the Guidelines effective October 1, 2010 (73 FR 71858).

One commenter suggested modifying 15.3(a)(5) to read ''donor identification number'' which would include a social security number or an employee identification number since many employers no longer use social security numbers for employee identification. The Department agrees and has revised Section 15.3(a)(5) to include ''employee identification number'' in addition to ''Social Security Number.''

15.4 What discrepancies may require an MRO to cancel a test?

One commenter suggested adding the scenario where the donor did not sign the CCF because the collector forgot to ask the donor to sign, rather than the donor's refusal to sign. The Department has evaluated the comment and has concluded that no change is needed. As stated in Section 15.4, the MRO contacts the collector ''to obtain a statement to verify that the donor refused to sign the MRO copy.''

Regulatory Impact and Notices

Executive Order 12866

The Secretary has examined the impact of the Guidelines under Executive Order 12866, which directs federal agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). In addition, the Department published a **Federal Register** notice in June 2011 to solicit comments regarding the science and practice of oral fluid testing via a Request for Information (RFI) [76 FR 34086].

According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million; adversely affecting in a material way a sector of the economy, competition, or jobs; or if it raises novel legal or policy issues. The Guidelines do establish additional regulatory requirements and allow an activity that was otherwise prohibited. The Administrative Procedure Act (APA) delineates an exception to its rulemaking procedures for ''a matter relating to agency management or personnel'' 5 U.S.C. 553(a)(2). Because the Guidelines issued by the Secretary govern federal workplace drug testing programs, HHS has taken the position that the Guidelines are a ''matter relating to agency management or personnel'' and, thus, are not subject to the APA's requirements for notice and comment rulemaking. This position is consistent with Executive Order 12564 regarding Drug-Free Workplaces, which directs the Secretary to promulgate scientific and technical guidelines for executive agency drug testing programs.

The Department included a Regulatory Impact and Notices section with cost and benefits analysis and burden estimates in the May 15, 2015

Federal Register Notice for the proposed OFMG (80 FR 28054), and requested public comment on all estimates and assumptions.

One commenter disagreed with the Department's projected numbers of oral fluid and urine drug tests by federal agencies and industries regulated by the Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC). This commenter predicted that there will be a large shift from urine to oral fluid testing when oral fluid is allowed in regulated testing, stating that the oral fluid collection is a more efficient and direct process for the collector, oral fluid is much less likely to be adulterated than urine, oral collections are quicker than most urine collections, and oral fluid is looked upon favorably from a hygienic perspective by donors and collectors. The commenter did not provide any substantive evidence or data to support these comments. One commenter disagreed with inclusion of cost estimates within the Guidelines due to the difficulty in comparing urine and oral fluid costs. The Department has evaluated the comments and has concluded that no change is needed. The Department's projections were developed using information from current HHS-certified urine testing laboratories, with input from DOT and NRC, and cost analysis was based on information provided by multiple oral fluid testing laboratories and MROs. Each federal agency will decide whether to collect urine, oral fluid, or both specimen types in their workplace testing programs, and DOT and NRC will decide whether to allow oral fluid testing in workplace drug testing regulations for their regulated industries. Costs are expected to vary among individual laboratories and MROs, depending on their processes and testing populations. Additional information on the estimated costs associated is below.

Need for Regulation

Enhances Flexibility

The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) revise the requirement to collect only a urine specimen, which has existed since the Guidelines were first published in 1988, while continuing to promulgate established standards to ensure the full reliability and accuracy of drug test results. Urine testing is subject to issues related to a donor's inability to produce a urine specimen due to a legitimate medical condition. In such situations, the test may produce an invalid result or create delays accruing from the need to reschedule the test or medically assess the donor's inability to provide a urine sample. When the OFMG are implemented by an agency, such agency will be authorized to collect an oral fluid specimen from an individual who is unable to provide a urine specimen. This added flexibility will reduce both the need to reschedule collections and the need for the Medical Review Officer (MRO) to arrange a medical evaluation of a donor's inability to provide a specimen. Therefore, the OFMG provide flexibility to address workplace drug testing needs of federal agencies by permitting the selection of the specimen type best suited for their needs and authorizing collection of an alternative specimen type when a donor is unable to provide a specimen. The added flexibility will also benefit donors, who should be able to provide one of the specimen types, thereby facilitating the drug test required for their employment.

Enhances Versatility

Urine collection requires use of a specialized collection facility, secured restrooms, the same gender, and other special requirements. Oral fluid may be collected in various settings. An acceptable oral fluid collection site must allow the collector to observe the donor, maintain control of the collection device(s) during the process, maintain record storage, and protect donor privacy.

Decreases Invalid Tests

All unobserved specimen collections are at risk for substitution and adulteration. Studies conducted by the drug testing industry indicate that 0.05 to 3% of urine specimens collected for drug use detection are determined to be substituted or adulterated.[5 27 28] Oral fluid collections will occur under observation, which should substantially lessen the risks of specimen substitution and adulteration that has been associated with urine specimen collections, most of which are unobserved. Specimen validity testing of oral fluid specimens will be allowed to identify invalid specimens (*e.g.,* testing for a biomarker such as albumin or immunoglobulin G, IgG).

Saves Time

Oral fluid collection can require less time than urine collection, reducing employee time away from the workplace and, therefore, reducing costs to the federal agency employer. Oral fluid collection does not require a facility that provides visual privacy during the collection. Unlike urine specimen collections, it is expected that many oral fluid collections will occur at or near the workplace, and not at a dedicated collection site, thereby reducing the amount of time away from the workplace. The collector is allowed to be in the vicinity of the donor, reducing the loss of productive time. The option to collect a urine specimen in the event that the donor cannot provide an oral fluid specimen (and vice versa) will reduce both the need to reschedule a collection and the need for the MRO to arrange a medical evaluation of a donor's inability to provide a specimen. Administrative data for urine collections indicates it takes, on average, about 4 hours from the start of the notification of the drug test to the actual time a donor reports back to the worksite. Since oral fluid collection does not have the same privacy concerns as urine collection, onsite collections are likely, thereby reducing the time a donor is away from the worksite. The Department estimates the time savings to be more than 2 hours. This estimate takes into account the time savings if the oral fluid collection was conducted at the employee's workplace, and thus incorporates travel time savings. Using OPM's estimate for the average annual salary of Federal employees converted to an hourly wage, the savings generated for the Federal Government would be roughly $400,000 to $1.2 million a year, or $38 to $114 per test.

Versatility in Detection

The time course of drugs and metabolites differs between oral fluid and urine, resulting in some differences in analytes and detection times. Oral fluid tests generally are positive as soon as the drug is absorbed into the body. In contrast, urine tests that are based solely on detection of a metabolite are dependent upon the rate and extent of metabolite formation. Thus, oral fluid may permit more interpretative insight into recent drug use drug-induced effects that may be present shortly before or at the time the specimen is collected. A federal agency may select the specimen type for collection based on the circumstances of the test. For example, in situations where drug use at the work-site is suspected, the testing of oral fluid may show the presence of an active drug, which may indicate recent administration of the drug and be advantageous when assessing whether the drug contributed to an observed behavior.

Current Testing in the Drug Free Workplace Program

Urine was the original specimen of choice for forensic workplace drug

testing, and urine testing is expected to remain an established and reliable component of federal workplace drug testing programs. Urine testing provides scientifically accurate and legally defensible results and has proven to be an effective deterrent to drug use in the workplace.

A major challenge to urine drug testing has been the proliferation of commercial products used to adulterate or substitute a donor's urine specimen. Due to individual privacy rights, most urine collections are unobserved, allowing the opportunity to use such products. As the Department has established requirements and laboratories have developed procedures to control for adulterated and substituted specimens, manufacturers have developed new products to avoid detection. The use of these products is expected to continue.

Cost and Benefit

Using data obtained from the Federal Workplace Drug Testing Programs and HHS-certified laboratories, the Department estimates the number of specimens tested annually for federal agencies to be 150,000. The Department projects that approximately 7% (or 10,500) of the 150,000 specimens tested per year will be oral fluid specimens and 93% (or 139,500) will be urine specimens. The subsequent transition to oral fluid testing is expected to be gradual and steady over the course of four years, when it should plateau to account for 25 to 30% of federal agency drug testing (*i.e.,* 37,500 to 45,000 specimens). This transition estimate is based on the non-regulated sector's time course of the testing of oral fluid and urine in the four years preceding the final OFMG.

The approximate annual numbers of regulated specimens collected from applicants and employees under the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) drug testing regulations are 6 million and 155,000, respectively. Should DOT and NRC allow oral fluid testing in regulated industries' workplace programs, the estimated annual numbers of specimens for DOT would be 180,000 oral fluid and 5,820,000 urine, and numbers of specimens for NRC would be 10,850 oral fluid and 144,150 urine. Assuming the same four-year transition time for DOT- and NRC-regulated industries, the numbers of oral fluid specimens are expected to be 1,500,000 to 1,800,000 specimens under DOT regulations and 38,750 to 46,500 specimens under NRC regulations.

In Section 3.4, the Department included criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specified the cross-reactivity of the immunoassay to the other analytes(s) within the group. These Guidelines allow the use of methods other than immunoassay for initial testing. An immunoassay manufacturer may incur costs if they choose to alter their existing product and resubmit the immunoassay for FDA clearance.

Costs associated with the addition of oral fluid testing and testing for oxycodone, oxymorphone, hydrocodone and hydromorphone will be minimal based on information from some HHS-certified laboratories currently testing private sector oral fluid specimens.

Prior to being allowed to test regulated oral fluid specimens, laboratories must be certified by the Department through the NLCP. Estimated laboratory costs to complete and submit the application are $3,000, and estimated costs for the Department to process the application are $7,200. These estimates are from SAMHSA and are based on the NLCP fee schedule and historical costs. The initial certification process includes the requirement to demonstrate that the applicant laboratory's performance meets Guidelines requirements by testing three (3) groups of PT samples. The Department will provide the three groups of PT samples through the NLCP at no cost. Based on costs charged for urine specimen testing, laboratory costs to conduct the PT testing would range from $900 to $1,800 for each applicant laboratory.

Agencies choosing to use oral fluid in their drug testing programs may also incur some costs for training of federal employees such as drug program coordinators. Based on current training modules offered to drug program coordinators, and other associated costs including travel for 90% of drug program coordinators, the estimated total training cost for a one-day training session would be between $108,000 and $138,000 (*i.e.,* assuming 8 hours of time multiplied by a GS 12/13 wage including benefits and overhead adjustments). This training cost is included in the costs of the revised URMG. The Department will offer the choice of online or in-person training. This will eliminate travel costs for those federal agencies who choose to use online training.

SUMMARY OF ONE-TIME COSTS

	Lower bound	Upper bound	Primary
Cost of Application *	.....	.....	$93,000.00
Application Processing *	.....	.....	217,000.00
Performance Testing *	$27,900.00	$55,800.00	.....
Training *	108,000.00	138,000.00	.....
Total	445,900.00	503,800.00	.....

* Estimated using costs presented above multiplied by the number of Laboratories (31).

Costs and Benefits

Thus, the Department estimates one-time, upfront costs of between $446,000 and $504,000. While the Department has only monetized a small portion of the benefits (time savings) to a small subset of the workplace drug testing programs that could be affected by the OFMG (*i.e.,* federal employee testing programs and not drug testing programs conducted under NRC and DOT regulations), the Department is confident that the benefits would outweigh the costs. Even if NRC and DOT do not implement oral fluid testing for their regulated industries' drug testing programs, the benefits to Federal workplace testing programs, estimated at between $400,000 and $1.2 million, would recur on an annual basis.

Executive Order 13771: Reducing Regulation and Controlling Regulatory Costs

This set of Guidelines is considered an E.O. 13771 deregulatory action. The net cost savings, annualized over a perpetual time horizon using a 7% discount rate and expressed in 2016 dollars, is estimated to be $87.34 million.

Regulatory Flexibility Analysis

For the reasons outlined above, the Secretary has determined that the Guidelines will not have a significant impact upon a substantial number of small entities within the meaning of the Regulatory Flexibility Act [5 U.S.C. 605(b)]. The flexibility added by the OFMG will not require additional expenditures. Therefore, a final regulatory flexibility analysis is not required for this notice.

As mentioned in the section on Executive Order 12866, the Secretary anticipates that there will be an overall reduction in costs if drug testing is expanded under the OFMG. The costs to implement this change to regulation are negligible. The added flexibility will permit federal agencies to select the specimen type best suited for their needs and to authorize collection of an alternative specimen type when an employee is unable to provide the originally authorized specimen type. Insofar as there are costs associated with each drug test, this could lead to lower overall testing costs for federal agencies. The added flexibility will also benefit federal employees, who should be able to provide one of the specimen types, thereby facilitating the drug test required for their employment.

The Secretary has determined that the Guidelines are not a major rule for the purpose of congressional review. For the purpose of congressional review, a major rule is one which is likely to cause an annual effect on the economy of $100 million; a major increase in costs or prices; significant effects on competition, employment, productivity, or innovation; or significant effects on the ability of U.S.-based enterprises to compete with foreign-based enterprises in domestic or export markets. This is not a major rule under the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996.

Unfunded Mandates

The Secretary has examined the impact of the Guidelines under the Unfunded Mandates Reform Act (UMRA) of 1995 (Pub. L. 104–4). This notice does not trigger the requirement for a written statement under section 202(a) of the UMRA because the Guidelines do not impose a mandate that results in an expenditure of $100 million (adjusted annually for inflation) or more by either state, local, and tribal governments in the aggregate or by the private sector in any one year.

Environmental Impact

The Secretary has considered the environmental effects of the OFMG. No information or comments have been received that would affect the agency's determination there would be a significant impact on the human environment and that neither an environmental assessment nor an environmental impact statement is required.

Executive Order 13132: Federalism

The Secretary has analyzed the Guidelines in accordance with Executive Order 13132: Federalism. Executive Order 13132 requires federal agencies to carefully examine actions to determine if they contain policies that have federalism implications or that preempt state law. As defined in the Order, ''policies that have federalism implications'' refer to regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

In this notice, the Secretary establishes standards for certification of laboratories engaged in oral fluid drug testing for federal agencies and the use of oral fluid testing in federal drug-free workplace programs. The Department of Health and Human Services, by authority of Section 503 of Public Law 100–71, 5 U.S.C. 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in urine drug testing for federal agencies. Because the Mandatory Guidelines govern standards applicable to the management of federal agency personnel, there should be little, if any, direct effect on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Secretary has determined that the Guidelines do not contain policies that have federalism implications.

Privacy Act

The Secretary has determined that the Guidelines do not contain information collection requirements constituting a system of records under the Privacy Act. The **Federal Register** notice announcing the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid is not a system of records as noted in the information collection/recordkeeping requirements below. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the **Federal Register** on April 11, 1988 [53 FR 11979]. SAMHSA subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858] with an effective date of May 1, 2010 (correct effective date published on December 10, 2008 [73 FR 75122]). The effective date of the Guidelines was further changed to October 1, 2010 on April 30, 2010 [75 FR 22809]. The revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) were published on January 23, 2017 [82 FR 7920] with an effective date of October 1, 2017.

Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

Executive Order 13175 (65 FR 67249, November 6, 2000) requires SAMHSA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' as defined in the Executive Order, include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the federal government and the Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes.'' The Guidelines do not have tribal implications. The Guidelines will not have substantial direct effects on tribal governments, on the relationship between the federal government and Indian tribes, or on the distribution of power and responsibilities between the federal government and Indian tribes, as specified in Executive Order 13175.

Information Collection/Record Keeping Requirements

The information collection requirements (*i.e.,* reporting and recordkeeping) in the current Guidelines (82 FR 7920), which 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 5 U.S.C. 7301 and Executive Order 12564, are approved by the Office of Management and Budget (OMB) under control number 0930–0158. The Federal Drug Testing Custody and Control Form used to document the collection and chain of custody of urine

specimens at the collection site, for laboratories to report results, and for Medical Review Officers to make a determination, the National Laboratory Certification Program (NLCP) application, the NLCP Laboratory Information Checklist, and recordkeeping requirements in the current Guidelines, as approved under control number 0930–0158, will remain in effect for regulated urine drug testing under the UrMG. The same documents specifically for regulated oral fluid drug testing under the OFMG will be submitted for OMB approval under a new control number.

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: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid Specimens

Description: The 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 No. 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 specimen testing since 1988; the reporting, recordkeeping and disclosure requirements associated with urine specimen testing are approved under OMB control number 0930–0158. These Guidelines establish when oral fluid specimens may be collected, the procedures that must be used in collecting an oral fluid specimen, and the certification process for approving a laboratory to test oral fluid specimen.

Description of Respondents: Individuals or households; businesses; or other-for-profit; not-for-profit institutions.

The annual burden estimates in the tables below are based on the following number of respondents: 10,500 donors who apply for employment or are employed in testing designated positions, 100 collectors, 10 oral fluid specimen testing laboratories, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
9.2(a)(1)	Laboratory required to submit application for certification.	10	1	3	30
9.10(a)(3)	Materials to submit to become an HHS inspector.	10	1	2	20
11.3(a)	Laboratory submits qualifications of RP to HHS	10	1	2	20
11.4(c)	Laboratory submits information to HHS on new RP or alternate RP.	10	1	2	20
11.20	Specifications for laboratory semi-annual statistical report of test results to each federal agency.	10	5	0.5	25
13.9 & 14.6	Specifies that MRO must report all verified primary and split specimen test results to the federal agency.	100	14	*0.05	70
16.1(b) & 16.5(a)	Specifies content of request for informal review of suspension/proposed revocation of certification.	1	1	3	3
16.4	Specifies information appellant provides in first written submission when laboratory suspension/revocation is proposed.	1	1	0.5	0.5
16.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period.	1	1	0.5	0.5
16.7(a)	Specifies contents of appellant submission for review.	1	1	50	50
16.9(a)	Specifies content of appellant request for expedited review of suspension or proposed revocation.	1	1	3	3
16.9(c)	Specifies contents of review file and briefs	1	1	50	50
Total		156			292

*(3 min).

The following reporting requirements are also in the Guidelines, but have not been addressed in the above reporting burden table: Collector must report any unusual donor behavior or refuse to participate in the collection process on the Federal CCF (sections 1.8, 8.9); collector annotates the Federal CCF when a sample is a blind sample (section 10.3(a)); MRO notifies the federal agency and HHS when an error occurs on a blind sample (section 10.4(c)); section 13.5 describes the actions an MRO takes to report a primary specimen result; and section 14.5 describes the actions an MRO takes to report a split specimen result. SAMHSA has not calculated a separate reporting burden for these requirements because they will be 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
8.3(a) & 8.6(b)(2)	Collector must contact federal agency point of contact.	100	1	*0.05	5
11.21 & 11.22	Information on drug test that laboratory must provide to federal agency upon request or to donor through MRO.	50	10	3	1,500
13.8 (b)	MRO must inform donor of right to request split specimen test when a positive or adulterated result is reported.	100	14	3	4,200
Total		210			5,705

*(3 min).

The following disclosure requirements are also included in the 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 8.3(f) and (h), and must review the procedures for the oral fluid specimen collection device used with the donor (section 8.4(b)). The Department believes having the collector explain the collection procedure to the donor and answer any questions is a standard business practice and not a disclosure burden.

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

Section	Purpose	No. of respondents	Responses/ respondent	Hours/ response	Total hours
8.3, 8.5, & 8.8	Collector completes Federal CCF for specimen collected.	100	380	0.07 (4 min)	2,534
8.8(d) & (f)	Donor initials specimen labels/seals and signs statement on the Federal CCF.	10,500	1	0.08 (5 min)	875
11.8(a) & 11.17	Laboratory completes Federal CCF upon receipt of specimen and before reporting result.	10	3,800	0.05 (3 min)	1,900
13.4(d) (4), 13.9 (c), & 14.6(c).	MRO completes Federal CCF before reporting the result.	100	380	0.05 (3 min)	1,900
14.1(b)	MRO documents donor's request to have split specimen tested.	300	1	0.05 (3 min)	15
Total		11,010			7,224

The 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)(3)] and the documentation must be maintained in the collector's training file [section 4.3(c)]. Because this is required by the current Guidelines using urine specimens as well as these Guidelines using oral fluid specimens and is consistent with general forensic requirements, 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 8.4(d) and 8.5(a)(1)] requires collectors to enter any information on the Federal CCF of any unusual findings during the oral fluid 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 describe a number of recordkeeping requirements for laboratories associated with their testing procedures, maintaining chain of custody, and keeping records (*i.e.,* sections 11.1(a) and (d); 11.2(b), (c), and (d); 11.6(b); 11.7(c); 11.8; 11.10(1); 11.13(a); 11.16; 11.17(a), (b), and (c); 11.20; 11.21, and 11.22. These recordkeeping requirements are necessary for any laboratory 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.

Thus, the total annual response burden associated with the testing of oral fluid specimens by the laboratories is estimated to be 13,221 hours (that is, the sum of the total hours from the above tables). Because of the expected transition from urine to oral fluid testing, this number will replace some of the 1,788,809 hours currently approved by OMB under control number 0930–0158 for urine testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary submitted a copy of the proposed Guidelines to OMB for its review. Comments on the information collection requirements were 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.

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Dated: October 7, 2019.

Elinore F. McCance-Katz,

Assistant Secretary for Mental Health and Substance Use.

Dated: October 7, 2019.

Alex M. Azar II,

Secretary, Department of Health and Human Services.

The Mandatory Guidelines using Oral Fluid Specimens are hereby adopted in accordance with section 503 of Public Law 100–71 and Executive Order 12564.

Mandatory Guidelines For Federal Workplace Drug Testing Programs Using Oral Fluid Specimens

Subpart A—Applicability

Subpart A—Applicability

Section 1.1 To whom do these Guidelines apply?

(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 Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;

(5) Laboratories that provide drug testing services to the federal agencies;

(6) Collectors who provide specimen collection services to the federal agencies; and

(7) Medical Review Officers (MROs) who provide drug testing review and interpretation of results services to the federal agencies.

(b) These 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]

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) To ensure the full reliability and accuracy of specimen 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 signs the Federal Drug Testing Custody and Control Form at the time of specimen receipt at the HHS-certified laboratory or (for urine) the HHS-certified IITF.

[1] The NRC-related information in this notice pertains to individuals subject to drug testing conducted pursuant to 10 CFR Part 26, ''Fitness for Duty Programs'' (*i.e.,* employees of certain NRC-regulated entities).

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 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 at 49 CFR Part 40 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 HHS Mandatory Guidelines.

Adulterated Specimen. A specimen that has been altered, as evidenced by test results showing either a substance that is not a normal constituent for that type of specimen or showing an abnormal concentration of an endogenous substance.

Aliquot. A portion of a specimen used for testing.

Alternate Responsible Person. The person who assumes professional, organizational, educational, and administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fulfill these obligations.

Alternate Technology Initial Drug Test. An initial drug test using technology other than immunoassay to differentiate negative specimens from those requiring further testing.

Batch. A number of specimens or aliquots handled concurrently as a group.

Biomarker. An endogenous substance used to validate a biological specimen.

Blind Sample. A sample submitted to an HHS-certified test facility for quality assurance purposes, with a fictitious identifier, so that the test facility cannot distinguish it from a donor specimen.

Calibrator. A sample of known content and analyte concentration prepared in the appropriate matrix used to define expected outcomes of a testing procedure. The test result of the calibrator is verified to be within established limits prior to use.

Cancelled Test. The result reported by the MRO to the federal agency when a specimen has been reported to the MRO as an invalid result (and the donor has no legitimate explanation) or rejected for testing, when a split specimen fails to reconfirm, or when the MRO determines that a fatal flaw or unrecovered correctable flaw exists in the forensic records (as described in Sections 15.1 and 15.2).

Carryover. The effect that occurs when a sample result (*e.g.,* drug concentration) is affected by a preceding sample during the preparation or analysis of a sample.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of a test result reported by an HHS-certified laboratory.

Certifying Technician (CT). The individual responsible for verifying the chain of custody and scientific reliability of negative, rejected for testing, and (for urine) negative/dilute results reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF.

Chain of Custody (COC) Procedures. Procedures that document the integrity of each specimen or aliquot from the point of collection to final disposition.

Chain of Custody Documents. Forms used to document the control and security of the specimen and all aliquots. The document may account for an individual specimen, aliquot, or batch of specimens/aliquots and must include the name and signature of each individual who handled the specimen(s) or aliquot(s) and the date and purpose of the handling.

Collection Device. A product that is used to collect an oral fluid specimen and may include a buffer or diluent.

Collection Site. The location where specimens are collected.

Collector. A person trained to instruct and assist a donor in providing a specimen.

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

Confirmatory Specimen Validity Test. A second test performed on a separate aliquot of a specimen to further support a specimen validity test result.

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

Cutoff. The analytical value (*e.g.,* drug or drug metabolite concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or, for urine, substituted) or the need for further testing.

Donor. The individual from whom a specimen is collected.

External Service Provider. An independent entity that performs services related to federal workplace drug testing on behalf of a federal agency, a collector/collection site, an HHS-certified laboratory, a Medical Review Officer (MRO), or, for urine, an HHS-certified Instrumented Initial Test Facility (IITF).

Failed to Reconfirm. The result reported for a split (B) specimen when a second HHS-certified laboratory is unable to corroborate the result reported for the primary (A) specimen.

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 and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (*i.e.,* HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic, or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

HHS. The Department of Health and Human Services.

Initial Drug Test. An analysis used to differentiate negative specimens from those requiring further testing.

Initial Specimen Validity Test. The first analysis used to determine if a specimen is invalid, adulterated, or (for urine) diluted or substituted.

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

Invalid Result. The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.7 when a positive or negative result cannot be established for a specific drug or specimen validity test.

Laboratory. A permanent location where initial and confirmatory drug testing, reporting of results, and recordkeeping are performed under the supervision of a responsible person.

Limit of Detection. The lowest concentration at which the analyte (*e.g.,* drug or drug metabolite) can be identified.

Limit of Quantification. For quantitative assays, the lowest concentration at which the identity and concentration of the analyte (*e.g.,* drug or drug metabolite) can be accurately established.

Lot. A number of units of an item (*e.g.,* reagents, quality control material, oral fluid collection device) manufactured from the same starting materials within a specified period of time for which the manufacturer ensures that the items have essentially the same performance characteristics and expiration date.

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

Negative Result. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF to an MRO when a specimen contains no drug and/or drug metabolite; or the concentration of the drug or drug metabolite is less than the cutoff for that drug or drug class.

Oral Fluid Specimen. An oral fluid specimen is collected from the donor's oral cavity and is a combination of physiological fluids produced primarily by the salivary glands.

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.

Performance Testing (PT) Sample. A program-generated sample sent to a laboratory or (for urine) to an IITF to evaluate performance.

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

Reconfirmed. The result reported for a split (B) specimen when the second HHS-certified laboratory corroborates the original result reported for the primary (A) specimen.

Rejected for Testing. The result reported by an HHS-certified laboratory or (for urine) an HHS-certified IITF when no tests are performed on a specimen because of a fatal flaw or an unrecovered correctable error (see Sections 15.1 and 15.2)

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

Sample. A performance testing sample, calibrator or control used during testing, or a representative portion of a donor's specimen.

Secretary. The Secretary of the U.S. Department of Health and Human Services.

Specimen. Fluid or material collected from a donor at the collection site for the purpose of a drug test.

Split Specimen Collection (for Oral Fluid). A collection in which two specimens [primary (A) and split (B)] are collected, concurrently or serially, and independently sealed in the presence of the donor; or a collection in which a single specimen is collected using a single collection device and is subdivided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

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

Undiluted (neat) oral fluid. An oral fluid specimen to which no other solid or liquid has been added. For example, see Section 2.4: A collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.

Section 1.6 What is an agency required to do to protect employee records?

Consistent with 5 U.S.C. 552a and 48 CFR 24.101–24.104, all agency contracts with laboratories, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552a. In addition, the contracts must require compliance with employee access and confidentiality provisions of Section 503 of Public Law 100–71. Each federal 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.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR parts 160 and 164, Subparts A and E, may be applicable to certain health care providers with whom a federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding the HIPAA Privacy Rule, please visit *http://www.hhs.gov/ocr/hipaa.*

Section 1.7 What is a refusal to take a federally regulated drug test?

(a) As a donor for a federally regulated drug test, you have refused to take a federally regulated drug test if you:

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the federal agency, consistent with applicable agency regulations, after being directed to do so by the federal agency;

(2) Fail to remain at the collection site until the collection process is complete with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test as described in section 8.4(a);

(3) Fail to provide a specimen (*e.g.,* oral fluid or another authorized specimen type) for any drug test required by these Guidelines or federal agency regulations with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test as described in section 8.4(a);

(4) Fail to provide a sufficient amount of oral fluid when directed, and it has been determined, through a required medical evaluation, that there was no legitimate medical explanation for the failure as determined by the process described in Section 13.6;

(5) Fail or decline to participate in an alternate specimen collection (*e.g.,* urine) as directed by the federal agency or collector (*i.e.,* as described in Section 8.6);

(6) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process (*i.e.,* Section 13.6) or as directed by the federal agency. In the case of a federal agency applicant/pre-employment drug test, the donor is deemed to have refused to test on this basis only if the federal agency applicant/pre-employment test is conducted following a contingent offer of employment. If there was no contingent offer of employment, the MRO will cancel the test;

(7) Fail to cooperate with any part of the testing process (*e.g.,* disrupt the collection process; fail to rinse the mouth after being directed to do so by the collector; refuse to provide a split specimen);

(8) Bring materials to the collection site for the purpose of adulterating, substituting, or diluting the specimen;

(9) Attempt to adulterate, substitute, or dilute the specimen; or

(10) Admit to the collector or MRO that you have adulterated or substituted the specimen.

Section 1.8 What are the potential consequences for refusing to take a federally regulated drug test?

(a) As a federal agency employee or applicant, a refusal to take a test may result in the initiation of disciplinary or adverse action, up to and including removal from, or non-selection for, federal employment.

(b) When a donor has refused to participate in a part of the collection process, including failing to appear in a reasonable time for any test except a pre-employment test as described in Section 1.7(a)(1), the collector must terminate the collection process and take action as described in Section 8.9. Required action includes immediately notifying the federal agency's designated representative by any means (*e.g.,* telephone or secure fax machine) that ensures that the refusal notification is immediately received and, if a Federal CCF has been initiated, documenting the refusal on the Federal CCF, signing and dating the Federal

CCF, and sending all copies of the Federal CCF to the federal agency's designated representative.

(c) When documenting a refusal to test during the verification process as described in Sections 13.4, 13.5, and 13.6, the MRO must complete the MRO copy of the Federal CCF to include:

(1) Checking the refusal to test box;

(2) Providing a reason for the refusal in the remarks line; and

(3) Signing and dating the MRO copy of the Federal CCF.

Subpart B—Oral Fluid Specimens

Section 2.1 What type of specimen may be collected?

A federal agency may collect oral fluid and/or an alternate specimen type for its workplace drug testing program. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected. An agency using oral fluid must follow these Guidelines.

Section 2.2 Under what circumstances may an oral fluid specimen be collected?

A federal agency may collect an oral fluid specimen for the following reasons:

(a) Federal agency applicant/Pre-employment test;

(b) Random test;

(c) Reasonable suspicion/cause test;

(d) Post accident test;

(e) Return to duty test; or

(f) Follow-up test.

Section 2.3 How is each oral fluid specimen collected?

Each oral fluid specimen is collected as a split specimen (*i.e.,* collected either simultaneously or serially) as described in Sections 2.5 and 8.8.

Section 2.4 What volume of oral fluid is collected?

A volume of at least 1 mL of undiluted (neat) oral fluid for each oral fluid specimen (designated ''Tube A'' and ''Tube B'') is collected using a collection device. If the device does not include a diluent (or other component, process, or method that modifies the volume of the testable specimen), the A and B tubes must have a volume marking clearly noting a level of 1 mL.

Section 2.5 How is the split oral fluid specimen collected?

The collector collects at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ''A'' (primary) and at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ''B'' (split) either simultaneously or serially (*i.e.,* using two devices or using one device and subdividing the specimen), as described in Section 8.8.

Section 2.6 When may an entity or individual release an oral fluid specimen?

Entities and individuals subject to these Guidelines under Section 1.1, may not release specimens collected pursuant to Executive Order 12564, Public Law 100–71 and these Guidelines, to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable federal law. This section does not prohibit a donor's request to have a split (B) specimen tested in accordance with Section 13.8.

Subpart C—Oral Fluid Drug and Specimen Validity Tests

Section 3.1 Which tests are conducted on an oral fluid specimen?

A federal agency:

(a) Must ensure that each specimen is tested for marijuana and cocaine as provided under Section 3.4;

(b) Is authorized to test each specimen for opioids, amphetamines, and phencyclidine, as provided under Section 3.4; and

(c) Is authorized upon a Medical Review Officer's request to test an oral fluid specimen to determine specimen validity using, for example, a test for a biomarker such as albumin or immunoglobulin G (IgG) or a test for a specific adulterant.

(d) If a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then additional testing may be performed.

Section 3.2 May a specimen be tested for additional drugs?

(a) On a case-by-case basis, a specimen may be tested for additional drugs, if a federal agency is conducting the collection for reasonable suspicion or post accident testing. A specimen collected from a federal agency employee may be tested by the federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act. The federal agency must request the HHS-certified laboratory to test for the 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. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the federal agency can request an HHS-certified laboratory to test for the drug by analyzing two separate aliquots of the specimen in two separate testing batches using the confirmatory analytical method. Additionally, the split (B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

(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) 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 in accordance with Subpart C of these Guidelines. Use of specimens by donors, their designees or any other entity, for other purposes (*e.g.,* deoxyribonucleic acid, DNA, testing) is prohibited unless authorized in accordance with applicable federal law.

(b) These Guidelines are not intended to prohibit federal agencies 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 drug test cutoff concentrations for undiluted (neat) oral fluid?

Initial test analyte	Initial test cutoff [1] (ng/mL)	Confirmatory test analyte	Confirmatory test cutoff concentration (ng/mL)
Marijuana (THC) [2]	[3] 4	THC	2
Cocaine/Benzoylecgonine	15	Cocaine	8
		Benzoylecgonine	8
Codeine/Morphine	30	Codeine	15
		Morphine	15
Hydrocodone/Hydromorphone	30	Hydrocodone	15
		Hydromorphone	15
Oxycodone/Oxymorphone	30	Oxycodone	15
		Oxymorphone	15
6-Acetylmorphine	[3] 4	6-Acetylmorphine	2
Phencyclidine	10	Phencyclidine	10
Amphetamine/Methamphetamine	50	Amphetamine	25
		Methamphetamine	25
MDMA [4]/MDA [5]	50	MDMA	25
		MDA	25

[1] *For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):*
Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.
Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (*i.e.*, equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.
[2] An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol (THC).
[3] *Alternate technology (THC and 6–AM):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (*i.e.*, 2 ng/mL for THC, 2 ng/mL for 6–AM).
[4] Methylenedioxymethamphetamine (MDMA).
[5] Methylenedioxyamphetamine (MDA).

Section 3.5 May an HHS-certified laboratory perform additional drug and/or specimen validity tests on a specimen at the request of the Medical Review Officer (MRO)?

An HHS-certified laboratory is authorized to perform additional drug and/or specimen validity tests on a case-by-case basis as necessary to provide information that the MRO would use to report a verified drug test result (*e.g.,* specimen validity tests including biomarker and/or adulterant tests, tetrahydrocannabivarin). An HHS-certified laboratory is not authorized to routinely perform additional drug and/or specimen validity tests at the request of an MRO without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D,L stereoisomers of amphetamine and methamphetamine. All tests must meet appropriate validation and quality control requirements in accordance with these Guidelines.

Section 3.6 What criteria are used to report an oral fluid specimen as adulterated?

An HHS-certified laboratory reports an oral fluid specimen as adulterated when the presence of an adulterant is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

Section 3.7 What criteria are used to report an invalid result for an oral fluid specimen?

An HHS-certified laboratory reports a primary (A) oral fluid specimen as an invalid result when:

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

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

(c) The physical appearance of the specimen (*e.g.,* viscosity) is such that testing the specimen may damage the laboratory's instruments;

(d) The specimen has been tested and the appearances of the primary (A) and the split (B) specimens (*e.g.,* color) are clearly different; or

(e) The concentration of a biomarker (*e.g.,* albumin or IgG) is not consistent with that established for human oral fluid for both the initial (first) test and the second test on two separate aliquots.

Subpart D—Collectors

Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

(b) The immediate supervisor of a federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

(c) The hiring official of a federal agency applicant may only collect that federal agency applicant's specimen when no other collector is available. The hiring official must be a trained collector.

Section 4.2 Who may not collect a specimen?

(a) A federal agency employee who is in a testing designated position and subject to the federal agency drug testing rules must not be a collector for co-workers in the same testing pool or who work together with that employee on a daily basis.

(b) A federal agency applicant or employee must not collect their own drug testing specimen.

(c) An employee working for an HHS-certified laboratory must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (*e.g.,* spouse, ex-spouse, relative) or a close personal friend (*e.g.,* fiancée).

Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector if they fulfill the following conditions:

(1) Is knowledgeable about the collection procedure described in these Guidelines;

(2) Is knowledgeable about any guidance provided by the federal agency's Drug-Free Workplace Program and additional information provided by the Secretary relating to these Guidelines;

(3) Is trained and qualified to use the specific oral fluid collection device. Training must include the following:

(i) All steps necessary to complete an oral fluid collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

(iv) Fatal flaws, correctable flaws, and how to correct problems in collections; and

(v) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of the donor, ensuring the security of the specimen, and avoiding conduct or statements that could be viewed as offensive or inappropriate.

(4) Has demonstrated proficiency in collections by completing five consecutive error-free mock collections.

(i) The five mock collections must include two uneventful collection scenarios, one insufficient specimen quantity scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen tube tamper-evident seal.

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

(b) A trained collector must complete refresher training at least every five years that includes the requirements in paragraph (a) of this section.

(c) The collector must maintain the documentation of their training and provide that documentation to a federal agency when requested.

(d) An individual may not collect specimens for a federal agency until the individual's training as a collector has been properly documented.

Section 4.4 What are the requirements to be a trainer for collectors?

(a) Individuals are considered qualified trainers for collectors for a specific oral fluid collection device and may train others to collect oral fluid specimens using that collection device when they have completed the following:

(1) Qualified as a trained collector and regularly conducted oral fluid drug test collections using that collection device for a period of at least one year or

(2) Completed a ''train the trainer'' course given by an organization (*e.g.,* manufacturer, private entity, contractor, federal agency).

(b) A qualified trainer for collectors must complete refresher training at least every five years in accordance with the collector requirements in Section 4.3(a).

(c) A qualified trainer for collectors must maintain the documentation of the trainer's training and provide that documentation to a federal agency when requested.

Section 4.5 What must a federal agency do before a collector is permitted to collect a specimen?

A federal agency must ensure the following:

(a) The collector has satisfied the requirements described in Section 4.3;

(b) The collector, who may be self-employed, or an organization (*e.g.,* third party administrator that provides a collection service, collector training company, federal agency that employs its own collectors) maintains a copy of the training record(s); and

(c) The collector has been provided the name and telephone number of the federal agency representative.

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) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (*e.g.,* an accident investigation), another site may be used for the collection, providing the collection is performed by a collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

Section 5.2 What are the requirements for a collection site?

The facility used as a collection site must have the following:

(a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);

(b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;

(c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory;

(d) A restricted access area where only authorized personnel may be present during the collection;

(e) A restricted access area for the storage of collection supplies; and

(f) The ability to store records securely.

Section 5.3 Where must collection site records be stored?

Collection site records must be stored at a secure site designated by the collector or the collector's employer.

Section 5.4 How long must collection site records be stored?

Collection site records (*e.g.,* collector copies of the OMB-approved Federal CCF) must be stored securely for a minimum of 2 years. The collection site may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

Section 5.5 How does the collector ensure the security and integrity of a specimen at the collection site?

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

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

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

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

(4) Ensure that only the collector and the donor are allowed to handle the unsealed specimen;

(5) Ensure the chain of custody process is maintained and documented throughout the entire collection, storage, and transport procedures;

(6) Ensure that the Federal CCF is completed and distributed as required; and

(7) Ensure that specimens transported to an HHS-certified laboratory are sealed and placed in transport containers designed to minimize the possibility of damage during shipment (*e.g.,* specimen boxes, padded mailers, or other suitable shipping container), and those containers are securely sealed to eliminate the possibility of undetected tampering.

(b) Couriers, express carriers, and postal service personnel are not

required to document chain of custody since specimens are sealed in packages that would indicate tampering during transit to the HHS-certified laboratory.

Section 5.6 What are the privacy requirements when collecting an oral fluid specimen?

Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

Subpart F—Federal Drug Testing Custody and Control Form

Section 6.1 What federal form is used to document custody and control?

The OMB-approved Federal CCF must be used to document custody and control of each specimen at the collection site.

Section 6.2 What happens if the correct OMB-approved Federal CCF is not available or is not used?

(a) The use of a non-federal CCF or an expired Federal CCF is not, by itself, a reason for the HHS-certified laboratory to automatically reject the specimen for testing or for the MRO to cancel the test.

(b) If the collector does not use the correct OMB-approved Federal CCF, the collector must document that it is a federal agency specimen collection and provide the reason that the incorrect form was used. Based on the documentation provided by the collector, the HHS-certified laboratory must handle and test the specimen as a federal agency specimen.

(c) If the HHS-certified laboratory or MRO discovers that the collector used an incorrect form, the laboratory or MRO must obtain a memorandum for the record from the collector describing the reason the incorrect form was used. If a memorandum for the record cannot be obtained, the laboratory reports a rejected for testing result to the MRO and the MRO cancels the test. The HHS-certified laboratory must wait at least 5 business days while attempting to obtain the memorandum before reporting a rejected for testing result to the MRO.

Subpart G—Oral Fluid Specimen Collection Devices

Section 7.1 What is used to collect an oral fluid specimen?

An FDA-cleared single-use collection device intended to collect an oral fluid specimen must be used. This collection device must maintain the integrity of such specimens during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites.

Section 7.2 What are the requirements for an oral fluid collection device?

An oral fluid specimen collection device must provide:

(a) An indicator that demonstrates the adequacy of the volume of oral fluid specimen collected;

(b) A sealable, non-leaking container that maintains the integrity of the specimen during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites;

(c) Components that ensure pre-analytical drug and drug metabolite stability; and

(d) Components that do not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen.

Section 7.3 What are the minimum performance requirements for a collection device?

An oral fluid collection device must meet the following minimum performance requirements.

(a) Reliable collection of a minimum of 1 mL of undiluted (neat) oral fluid;

(b) If the collection device contains a diluent (or other component, process, or method that modifies the volume of the testable specimen):

(1) The volume of oral fluid collected should be at least 1.0 mL ±10 percent, and

(2) The volume of diluent in the device should be within ±2.5 percent of the diluent target volume;

(c) Stability (recoverable concentrations ≥80 percent of the concentration at the time of collection) of the drugs and/or drug metabolites for five days at room temperature (64–77 °F/18–25 °C) and under the manufacturer's intended shipping and storage conditions; and

(d) Recover ≥80 percent (but no more than 120 percent) of drug and/or drug metabolite in the undiluted (neat) oral fluid at (or near) the initial test cutoff (see Section 3.4).

Subpart H—Oral Fluid Specimen Collection Procedure

Section 8.1 What privacy must the donor be given when providing an oral fluid specimen?

The following privacy requirements apply when a donor is providing an oral fluid specimen:

(a) Only authorized personnel and the donor may be present in the restricted access area where the collection takes place.

(b) The collector is not required to be the same gender as the donor.

Section 8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?

The collector must deter the adulteration or substitution of an oral fluid specimen at the collection site.

Section 8.3 What are the preliminary steps in the oral fluid specimen collection procedure?

The collector must take the following steps before beginning an oral fluid specimen collection:

(a) If a donor fails to arrive at the collection site at the assigned time, the collector must follow the federal agency policy or contact the federal agency representative to obtain guidance on action to be taken.

(b) When the donor arrives at the collection site, the collector should begin the collection procedure without undue delay. For example, the collection should not be delayed because an authorized employer or employer representative is late in arriving.

(c) The collector requests the donor to present photo identification (*e.g.,* driver's license; employee badge issued by the employer; an alternative photo identification issued by a federal, state, or local government agency). If the donor does not have proper photo identification, the collector shall contact the supervisor of the donor or the federal agency representative who can positively identify the donor. If the donor's identity cannot be established, the collector must not proceed with the collection.

(d) The collector requests that the donor open the donor's mouth, and the collector inspects the oral cavity to ensure that it is free of any items that could impede or interfere with the collection of an oral fluid specimen (*e.g.,* candy, gum, food, tobacco) or could be used to adulterate, substitute, or dilute the specimen. If an item is present that appears to have been brought to the collection site with the intent to adulterate, substitute, or dilute the specimen, this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.9.

(1) At this time, the collector starts the 10-minute wait period and proceeds with the steps below before beginning the specimen collection as described in Section 8.5.

(2) If the collector's inspection of the donor's oral cavity reveals any items that could impede or interfere with the collection of an oral fluid specimen (including abnormally colored saliva),

or the donor claims to have ''dry mouth,'' the collector gives the donor water (*e.g.,* up to 4 oz.) to rinse their mouth. The donor may drink the water. The collector must then wait 10 minutes before beginning the specimen collection. If the donor refuses to remove the item or refuses to rinse, this is a refusal to test.

(3) If the donor claims that they have a medical condition that prevents opening their mouth for inspection, the collector follows the procedure in Section 8.6(b)(2).

(e) The collector must provide identification (*e.g.,* employee badge, employee list) if requested by the donor.

(f) The collector explains the basic collection procedure to the donor.

(g) The collector informs the donor that the instructions for completing the Federal Custody and Control Form are located on the back of the Federal CCF or available upon request.

(h) The collector answers any reasonable and appropriate questions the donor may have regarding the collection procedure.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

(a) The collector will provide or the donor may select a specimen collection device that is clean, unused, and wrapped/sealed in original packaging. The specimen collection device will be opened in view of the donor.

(1) Both the donor and the collector must keep the unwrapped collection devices in view at all times until each collection device containing the donor's oral fluid specimen has been sealed and labeled.

(b) The collector reviews with the donor the procedures required for a successful oral fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(c) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* an attempt to bring into the collection site an adulterant or oral fluid substitute), the collector must report a refusal to test in accordance with Section 8.9.

Section 8.5 What steps does the collector take during and after the oral fluid specimen collection procedure?

Integrity and Identity of the Specimen. The collector must take the following steps during and after the donor provides the oral fluid specimen:

(a) The collector shall be present and maintain visual contact with the donor during the procedures outlined in this section.

(1) Under the observation of the collector, the donor is responsible for positioning the specimen collection device for collection. The collector must ensure the collection is performed correctly and that the collection device is working properly. If there is a failure to collect the specimen, the collector must begin the process again, beginning with Step 8.4(b), using a new specimen collection device (for both A and B specimens) and notes the failed collection attempt on the Federal CCF. If the donor states that they are unable to provide an oral fluid specimen during the collection process or after multiple failures to collect the specimen, the collector follows the procedure in Section 8.6.

(2) The donor and collector must complete the collection in accordance with the manufacturer instructions for the collection device.

(b) If the donor fails to remain present through the completion of the collection, fails to follow the instructions for the collection device, refuses to begin the collection process after a failure to collect the specimen as required in step (a)(1) above, refuses to provide a split specimen as instructed by the collector, or refuses to provide an alternate specimen as authorized in Section 8.6, the collector stops the collection and reports the refusal to test in accordance with Section 8.9.

Section 8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?

(a) If the donor states that they are unable to provide an oral fluid specimen during the collection process, the collector requests that the donor follow the collector instructions and attempt to provide an oral fluid specimen.

(b) The donor demonstrates their inability to provide a specimen when, after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device.

(1) If the donor states that they could provide a specimen after drinking some fluids, the collector gives the donor a drink (up to 8 ounces) and waits an additional 10 minutes before beginning the specimen collection (a period of 1 hour must be provided or until the donor has provided a sufficient oral fluid specimen). If the donor simply needs more time before attempting to provide an oral fluid specimen, the donor is not required to drink any fluids during the 1 hour wait time. The collector must inform the donor that the donor must remain at the collection site (*i.e.,* in an area designated by the collector) during the wait period.

(2) If the donor states that they are unable to provide an oral fluid specimen, the collector records the reason for not collecting an oral fluid specimen on the Federal CCF, notifies the federal agency's designated representative for authorization of an alternate specimen to be collected, and sends the appropriate copies of the Federal CCF to the MRO and to the federal agency's designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

Section 8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?

Yes, if the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the federal agency.

Section 8.8 How does the collector prepare the oral fluid specimens?

(a) All federal agency collections are to be split specimen collections.

An oral fluid split specimen collection may be:

(1) Two specimens collected simultaneously with two separate collection devices;

(2) Two specimens collected serially with two separate collection devices. The donor is not allowed to drink or rinse their mouth between the two collections. Collection of the second specimen must begin within two minutes after the completion of the first collection and recorded on the Federal CCF;

(3) Two specimens collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes; or

(4) A single specimen collected using a single collection device, that is subsequently subdivided into two specimens.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube

A'' and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube B''.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over the cap of each specimen tube. The collector records the date of the collection on the tamper-evident labels/seals.

(d) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen tube. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

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

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from the donor. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints their name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

(h) The collector seals the specimens (Tube A and Tube B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory that will be testing the Tube A oral fluid specimen.

(i) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

Section 8.9 How does the collector report a donor's refusal to test?

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any oral fluid specimen collected and reports the refusal to test by:

(a) Notifying the federal agency by means (*e.g.,* telephone, email, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test on the Federal CCF, and

(c) Sending all copies of the Federal CCF to the federal agency's designated representative.

Section 8.10 What are a federal agency's responsibilities for 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.

(b) A federal agency (or only one federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (*e.g.,* virtual, onsite, or self-evaluation).

(c) A federal agency must investigate reported collection site deficiencies (*e.g.,* specimens reported ''rejected for testing'' by an HHS-certified laboratory) and take appropriate action which may include a collection site self-assessment (*i.e.,* using the Collection Site Checklist for the Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

Subpart I—HHS Certification of Laboratories

Section 9.1 Who has the authority to certify laboratories to test oral fluid 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 HHS-certified laboratory, including suspending the use of certain analytical procedures when necessary to protect the integrity of the testing process; ordering any HHS-certified laboratory to undertake corrective actions to respond to material deficiencies identified by an inspection or through performance testing; ordering any HHS-certified laboratory to send specimens or specimen aliquots to another HHS-certified 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 is prohibited from stating or implying that it is certified by HHS under these Guidelines to test oral fluid specimens for federal agencies unless it holds such certification.

Section 9.2 What is the process for a laboratory to become HHS-certified?

(a) A laboratory seeking HHS certification must:

(1) Submit a completed OMB-approved application form (*i.e.,* the applicant laboratory provides detailed information on both the administrative and analytical procedures to be used for federally regulated specimens);

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

(3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;

(4) Satisfy all the requirements for an initial inspection; and

(5) Receive notification of certification from the Secretary before testing specimens for federal agencies.

Section 9.3 What is the process for a laboratory to maintain HHS certification?

(a) To maintain HHS certification, a laboratory must:

(1) 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 at a minimum of every 6 months thereafter);

(2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and

(3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

Section 9.4 What is the process when a laboratory does not maintain its HHS certification?

(a) A laboratory that does not maintain its HHS certification must:

(1) Stop testing federally regulated specimens;

(2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.18, 11.19, and 14.7;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.21 and 11.22 and Subpart P; and

(4) Follow the HHS suspension and revocation procedures when imposed by the Secretary, follow the HHS procedures in Subpart P that will be

used for all actions associated with the suspension and/or revocation of HHS-certification.

Section 9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?

(a) PT samples used to evaluate drug tests will be prepared using the following specifications:

(1) PT samples may contain one or more of the drugs and drug metabolites in the drug classes listed in Section 3.4 and may be sent to the laboratory as undiluted (neat) oral fluid. The PT samples must satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff concentration for the drug or drug metabolite;

(ii) The concentration of a drug or metabolite may be as low as 40 percent of the confirmatory test cutoff concentration when the PT sample is designated as a retest sample; or

(iii) The concentration of drug or metabolite may differ from 9.5(a)(1)(i) and 9.5(a)(1)(ii) for a special purpose.

(2) A PT sample may contain an interfering substance or other substances for special purposes.

(3) A negative PT sample will not contain a measurable amount of a target analyte.

(b) The laboratory 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?

(a) An applicant laboratory that seeks certification under these Guidelines must satisfy the following criteria on three consecutive sets of PT samples:

(1) Have no false positive results;

(2) Correctly identify, confirm, and report at least 90 percent of the total drug challenges over the three sets of PT samples;

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the three sets of PT samples;

(4) For the confirmatory drug tests, correctly determine the concentrations [*i.e.,* no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 80 percent of the total drug challenges over the three sets of PT samples;

(5) For the confirmatory drug tests, must not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations [*i.e.,* no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means] for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?

(a) A laboratory certified under these Guidelines must satisfy the following criteria on the maintenance PT samples:

(1) Have no false positive results;

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

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over two consecutive PT cycles;

(4) For the confirmatory drug tests, correctly determine that the concentrations for at least 80 percent of the total drug challenges are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(5) For the confirmatory drug tests, obtain no more than one drug concentration on a PT sample that differs by more than ±50 percent from the appropriate reference or peer group mean over two consecutive PT cycles;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

Section 9.8 What are the inspection requirements for an applicant laboratory?

(a) An applicant laboratory is inspected by a team of two inspectors.

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

Section 9.9 What are the maintenance inspection requirements for an HHS-certified laboratory?

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

(b) An HHS-certified laboratory is inspected by one or more inspectors. The number of inspectors is determined according to the number of specimens reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's procedures, records, and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory must continue to satisfy the minimum requirements as stated in these Guidelines.

Section 9.10 Who can inspect an HHS-certified laboratory and when may the inspection be conducted?

(a) An individual may be selected as an inspector for the Secretary if they satisfy the following criteria:

(1) Has experience and an educational background similar to that required for either a responsible person or a certifying scientist for an HHS-certified laboratory as described in Subpart K;

(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) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory.

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

Section 9.11 What happens if an applicant laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

If an applicant laboratory fails to satisfy the requirements established for the initial certification process, the laboratory must start the certification process from the beginning.

Section 9.12 What happens if an HHS-certified laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

(a) If an HHS-certified laboratory fails to satisfy the minimum requirements for certification, the laboratory is given a period of time (*e.g.,* 5 or 30 working days depending on the nature of the

deficiency) to provide any explanation for its performance and evidence that all deficiencies have been corrected.

(b) A laboratory's HHS certification may be revoked, suspended, or no further action taken depending on the seriousness of the deficiencies and whether there is evidence that the deficiencies have been corrected and that current performance meets the requirements for certification.

(c) An HHS-certified laboratory may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

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

Section 9.13 What factors are considered in determining whether revocation of a laboratory's HHS certification is necessary?

(a) The Secretary shall revoke certification of an HHS-certified laboratory in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug test results and reports.

(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 tests (*e.g.,* an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

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

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

(5) Any other cause that materially affects the ability of the HHS-certified laboratory to ensure fully reliable and accurate drug test results and reports.

(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 testing.

Section 9.14 What factors are considered in determining whether to suspend a laboratory's HHS certification?

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's HHS certification to conduct drug testing for federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

Section 9.15 How does the Secretary notify an HHS-certified laboratory that action is being taken against the laboratory?

(a) When a laboratory's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified 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) 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 P 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 HHS-certified laboratory that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any HHS-certified laboratory that 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 HHS 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 P.

Section 9.16 May a laboratory that had its HHS certification revoked be recertified to test federal agency specimens?

Following revocation, a laboratory may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under Section 9.15 or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory which has had its certification revoked may reapply for HHS certification as an applicant laboratory.

Section 9.17 Where is the list of HHS-certified laboratories published?

(a) The list of HHS-certified laboratories is published monthly in the **Federal Register**. This notice is also available on the internet at *http://www.samhsa.gov/workplace.*

(b) An applicant laboratory 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?

(a) Each federal agency is required to submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory that the collector sends employee specimens.

(b) Each federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency must be negative and 25 percent must be positive for one or more drugs.

Section 10.2 What are the requirements for blind samples?

(a) Drug positive blind samples must be validated by the supplier in the selected manufacturer's collection

device as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must be fortified with one or more of the drugs or metabolites listed in Section 3.4.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff concentration.

(b) Drug negative blind samples (*i.e.,* certified to contain no drugs) must be validated by the supplier in the selected manufacturer's collection device as negative using appropriate initial and confirmatory tests.

(c) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory, and must provide the information upon request to the MRO, the federal agency for which the blind sample was submitted, or the Secretary.

Section 10.3 How is a blind sample submitted to an HHS-certified laboratory?

(a) A blind sample must be submitted as a split specimen (specimens A and B) with the current Federal CCF that the HHS-certified laboratory uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

Section 10.4 What happens if an inconsistent result is reported for a blind sample?

If an HHS-certified laboratory reports a result for a blind sample that is inconsistent with the expected result (*e.g.,* a laboratory reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory and attempt to determine if the laboratory made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory;

(d) 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

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the federal agency. The Secretary shall ensure notification of the finding as appropriate to other federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

Subpart K—Laboratory

Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, 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, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

Section 11.2 What are the responsibilities of the responsible person (RP)?

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: Quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 11.3 What scientific qualifications must the RP have?

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or 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) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (*e.g.,* publications, court testimony,

conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (*e.g.,* temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated 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 RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated 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.

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: The candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as required prior to conducting federally regulated 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) A certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?

(a) All HHS-certified laboratory staff (*e.g.,* technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(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, including training in forensic procedures related to their job duties) before they are permitted to work independently with federally regulated specimens. All training must be documented.

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 (*e.g.,* firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 11.9 What are the requirements for an initial drug test?

(a) An initial drug test may be:

(1) An immunoassay or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified laboratory must validate an initial drug test before testing specimens.

(c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.

(d) An HHS-certified laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.11.

Section 11.10 What must an HHS-certified laboratory do to validate an initial drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff concentration, using samples at several concentrations between 0 and 150 percent of the cutoff concentration;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 11.11 What are the batch quality control requirements when conducting an initial drug test?

(a) Each batch of specimens must contain the following controls:

(1) At least one control certified to contain no drug or drug metabolite;

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

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

(4) At least one control that appears as a donor specimen to the analysts.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.12 What are the requirements for a confirmatory drug test?

(a) The analytical method must use mass spectrometric identification [*e.g.,* gas chromatography/mass spectrometry (GC/MS), liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS] or equivalent.

(b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.

(c) Confirmatory drug tests must be accurate and reliable for the testing of an oral fluid specimen when identifying and quantifying drugs or their metabolites.

Section 11.13 What must an HHS-certified laboratory do to validate a confirmatory drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each confirmatory drug test:

(1) The linear range of the analysis;

(2) The limit of detection;

(3) The limit of quantification;

(4) The accuracy and precision at the cutoff concentration;

(5) The accuracy (bias) and precision at 40 percent of the cutoff concentration;

(6) The potential for interfering substances;

(7) The potential for carryover; and

(8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

Section 11.14 What are the batch quality control requirements when conducting a confirmatory drug test?

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

(1) A calibrator at the cutoff concentration;

(2) At least one control certified to contain no drug or drug metabolite;

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

(4) At least one control targeted at or less than 40 percent of the cutoff.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.15 What are the analytical and quality control requirements for conducting specimen validity tests?

(a) Each invalid or adulterated specimen validity test result must be based on an initial specimen validity test on one aliquot and a confirmatory specimen validity test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results; and

(c) Controls must be analyzed concurrently with specimens.

Section 11.16 What must an HHS-certified laboratory do to validate a specimen validity test?

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 11.17 What are the requirements for an HHS-certified laboratory to report a test result?

(a) Laboratories must report a test result to the agency's MRO within an average of 5 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report. Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or if the specimen is negative upon confirmatory drug testing, and the specimen does not meet invalid criteria as described in items (e)(1) through (e)(4) below.

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with Section 3.4.

(d) For a specimen that has an invalid result for one of the reasons stated in items (e)(1) through (e)(4) below, the HHS-certified laboratory shall contact the MRO and both will decide if testing by another HHS-certified laboratory would be useful in being able to report a positive or adulterated result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

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

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

(2) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the HHS-certified laboratory is unable to identify the interfering substance;

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

(4) The physical appearances of the A and B specimens are clearly different (note: A is tested); or

(5) The concentration of a biomarker (*e.g.,* albumin or IgG) is not consistent with that established for human oral fluid.

(f) An HHS-certified laboratory shall reject a primary (A) specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not

recovered. The HHS-certified 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 positive, adulterated, and invalid test results for an oral fluid specimen. For example, a specimen can be positive for a specific drug and adulterated.

(h) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported for a positive result.

(i) An HHS-certified laboratory must report numerical values of the specimen validity test results that support a specimen that is reported adulterated or invalid (as appropriate).

(j) When the concentration of a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than ''insert the actual value for the upper limit of the linear range,'' or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method's linear range and multiplying the result by the appropriate dilution factor.

(k) HHS-certified laboratories may transmit test results to the MRO by various electronic means (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(l) HHS-certified laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test results can accurately represent the content of the custody and control form that the MRO received from the collector.

(m) For positive, adulterated, invalid, and rejected specimens, laboratories must facsimile, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 11.18 How long must an HHS-certified laboratory retain specimens?

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, or as an invalid result for a minimum of 1 year.

(b) Retained specimens must be kept in secured frozen storage (-20 °C or less) to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the 1-year period.

Section 11.19 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. The laboratory may convert hardcopy records to electronic records for storage and then discard the hardcopy records after 6 months.

(b) A federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.21) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal 2-year period of time.

Section 11.20 statistical summary reports must an HHS-certified laboratory provide for oral fluid testing?

(a) HHS-certified laboratories must provide to each federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, facsimile, or email within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

(1) Reporting period (inclusive dates);

(2) HHS-certified laboratory name and address;

(3) Federal agency name;

(4) Number of specimen results reported;

(5) Number of specimens collected by reason for test;

(6) Number of specimens reported negative;

(7) Number of specimens rejected for testing because of a fatal flaw;

(8) Number of specimens rejected for testing because of an uncorrected flaw;

(9) Number of specimens tested positive by each initial drug test;

(10) Number of specimens reported positive;

(11) Number of specimens reported positive for each drug and drug metabolite;

(12) Number of specimens reported adulterated; and

(13) Number of specimens reported as invalid result.

(b) An HHS-certified laboratory must make copies of an agency's test results available when requested to do so by the Secretary or by the federal agency for which the laboratory is performing drug-testing services.

(c) An HHS-certified laboratory must ensure that a qualified individual is available to testify in a proceeding against a federal employee when the proceeding is based on a test result reported by the laboratory.

Section 11.21 What HHS-certified laboratory information is available to a federal agency?

(a) Following a federal agency's receipt of a positive or adulterated drug test report, the federal agency may submit a written request for copies of the records relating to the drug test results or a documentation package or any relevant certification, review, or revocation of certification records.

(b) Standard documentation packages provided by an HHS-certified laboratory must contain the following items:

(1) A cover sheet providing a brief description of the procedures and tests performed on the donor's specimen;

(2) A table of contents that lists all documents and materials in the package by page number;

(3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the HHS-certified laboratory, and a copy of the electronic report (if any) generated by the HHS-certified laboratory;

(4) A brief description of the HHS-certified laboratory's initial drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the initial tests;

(6) A brief description of the HHS-certified laboratory's confirmatory drug

(and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the confirmatory tests; and

(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

Section 11.22 What HHS-certified laboratory information is available to a federal employee?

A federal employee who is the subject of a workplace drug test may submit a written request through the MRO and/or the federal agency requesting copies of any records relating to the employee's drug test results or a documentation package as described in Section 11.21(b) and any relevant certification, review, or revocation of certification records. Federal employees, or their designees, are not permitted access to their specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines.

Section 11.23 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

An HHS-certified laboratory must not enter into any relationship with a federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a federal agency use a specific MRO.

This means 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 HHS-certified 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 HHS-certified laboratory or have any agreement with an HHS-certified laboratory that may be construed as a potential conflict of interest.

Subpart L—Instrumented Initial Test Facility (IITF)

Section 12.1 May an IITF test oral fluid specimens for a federal agency's workplace drug testing program?

No, only HHS-certified laboratories are authorized to test oral fluid specimens for federal agency workplace drug testing programs in accordance with these Guidelines.

Subpart M—Medical Review Officer (MRO)

Section 13.1 Who may serve as an MRO?

(a) A currently licensed physician who has:

(1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;

(2) Knowledge regarding the pharmacology and toxicology of illicit drugs;

(3) The training necessary to serve as an MRO as set out in Section 13.3;

(4) Satisfactorily passed an initial examination administered by a nationally recognized entity or subspecialty board that has been approved by the Secretary to certify MROs; and

(5) At least every five years from initial certification, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

Section 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (*e.g.,* answers, previous examination statistics or other background examination information, if requested). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and content of the examination. Each approved MRO certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notice in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notice is also available on the internet at *http://www.samhsa.gov/workplace/drug-testing.*

Section 13.3 What training is required before a physician may serve as an MRO?

(a) A physician must receive training that includes a thorough review of the following:

(1) The collection procedures used to collect federal agency specimens;

(2) How to interpret test results reported by HHS-certified IITFs and laboratories (*e.g.,* negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);

(3) Chain of custody, reporting, and recordkeeping requirements for federal agency specimens;

(4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types; and

(5) Procedures for interpretation, review (*e.g.,* donor interview for legitimate medical explanations, review of documentation provided by the donor to support a legitimate medical explanation), and reporting of results specified by any federal agency for which the individual may serve as an MRO;

(b) Certified MROs must complete training on any revisions to these Guidelines prior to their effective date, to continue serving as an MRO for federal agency specimens.

Section 13.4 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and (for urine) substituted test results.

(b) Staff under the direct, personal supervision of the MRO may review and report negative and (for urine) negative/dilute test results to the agency's designated representative. The MRO must review at least 5 percent of all negative results reported by the MRO staff to ensure that the MRO staff are properly performing the review process.

(c) The MRO must discuss potential invalid results with the HHS-certified laboratory, as addressed in Section 11.17(d) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) HHS-certified IITF, 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 or HHS-certified IITF;

(2) Interview the donor when required;

(3) Make a determination regarding the test result; and

(4) Report the verified result to the federal agency.

(e) The MRO must maintain records for a minimum of 2 years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records

for storage and discard the hardcopy records after 6 months.

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen, as addressed in Section 8.6.

Section 13.5 What must an MRO do when reviewing an oral fluid specimen's test results?

(a) When the HHS-certified laboratory reports a negative result for the primary (A) specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory reports multiple results for the primary (A) specimen, as the MRO, you must follow the verification procedures described in 13.5(c) through (f) and:

(1) Report all verified positive and/or refusal to test results to the federal agency.

(2) If an invalid result was reported in conjunction with a positive or adulterated result, do not report the verified invalid result to the federal agency at this time. The MRO reports the verified invalid result(s) for the primary (A) specimen only if the split specimen is tested and reported as a failure to reconfirm as described in Section 14.5(c).

(c) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is any legitimate medical explanation for the positive result.

(1) If the donor provides documentation (*e.g.,* a valid prescription) to support a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency.

(i) Passive exposure to a drug (*e.g.,* exposure to secondhand marijuana smoke) is not a legitimate medical explanation for a positive drug test result.

(ii) Ingestion of food products containing marijuana is not a legitimate medical explanation for a positive drug test result.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a positive result to the agency for all drugs except codeine and/or morphine as follows:

(i) For codeine and/or morphine less than 150 ng/mL and no legitimate medical explanation: The MRO must determine if there is clinical evidence of illegal use (in addition to the drug test result) to report a positive result to the agency. If there is no clinical evidence of illegal use, the MRO reports a negative result to the agency. 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).

(ii) For codeine and/or morphine equal to or greater than 150 ng/mL and no legitimate medical explanation: The MRO reports a positive result to the agency. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(d) When the HHS-certified laboratory reports an adulterated result for the primary (A) oral fluid specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated result.

(1) If the donor provides a legitimate medical explanation, the MRO reports a negative result to the federal agency.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a refusal to test to the federal agency because the oral fluid specimen was adulterated.

(e) When the HHS-certified laboratory reports an invalid result for the primary (A) oral fluid specimen, the MRO must contact the donor to determine if there is a legitimate explanation for the invalid result.

(1) If the donor provides a legitimate explanation (*e.g.,* a prescription medication), the MRO reports a test cancelled result with the reason for the invalid result and informs the federal agency that a recollection is not required because there is a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate explanation, the MRO reports a test cancelled result with the reason for the invalid result and directs the agency to collect another specimen from the donor.

(i) If the second specimen collected provides a valid result, the MRO follows the procedures in 13.5(a) through (d).

(ii) If the second specimen collected provides an invalid result, the MRO reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (*e.g.,* urine).

(f) When the HHS-certified laboratory reports a rejected for testing result for the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor.

13.6 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of oral fluid for a drug test?

(a) When another specimen type (*e.g.,* urine) was collected as authorized by the federal agency, the MRO reviews and reports the test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternative specimen.

(b) When the federal agency did not authorize the collection of an alternative specimen, the MRO consults with the federal agency. The federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. The MRO may perform this evaluation if the MRO has appropriate expertise.

(1) For purposes of this section, a medical condition includes an ascertainable physiological condition. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time.

(2) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of oral fluid to complete the test;

(ii) The consequences of the appropriate federal agency regulation for refusing to take the required drug test;

(iii) That, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in paragraph (b)(3) of this section and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the federal agency in writing:

(i) A medical condition as defined in paragraph (b)(1) of this section has, or

with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the federal agency.

(ii) A permanent or long-term medical condition as defined in paragraph (b)(1) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid and is highly likely to prevent the employee from providing a sufficient amount of oral fluid for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the federal agency and recommend that the agency authorize collection of an alternative specimen type (*e.g.,* urine) for any subsequent drug tests for the donor.

(iii) There is not an adequate basis for determining that a medical condition has or, with a high degree of probability, could have precluded the employee from providing a sufficient amount of oral fluid. As the MRO, you must report a refusal to test to the federal agency.

(4) When a federal agency receives a report from the MRO indicating that a test is cancelled as provided in paragraph (b)(3)(i) of this section, the agency takes no further action with respect to the donor. When a test is canceled as provided in paragraph (b)(3)(ii) of this section, the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (*i.e.,* authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the federal agency plan. The donor remains in the random testing pool.

13.7 What happens when an individual is unable to provide a sufficient amount of oral fluid for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which the donor has a medical condition that precludes the donor from providing a sufficient specimen for a federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test and the condition involves a permanent or long-term disability and the federal agency does not authorize collection of an alternative specimen. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.6.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient oral fluid specimen impossible, and for the determination that no signs and symptoms of drug use exist. The MRO recommends that the agency authorize collection of an alternate specimen type (*e.g.,* urine) for any subsequent collections.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state that a permanent or long-term medical condition [as defined in Section 13.6 (b)(1)] exists, making provision of a sufficient oral fluid specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*e.g.,* the federal agency is not authorized to allow the donor to begin or resume performing official functions because a negative test is needed for that purpose).

Section 13.8 Who may request a test of a split (B) specimen?

(a) For a positive or adulterated result reported on a primary (A) specimen, a donor may request through the MRO that the split (B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours (from the time the MRO notified the donor that the donor's specimen was reported positive, adulterated, or (for urine) substituted to request a test of the split (B) specimen. The MRO must inform the donor that the donor has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or (for urine) substituted result is being reported to the federal agency on the primary (A) specimen.

Section 13.9 How does an MRO report a primary (A) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(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 copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and (for urine) substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

Section 13.10 at types of relationships are prohibited between an MRO and an HHS-certified laboratory?

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.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with the HHS-certified laboratory that may be construed as a potential conflict of interest.

Subpart N—Split Specimen Tests

Section 14.1 When may a split (B) specimen be tested?

(a) The donor may request, verbally or in writing, through the MRO that the split (B) specimen be tested at a different (*i.e.,* second) HHS-certified oral fluid laboratory when the primary (A) specimen was determined by the MRO to be positive, adulterated, or (for urine) substituted.

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The MRO must

document in the MRO's records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) oral fluid specimen cannot be tested by a second HHS-certified laboratory (*e.g.,* insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory available to perform the test), the MRO reports to the federal agency that the test must be cancelled and the reason for the cancellation. The MRO directs the federal agency to ensure the immediate recollection of another oral fluid specimen from the donor, with no notice given to the donor of this collection requirement until immediately before the collection.

(d) If a donor chooses not to have the split (B) specimen tested by a second HHS-certified oral fluid laboratory, a federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original positive, adulterated, or (for urine) substituted result.

Section 14.2 How does an HHS-certified laboratory test a split (B) specimen when the primary (A) specimen was reported positive?

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoff concentrations established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (A) specimen.

Section 14.3 How does an HHS-certified laboratory test a split (B) oral fluid specimen when the primary (A) specimen was reported adulterated?

(a) The HHS-certified laboratory must use its confirmatory specimen validity test at an established limit of quantification (LOQ) to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

Section 14.4 Who receives the split (B) specimen result?

The second HHS-certified laboratory must report the result to the MRO.

Section 14.5 What action(s) does an MRO take after receiving the split (B) oral fluid specimen result from the second HHS-certified laboratory?

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split (B) oral fluid specimen as:

(a) *Reconfirmed the drug(s) or adulteration 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 specimen. The MRO gives the donor 72 hours to request that Laboratory A retest the primary (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. 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 not adulterated.* 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.

(d) *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 give the reason for the invalid result], cancels both tests, directs the agency to immediately collect another specimen and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) *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 responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(f) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and not 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. The MRO shall notify the HHS office 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 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.

(h) *Failed to reconfirm adulteration.* The MRO reports to the agency a failed to reconfirm result (specify adulterant) 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.

(i) *Failed to reconfirm a single or all drug positive results and reconfirmed an adulterant.* The MRO reports to the agency a reconfirmed result (specify adulterant) 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) although Laboratory B failed to reconfirm the drug(s) result.

(j) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterant.* The MRO reports to the agency a failed to reconfirm result [specify drug(s) and adulterant] 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 at least one drug and reconfirmed the adulterant.* The MRO reports to the agency a reconfirmed result [specify drug(s) and adulterant] 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 reconfirmed adulterant although Laboratory B failed to reconfirm one or more drugs.

(l) *Failed to reconfirm at least one drug and failed to reconfirm the adulterant.* The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s) and 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 adulterant.

Section 14.6 How does an MRO report a split (B) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* teleprinter, facsimile, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(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 copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

Section 14.7 How long must an HHS-certified laboratory retain a split (B) specimen?

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for the primary (A) specimen.

Subpart O—Criteria for Rejecting a Specimen for Testing

Section 15.1 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing?

The following discrepancies are considered to be fatal flaws. The HHS-certified laboratory must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

(a) The specimen ID number on the primary (A) or split (B) 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 either specimen label/seal;

(b) The primary (A) specimen label/seal is missing, misapplied, broken or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;

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

(d) There is an insufficient amount of specimen for analysis in the primary (A) specimen unless the split (B) specimen can be re-designated as the primary (A) specimen;

(e) The accessioner failed to document the primary (A) specimen seal condition on the Federal CCF at the time of accessioning, and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(f) The specimen was received at the HHS-certified laboratory without a CCF;

(g) The CCF was received at the HHS-certified laboratory without a specimen;

(h) The collector performed two separate collections using one CCF; or

(i) The HHS-certified laboratory identifies a flaw (other than those specified above) that prevents testing or affects the forensic defensibility of the drug test and cannot be corrected.

Section 15.2 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing unless the discrepancy is corrected?

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified 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 HHS-certified laboratory may report the test result for the specimen. If, after holding the specimen for at least 5 business days, the HHS-certified 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.

(b) If a specimen is submitted using a non-federal form or an expired Federal CCF, the HHS-certified 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, after holding the specimen for at least 5 business days, the HHS-certified 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.

Section 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory to reject an oral fluid specimen for testing or an MRO to cancel a test?

(a) The following omissions and discrepancies on the Federal CCF that are received by the HHS-certified laboratory should not cause an HHS-certified laboratory to reject an oral fluid specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appearing 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 Social Security Number or employee identification number;

(6) A telephone 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 lot number of the collection device used for the collection is missing;

(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 HHS-certified laboratory copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory should not cause an MRO to cancel a test:

(1) The testing laboratory fails to indicate the correct name and address in the results section when a different laboratory name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print their name;

(3) The certifying scientist or certifying technician fails to print their name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies should occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory 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 or HHS-certified laboratory (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

Section 15.4 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 Federal CCF for a specimen being reported drug positive, adulterated, invalid, or (for urine) substituted; or

(3) The electronic report provided by the HHS-certified laboratory does not contain all the data elements required for the HHS standard laboratory electronic report for a specimen being reported drug positive, adulterated, invalid result, or (for urine) substituted.

(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, after at least 5 business days, 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 certifying scientist that they inadvertently forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 5 business days, the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory. If, after at least 5 business days, the laboratory does not retransmit a corrected electronic report, the MRO must cancel the test.

Subpart P—Laboratory Suspension/ Revocation Procedures

Section 16.1 When may the HHS certification of a laboratory be suspended?

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory 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 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 16.2 What definitions are used for this subpart?

Appellant. Means the HHS-certified laboratory which has been notified of its suspension or proposed revocation of its certification to perform 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 the official's 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 16.3 Are there any limitations 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 relevant 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 16.4 Who represents the parties?

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

Section 16.5 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 16.6 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 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 16.7 What procedures are 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 testing, which is 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 16.8 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 their 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 the Oral Presentation.* The presiding official will attempt to schedule the oral presentation within 30 days of the date the 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 the official's 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 Federal 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 their 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 16.9 Are there expedited procedures for review of immediate suspension?

(a) *Applicability.* When the Secretary notifies an HHS-certified laboratory in writing that its certification to perform drug 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 HHS-certified 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, which is 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 16.8(c) and will conduct the oral presentation in accordance with the procedures of Sections 16.8(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 16.14 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, secured electronic transmissions, or overnight mail.

Section 16.10 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 16.11 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, secured electronic transmissions, 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 federal 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 16.12 What are 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 16.13 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 16.14 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 therefore 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 their 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 16.15 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 16.9(e) or 16.14(a) constitutes final agency action and is ripe for judicial review as of the date of the decision.

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