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

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

Section 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. 2015–11523 Filed 5–13–15; 4:15 pm]

BILLING CODE 4162–20–P

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: Notice of proposed revisions to the mandatory guidelines by the Secretary of Health and Human Services.

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

DATES: Submit comments on or before July 14, 2015.

ADDRESSES: In commenting, please refer to file code SAMHSA–2015–0002. Because of staff and resource limitations, SAMHSA cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

- *Electronically.* You may submit electronic comments on this regulation to *http://www.regulations.gov*. Follow ''Submit a comment'' instructions.
- *By regular mail.* You may mail written comments to the following address ONLY: SAMHSA, Attention Division of Workplace Programs (DWP), 1 Choke Cherry RD., Rm. #7–1045, Rockville, MD 20857. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- *By express or overnight mail.* You may send written comments to the following address ONLY: SAMHSA, Attention DWP, 1 Choke Cherry RD., Rm. #7–1045, Rockville, MD 20850.
- *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments ONLY to the following address prior to the close of the comment period: SAMHSA, Attention DWP, 1 Choke Cherry RD., Rm. #7–1045, Rockville, MD 20850. If you intend to deliver your comments to the Rockville address, call telephone number (240) 276–2600 in advance to schedule your arrival with one of our staff members. Because access to the interior of the SAMHSA Building is not readily available to persons without federal government identification, commenters are encouraged to schedule their delivery or to leave comments with the security guard front desk located in the main lobby of the building. Comments erroneously mailed to the address indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Charles LoDico, M.S., DABFT, Division of Workplace Programs, Center for Substance Abuse Prevention (CSAP), SAMHSA mail to: 1 Choke Cherry Road, Room 7–1045, Rockville, MD 20857, telephone (240) 276–2600, fax (240) 276–2610, or email at *charles.lodico@samhsa.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Executive Summary

This notice of proposed revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) will revise the initial and confirmatory drug test analytes and methods for urine testing, revise the cutoff for reporting a specimen as adulterated based on low pH, revise 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 is issuing a separate Notice in the **Federal Register** 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.

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 of the Controlled Substances Act prescription medications (*i.e.,* oxycodone, oxymorphone, hydrocodone and hydromorphone) in federal drug-free workplace programs, add methylenedioxyamphetamine (MDA) and methylenedioxyethylamphetamine (MDEA) as initial test analytes, 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 proposed wording changes and reorganization of the UrMG were made for clarity, to use current scientific terminology or preferred grammar, and for consistency with the proposed OFMG.

Costs and Benefits

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. HHS 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 once the proposed OFMG have been

implemented. The approximate annual numbers of regulated specimens for the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) are 6 million and 200,000, 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 number of specimens for NRC would be 14,000 oral fluid and 186,000 urine.

In Section 3.4, the Department is proposing criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specifying the cross-reactivity of the immunoassay to the other analyte(s) within the group. These proposed Guidelines allow the use of methods other than immunoassay for initial testing. In addition, these proposed Guidelines include an alternative for laboratories to continue to use existing FDA-cleared immunoassays which do not have the specified cross-reactivity, by establishing a decision point with the lowest-reacting analyte. 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.

For amphetamines, one of the three existing methylenedioxymeth amphetamine (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.

Costs associated with the addition of 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 and MDEA since the current immunoassays can be adapted to test for these analytes. 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 of the certified laboratories.

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 as positive due to costs of sample preparation and analysis. Based on information from non-regulated workplace drug testing for these analytes in 2012 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 total cost per specimen submitted for testing will increase by $0.11–$0.30.

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 this additional review of specimens confirmed positive for prescription medications, MRO costs are estimated to increase by approximately 3%.

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 cost 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. However, costs are expected to be minimal in the training process to understand the required changes in these Guidelines.

Based on the current figures, the cost for urine testing in the first year is estimated on 139,500 urine specimens for HHS, 5,820,000 urine specimens for DOT, and 186,000 urine specimens for NRC. Estimated costs are $99,045–$230,175 for HHS, $4,132,200–$9,603,000 for DOT, and $132,060–$306,900 for NRC.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public. Please note that all comments are posted in their entirety, including personal or confidential business information that is included in a comment. SAMHSA posts all comments before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on the Web site to view public comments. Comments received before the close of the comment period will also be available for public inspection as they are received, generally beginning approximately three weeks after publication of a document, at the Substance Abuse and Mental Health Services Administration, Division of Workplace Programs, 1 Choke Cherry RD., Rockville, MD, 20850, Monday through Friday of each week from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, call (240) 276–2600.

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].

History and Proposed Changes to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs

At the July 2011 meeting of SAMHSA's Drug Testing Advisory Board (DTAB), Board members voted unanimously for the following:

(1) Based on review of the science, DTAB recommends that SAMHSA include oral fluid as an alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs; and (2) DTAB recommends the inclusion of additional Schedule II prescription medications (*e.g.,* oxycodone, oxymorphone, hydrocodone and hydromorphone) in the Mandatory Guidelines for Federal Workplace Drug Testing Programs.

At the January 2012 DTAB meeting, the SAMHSA Administrator received the DTAB recommendations from the July 2011 meeting.

The responses to the April 13, 2004 notice proposing alternative specimen matrices (69 FR 19673) had made it clear that if the Department were to subsequently authorize alternative specimens for the Mandatory Guidelines for Federal Workplace Drug Testing Programs, separate Guidelines would be needed to provide clear and comprehensive information on the scientific and technical requirements for each specimen matrix. Therefore, HHS is proposing Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Urine (UrMG) and Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Oral Fluid (OFMG). The proposed UrMG and OFMG have been organized into analogous sections and use the same language where possible. The only differences are due to requirements that are specific for each specimen matrix.

Since the original Guidelines were published in 1988, a number of recommendations have been made for additional drugs to be included in federal workplace drug testing programs. Further, the Department monitors drug abuse trends and reviews information on new drugs of abuse from sources such as federal regulators, researchers, the drug testing industry, and public and private sector employers. The Department revised the Guidelines to include 6-acetylmorphine in 1998 (63 FR 63483) and three amphetamine analogues [methylenedioxymethamphetamine (MDMA), methylenedioxyamphetamine (MDA), and methylenedioxyethylamphetamine (MDEA)] in 2008 (73 FR 71858). The July 21, 2011 DTAB recommendations for the added drugs were based on the Board members' review of scientific information on the methods necessary to detect the analytes of these drugs and on drug abuse trends.

The DTAB recommendations, current drug abuse trends and other relevant information, and the private sector experience have led the Department to conclude that the additional opiates oxycodone, oxymorphone, hydrocodone, and hydromorphone should be added in the federal program.

Provisions for the Administration of the National Laboratory Certification Program (NLCP)

In accordance with the current practice, an HHS contractor will perform certain functions on behalf of the Department. These functions include maintaining laboratory inspection and performance testing (PT) programs that satisfy the requirements described in the Guidelines. These activities include, but are not limited to, reviewing inspection reports submitted by inspectors, reviewing PT results submitted by laboratories, preparing inspection and PT result reports, and making recommendations to the Department regarding certification or suspension/revocation of laboratories' certification. It is important to note that, although a contractor gathers and evaluates information provided by the inspectors or laboratories, all final decisions regarding laboratory certification, suspension, or revocation of certification are made by the Secretary.

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

Organization of Proposed Guidelines

This preamble describes the differences between the current Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) and the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine Specimens (UrMG), and the rationale for the differences. In addition, the Preamble presents two topics of special interest to be addressed for the revised Guidelines. These topics are presented first in summary as they appear in the text of the proposed UrMG and later as topics of special interest for which the Department is seeking public comments.

Subpart A—Applicability

Section 1.5 defines terms used in the UrMG. Where possible, the Department proposes to revise the definitions in the current Guidelines to apply to any specimen matrix allowed in federal workplace drug testing programs, so the terms and their definitions will be identical in both the UrMG and the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid Specimens (OFMG). In addition, the Department proposes to add new definitions or revise the definitions in the current Guidelines as needed for terms that apply only to urine (*e.g.,* collection container). The Department also proposes to revise and update terms and definitions in the current Guidelines for clarity and consistency with current scientific terminology (*e.g.,* changing the term limit of quantitation to limit of quantification; no longer using the term quality control samples for both calibrators and controls).

Sections 1.6, 1.7, and 1.8 contain the same policies as described in the current Guidelines with regard to what an agency is required to do to protect employee records, the conditions that constitute refusal to take a federally regulated drug test, and the consequences of a refusal to take a federally regulated drug test. In the proposed UrMG, Section 1.7 of the current Guidelines was divided into two sections for clarity: Section 1.7 describes what constitutes a refusal to test and Section 1.8 describes the subsequent actions and consequences. Section 1.7 also has been reworded as needed to address other authorized specimen types.

Subpart B—Urine Specimen

The Department proposes to revise Section 2.1 of the current Guidelines to reflect the Department's proposed expansion of the drug-testing program for federal agencies to permit the use of oral fluid specimens. There is no requirement for federal agencies to use oral fluid as part of their program. When the OFMG become effective and HHS has certified laboratories under the OFMG, a federal agency may choose to use urine, oral fluid, or both specimen types in their drug testing program. Any agency choosing to use urine is required to follow the UrMG and any agency choosing to use oral fluid is required to follow the OFMG. For example, an agency program can randomly assign

individuals to either urine or OF testing, for random or pre-employment testing. This would not only help reduce subversion, but would allow comparison of urine and OF testing outcomes for planning purposes.

Section 2.6 was added to clarify that all entities and individuals identified in Section 1.1 of these Guidelines are prohibited from releasing specimens collected under the federal workplace drug testing program to any individual or entity unless expressly authorized by these Guidelines or in accordance with applicable federal law.

While these Guidelines do not authorize the release of 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 from the time of collection through final disposition of the specimen. There are also procedures that allow federal employees to request the retesting of their specimen (for drugs, adulteration, or substitution) at a different certified laboratory. Furthermore, the Guidelines grant federal employees access to a wide variety of information and records related to the testing of their specimens, including a documentation package that includes, among other items, a copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, and any memoranda generated by the laboratory or Instrumented Initial Test Facility (IITF).

Therefore, the Guidelines offer federal employees and federal agencies transparent and definitive evidence of a specimen's identity, security, control and chain of custody. However, the Guidelines do not entitle employees access to the specimen itself or to a portion thereof. The reason for this prohibition is that specimens collected under the Guidelines are uniquely designed for the purpose of drug and validity testing only. They are not designed for other purposes such as deoxyribonucleic acid (DNA) testing. Furthermore, conducting additional testing outside the parameters of the Guidelines would not guarantee incorporation of the safeguards, quality control protocols, and the exacting scientific standards developed under the Guidelines to ensure the security, reliability and accuracy of the drug testing process.

Subpart C—Urine Specimen Tests

Section 3.3(a) includes the same requirement as the current Guidelines for urine specimens collected for federal agency workplace drug testing programs to be tested only for drugs and to determine their validity. While satisfied that the policy as stated in the current Guidelines prohibits other testing (*e.g.,* DNA testing) on a specimen, the Department has removed the phrase ''unless otherwise authorized by law'' and reworded for clarity. The revised section states that specimens must only be tested for drugs and to determine their validity in accordance with Subpart C of these Guidelines. The reasons for this prohibition are described above, in comments for Section 2.6.

Section 3.4 lists the drug test analytes and cutoff concentrations for urine. The table in Section 3.4 is the same in the current Guidelines with three notable exceptions. First, the proposed UrMG include the added opiates oxycodone, oxymorphone, hydrocodone, and hydromorphone as initial and confirmatory test analytes. Second, the proposed UrMG include methylenedioxyamphetamine (MDA) and methylenedioxyethylamphetamine (MDEA) as initial test and confirmatory test analytes. The current Guidelines include these two drugs as confirmatory test analytes only. Third, the requirement for initial testing using immunoassay-based technology has been changed to allow initial testing by ''alternate'' technologies (see footnote 2 of the table). This is also the reason for specifying the target analyte for each initial test. Considerable discussion was conducted in DTAB meetings regarding these proposed revisions. The DTAB received input from laboratories, reagent manufacturers, subject matter experts, and the FDA.

For initial tests for opiates and amphetamines using immunoassay, the Department is proposing that the immunoassay be calibrated with one analyte from the group that is identified as the target analyte. Footnote 2 of the table in Section 3.4 includes the proposed criteria for calibrating initial tests for these grouped analytes. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80% or greater. The Department is aware that an FDA-cleared immunoassay meeting these criteria may not exist at the time of the UrMG effective date. If an FDA-cleared immunoassay does not demonstrate at least 80 percent cross-reactivity to each analyte, the laboratory or IITF may use the lowest-reacting analyte to establish a decision point to identify specimens as negative or requiring confirmatory testing. This is accomplished by calibrating the FDA-cleared immunoassay using the manufacturer's target analyte, including a control containing the lowest-reacting analyte at its cutoff concentration in each initial test batch, and comparing the immunoassay responses of specimens in the batch to that of the lowest-reacting analyte control. Alternatively, the laboratory or IITF must use separate immunoassays. The proposed analytes and cutoffs are addressed separately and in detail below. The Department is proposing to permit the use of technologies other than immunoassay techniques for initial drug testing. In recent years, technological advances have been made to techniques (*e.g.,* methods using spectrometry or spectroscopy) that enable their use as efficient and cost-effective alternatives to the immunoassay techniques for initial drug testing while maintaining the required degree of sensitivity, specificity, and accuracy. The proposed Guidelines allow the use of alternate technologies provided that the laboratory or IITF validates the method in accordance with Section 11 for laboratories or Section 12 for IITFs and demonstrates acceptable performance in the PT program.

The proposed analytes and cutoffs follow.

Inclusion of Oxycodone, Oxymorphone, Hydrocodone, Hydromorphone

Misuse and abuse of psychotherapeutic prescription drugs, including opioid pain relievers, are issues of concern for all populations regardless of age, gender, ethnicity, race, or community. Recent data show that opioid-related overdose deaths in the U.S. now outnumber overdose deaths involving all illicit drugs such as heroin and cocaine combined. In addition to overdose deaths, emergency department visits, substance treatment admissions and economic costs associated with opioid abuse have all increased in recent years. The Department is continuing to work with partners at the federal, state, and local levels to implement policies and programs to reduce prescription drug abuse and improve public health.[1]

The Department proposes the inclusion of additional Schedule II prescription medications (*i.e.,* oxycodone, oxymorphone, hydrocodone and hydromorphone) in the list of authorized drug tests and cutoff concentrations. This action was recommended by the DTAB, reviewed by the Department's Prescription Drug Subcommittee of the Behavioral Health Coordinating Committee, and received by the SAMHSA Administrator in January 2012. The inclusion of oxycodone, oxymorphone, hydrocodone and hydromorphone is supported by various data. According to the 2012

National Survey on Drug Use and Health, which provides data on illicit drug use in the United Sates, current (past month) nonmedical users aged 12 years and older of prescription psychotherapeutic drugs increased from 2003 (6.5 million) to 2012 (6.8 million).[2] Psychotherapeutic drugs are defined as opioid pain relievers, tranquilizers, sedatives, and stimulants. The abuse of psychotherapeutic drugs non-medically is ranked second behind marijuana, where pain relievers represent the majority of the group. The Drug Abuse Warning Network (DAWN), which provides national estimates of drug-related visits to hospital emergency departments (ED), showed that, of the 1.2 million ED visits involving nonmedical use of pharmaceuticals in 2011, 46.0 percent involved nonmedical use of pain relievers, with 29 percent being narcotic pain relievers.[3] The most frequently involved narcotic pain relievers were oxycodone and hydrocodone. From 2004 to 2011, ED visits involving nonmedical use of narcotic pain relievers increased by 153 percent. ED visits involving opiates/opioids increased by 183 percent during this period, with increases of 438 percent for hydromorphone, 263 percent for oxycodone, and over 100 percent for hydrocodone, as well as fentanyl and morphine. In addition, the National Forensic Laboratory Information System (NFLIS) found that oxycodone and hydrocodone were among the top ten drugs seized in law enforcement operations and sent to federal, state, and municipal forensic laboratories.[4] Among prescription drugs, oxycodone and hydrocodone ranked first and second. Information on over 5 million drug tests in general workplace drug testing shows that the positivity rate for oxycodone and hydrocodone (0.96%) was second only to marijuana in 2012.[5]

The addition of these Schedule II prescription medications will require MRO review to verify legitimate drug use. Consistent with the current Guidelines, the MRO must contact the donor to determine if there is a legitimate medical explanation for a positive result. 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.

The use of medications, specifically Schedule II drugs, without a prescription is a growing concern for the Department in workplace drug testing, and the proposal for their inclusion offers the opportunity to deter nonmedical use of these drugs among federal workers. The Department does note that in recognition of the prescription drug abuse issue, the Department of Defense issued a memorandum on January 30, 2012, announcing the expansion of their drug testing panel to include hydrocodone and benzodiazepines starting on May 1, 2012. Similarly, the Department proposes that federal agencies include the testing of oxycodone, oxymorphone, hydrocodone, and hydromorphone in urine specimens as described below.

Oxycodone/Oxymorphone

The Department is proposing to test for oxycodone/oxymorphone using a 100 ng/mL cutoff concentration for the initial test and 50 ng/mL for the confirmatory test cutoff concentration. Both oxycodone and oxymorphone are potent analgesics that are available by prescription for pain relief. Oxycodone is partially metabolized by O-demethylation to oxymorphone and both parent drug and metabolite are excreted in urine following oxycodone administration.[6–10] Following oxymorphone administration, oxymorphone is metabolized and excreted in urine primarily as a glucuronide conjugate of the parent drug.[6 10]

An immunoassay initial test for oxycodone/oxymorphone should be calibrated with one of the two analytes and demonstrate sufficient cross-reactivity with the other analyte. The Department proposes that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 100 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The 50 ng/mL confirmatory test cutoff concentration applies equally to oxycodone and oxymorphone. A positive test would be comprised of either or both analytes with a confirmed concentration equal to or greater than 50 ng/mL.

Hydrocodone/Hydromorphone

The Department is proposing to test for hydrocodone/hydromorphone using a 300 ng/mL cutoff concentration for the initial test and 100 ng/mL for the confirmatory test cutoff concentration. Both hydrocodone and hydromorphone are potent analgesics that are available by prescription for pain relief. Hydrocodone is partially metabolized by O-demethylation to hydromorphone and both parent drug and metabolite are excreted in urine following hydrocodone administration.[6 9 12–14] Following hydromorphone administration, hydromorphone is metabolized and excreted in urine primarily as a glucuronide conjugate of the parent drug.[15] Hydrocodone has been reported to be a minor metabolite of codeine [16] and hydromorphone has been reported to be a minor metabolite of morphine.[17 18]

An immunoassay initial test for hydrocodone/hydromorphone should be calibrated with one of the two analytes and demonstrate sufficient cross-reactivity with the other analyte. The Department proposes that the minimum cross-reactivity with either analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or both analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the two analytes must be equal to or greater than 300 ng/mL. The quantitative sum of the two analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The confirmatory test cutoff concentration applies equally to hydrocodone and hydromorphone. A positive test would be comprised of either or both analytes with a confirmed concentration equal to or greater than 100 ng/mL.

In 2009, the U.S. Drug Enforcement Administration (DEA) asked the U.S. Department of Health and Human Services (HHS) for a recommendation regarding whether to change the schedule for hydrocodone combination drug products, such as Vicodin. The proposed change was from Schedule III to Schedule II, which would increase the controls on these products. Due to the unique history of this issue and the tremendous amount of public interest, in October 2013, the FDA Center for Drug Evaluation and Research announced the agency's intent to recommend to HHS that hydrocodone combination drug products should be reclassified to Schedule II. FDA stated that this determination came after a thorough and careful analysis of extensive scientific literature, review of hundreds of public comments on the issue, and several public meetings, during which FDA received input from a wide range of stakeholders, including patients, health care providers, outside experts, and other government entities.

In December 2013, FDA, with the concurrence of the National Institute on Drug Abuse (NIDA), submitted a formal recommendation package to HHS to

reclassify hydrocodone combination drug products into Schedule II. Also in December 2013, the Secretary of HHS submitted the scientific and medical evaluation and scheduling recommendation to the DEA for its consideration. On August 22, 2014, DEA published the Final Rule that moves hydrocodone combination drug products from Schedule III to Schedule II.

Inclusion of Methylenedioxyamphetamine (MDA) and Methylenedioxyethylamphetamine (MDEA) as Initial Test Analytes

The Department proposes adding MDA and MDEA as initial test analytes in the list of authorized drug tests and cutoff concentrations. The current Guidelines include these two drugs as confirmatory test analytes only, in conjunction with an initial test for MDMA. Specifying these compounds as initial test analytes (in addition to MDMA) improves their detection by initial tests using immunoassay, and enables detection by initial tests using an alternate technology, as allowed under these proposed Guidelines. All three analytes are Schedule I drugs. The Department is proposing to test for MDMA/MDA/MDEA using a 500 ng/mL cutoff concentration for the initial test and 250 ng/mL for the confirmatory test cutoff concentration.

An immunoassay initial test for MDMA/MDA/MDEA should be calibrated with one of the three analytes and demonstrate sufficient cross-reactivity with the other analytes. The Department proposes that the minimum cross-reactivity with each analyte be 80 percent or greater. If an alternate technology initial test is performed instead of immunoassay, either one or all analytes in the group should be used to calibrate, depending on the technology. The quantitative sum of the three analytes must be equal to or greater than 500 ng/mL. The quantitative sum of the three analytes must be based on quantitative values for each analyte that are equal to or above the laboratory's validated limit of quantification.

The confirmatory test cutoff concentration applies equally to MDMA, MDA, and MDEA. A positive test would be comprised of one or more analytes with a confirmed concentration equal to or greater than 250 ng/mL.

Section 3.5 authorizes HHS-certified laboratories to perform additional tests to assist the Medical Review Officer (MRO) in making a determination of positive or negative results. The Department believes that additional tests requested by the MRO can provide useful information to determine the veracity of a donor's medical explanation. This is a revision to the current Guidelines, but is consistent with current practices. An example of an additional test currently requested by an MRO is when the laboratory reports a positive methamphetamine result. The MRO may request a d,l-stereoisomer determination for methamphetamine, to determine whether the result could be attributed to use of an over-the-counter nasal inhaler. Another example of current practice is when the laboratory reports a positive THCA result, and the MRO requests testing for cannabivarin, to distinguish marijuana use from dronabinol (*e.g.,* Marinol®).

In Section 3.6, the Department proposes to revise the criteria to report a urine specimen as adulterated based on pH. Specifically, in paragraph 3.6(a), the Department is proposing to raise the low pH cutoff for adulteration from less than 3 to less than 4. 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.[19] Furthermore, there are no known medical conditions or medications that would cause urine pH to be less than 4.5. Any free hydrogen ions present in the renal tubular fluid are either buffered and secreted into urine in the form of ammonium, phosphate, sulfate, and weak organic acid ions with minimal change to the urine pH or they back leak into the extracellular fluid and are not excreted into the urine, which explains the physiological lower limit of 4.5 for urine pH. A proposed pH cutoff for adulteration of less than 4 creates an invalid pH range of ''equal to or greater than 4 and less than 4.5,'' which protects the donor from a pH test result less than 4.5 that could be due to analytical imprecision.

Section 3.8 contains the same criteria as the current Guidelines for reporting a urine specimen as dilute in conjunction with positive or negative drug test results. The section has been revised to clarify the criteria for specific gravity results measured to four-decimal places (*i.e.,* as required when creatinine is less than or equal to 5 mg/dL).

Section 3.9 contains the criteria for reporting an invalid result for a urine specimen. This section contains the same criteria for reporting an invalid result for a urine specimen as in the current Guidelines with four revisions. Paragraph 3.9(b) contains the criteria for reporting a specimen as invalid based on pH. The lower pH range has been changed to ''equal to or greater than 4 and less than 4.5,'' consistent with the proposed change to the low pH cutoff for adulteration [*i.e.,* raising the pH 3 cutoff to 4; Section 3.6(a)]. Paragraph 3.9(i) addresses interference using an alternate initial drug test method (*i.e.,* other than immunoassay) as proposed in the UrMG. This section includes an additional criterion in Paragraph 3.9(m) that allows reporting an invalid result when the specimen is not consistent with human urine as evidenced by additional specimen validity test results. This is consistent with the proposed Section 3.5 that allows the MRO to request additional tests. For example, at least one HHS-certified laboratory currently tests their non-regulated workplace urine specimens for a urine biomarker (*i.e.,* uric acid) to distinguish urine of human origin from synthetic urine. The Department believes that such tests can be useful, especially in light of the proliferation of urine substitution products that have been formulated to meet the criteria for routine specimen validity tests (*i.e.,* creatinine and pH). The tests must be forensically acceptable and scientifically sound.

Subpart D—Collectors

Sections 4.1 through 4.6 contain the same policies as the current Guidelines in regard to who may or may not collect a specimen, the requirements to be a collector, the requirements to be an observer for a direct observed collection, the requirements to be a trainer for collectors, and what a federal agency must do before a collector is permitted to collect a specimen. The only changes from the current Guidelines are some rewording for clarity and a minor change in the type of mock collections required for collector training in Section 4.3(a)(4).

Subpart E—Collection Sites

Sections 5.1 through 5.6 address requirements for collection sites, collection site records, how a collector ensures the security and integrity of a specimen at the collection site, and the privacy requirements when collecting a specimen. Most requirements are the same as in the current Guidelines, but some items have been reworded for clarity. The Department added a new Section 5.3 clarifying that collection site records must be stored at a secure site designated by the collector or the collector's employer. The Department also revised Section 5.4 to allow hardcopy records to be discarded 6 months after conversion to electronic records. This change ensures the availability of the records while reducing the recordkeeping burden, and is consistent with the Paperwork Reduction Act.

Subpart F—Federal Drug Testing Custody and Control Form

Sections 6.1 and 6.2 are the same as in the current Guidelines, requiring an OMB-approved Federal CCF be used to document custody and control of each specimen at the collection site, and specifying what should occur if the correct OMB-approved CCF is not used.

Subpart G—Urine Specimen Collection Containers and Bottles

Sections 7.1 through 7.3 describe requirements for the collection container, temperature strip, and bottles that must be used to for urine specimen collections. The Department has added detailed requirements for these items, to enable proper collection and maintenance of the urine specimen.

Section 7.1 requires a single use container that has a means to measure urine temperature and two specimen bottles for urine collection.

Section 7.2 requires that the urine collection container, including the temperature strip and the bottles, not substantially affect the composition of drug and/or drug metabolites in the specimen. In addition, the two bottles must be sealable and non-leaking and maintain the integrity of the specimen during storage and transport, and must be sufficiently transparent to enable an objective assessment of the A and B specimens' appearance and identification of abnormal physical characteristics upon receipt at the HHS-certified laboratory or IITF.

Section 7.3 details the minimum performance requirements for a collection container and bottles (*i.e.,* required volume capacity and volume markings) and for the thermometer used to measure specimen temperature. The thermometer may be affixed to or built into the collection container and must provide graduated temperature readings. 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

This subpart addresses the same topics, in the same order, as the OFMG procedures for oral fluid specimen collection. While the procedure is essentially the same as described in the current Guidelines, the Department has reordered and/or reworded steps for clarity and for consistency with the proposed OFMG. Differences exist due to the differences in urine and oral fluid collection procedures. In addition, the Department is proposing to allow federal agencies to authorize collection of oral fluid as an alternate specimen when a donor does not provide an adequate urine specimen. References to agency authorization and collection procedures for oral fluid are applicable only when the OFMG become effective and HHS has certified laboratories to perform oral fluid testing under the Guidelines.

Section 8.5 describes the responsibilities and procedures the collector must follow during and after a urine collection. The Department has revised Section 8.5 to enable a federal agency to authorize collection of oral fluid as an alternate specimen when a donor is unable to provide a sufficient volume of urine within the allowed wait period (*i.e.,* up to three hours). As noted above, this revision will be applicable when the OFMG become effective and HHS has certified laboratories to perform oral fluid testing under the Guidelines. Specifically, Paragraph 8.5(f)(2)(iii) instructs the collector to request authorization for the alternate specimen collection when he/she notifies the federal agency representative of the insufficient urine specimen.

Section 8.6 describes the procedures the collector must follow when a donor is unable to provide a urine specimen. The Department has revised Section 8.5 to enable a federal agency to authorize collection of oral fluid as an alternate specimen when a donor is unable to provide a urine specimen. As noted above, this revision will be applicable when the OFMG become effective and HHS has certified laboratories to perform oral fluid testing under the Guidelines. Specifically, Paragraph 8.6(b)(2) instructs the collector to request authorization for the alternate specimen collection when he/she notifies the federal agency representative of the donor's inability to provide a urine specimen.

Section 8.7 prohibits collection of an alternate specimen when a donor is unable to provide an adequate urine specimen, unless specifically authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs and by the federal agency. As noted above, Paragraphs 8.5(f)(2)(iii) and 8.6(b)(2) describe the circumstances in which the federal agency representative can authorize the collector to collect an alternate specimen (*e.g.,* oral fluid).

Section 8.14 describes a federal agency's responsibilities for a collection site. The Department has included an additional example of appropriate action that may be taken in response to a reported collection site deficiency: Self-assessment using the Collection Site Checklist for the Collection of Urine Specimens for Federal Agency Workplace Drug Testing Programs. This document is available on the SAMHSA Web site *http://www.samhsa.gov/workplace*.

Subpart I—HHS Certification of Laboratories and IITFs

This subpart contains the same requirements for HHS certification of laboratories and instrumented initial test facilities (IITFs) as the current Guidelines.

Section 9.5 includes the same qualitative and quantitative specifications for PT samples as the current Guidelines. Section 9.19 describes where the monthly list of laboratories and IITFs certified by HHS to conduct forensic drug testing for federal agencies is published. The list will indicate the type of specimen (*e.g.,* urine or oral fluid) that each laboratory is certified to test.

Subpart J—Blind Samples Submitted by an Agency

This subpart describes the policies for federal agency blind samples. In Section 10.1, the Department is keeping the annual 3 percent requirement for federal agency blind samples (*i.e.,* as a percentage of the agency's donor specimens) but is proposing to limit the annual number of blind samples to a maximum of 400.

Section 10.2 includes the same requirements for a blind sample as the current Guidelines. The Department has reworded the section for clarity. Also, in Paragraph 10.2(e), the Department added information that blind sample suppliers must provide and specified that the information is to be provided to the collection site/collector sending the sample and, upon request, to the MRO, federal agency, or the Secretary.

In Section 10.4, the Department added that the MRO must contact the laboratory or IITF as the first step after receiving a report for a blind sample with a result that is inconsistent with the expected result.

Subpart K—Laboratory

Section 11.10 addresses initial drug test requirements. These are the same as the current Guidelines requirements, except that the Department is proposing to allow the use of technologies other than immunoassay (*i.e.,* alternate initial test technologies). In recent years, technological advances have been made to techniques (*e.g.,* methods using spectrometry or spectroscopy) that enable their use as efficient and cost-effective alternatives to the

immunoassay techniques for initial drug testing while maintaining the required degree of sensitivity, specificity, and accuracy.

Section 11.11 describes validation requirements for initial drug tests. The Department has included a requirement in Paragraph 11.11(a)(5) for laboratories to assess potential interferences during assay validation. The revision is consistent with current requirements for HHS-certified laboratories. In Paragraphs 11.11(a)(6) and 11.11(c), the Department is proposing additional requirements for alternate technology initial drug tests based on the characteristics of these technologies.

Section 11.13 addresses confirmatory drug test requirements. The Department is proposing to allow analytical procedures using mass spectrometry or other equivalent technologies. Based on ongoing reviews of the scientific and forensic literature, and the assessment of a DTAB working group that has studied newer instruments and technologies, the Department believes that scientifically valid confirmatory methods other than combined chromatographic and mass spectrometric methods can be used to successfully detect and report the drug analytes in Subpart C—Urine Specimen Drug Tests.

Section 11.14 describes validation requirements for confirmatory tests. The Department has included a requirement for laboratories to assess matrix effects when validating a confirmatory drug test using liquid chromatography coupled with mass spectrometry and has added the requirement for laboratories to verify each new lot of reagent prior to placement into service. These revisions are consistent with current requirements for HHS-certified laboratories.

In Section 11.17, the Department added the requirement for laboratories to verify each new lot of reagent for specimen validity testing prior to placement into service, consistent with current requirements for HHS-certified laboratories.

The requirements for conducting each specimen validity test are the same as the current Guidelines, with the exception of pH testing and quality control requirements in Section 11.18(c) which have been revised in accordance with the proposed change to the low pH cutoff for adulteration [*i.e.,* raising the pH 3 cutoff to 4; Section 3.6(a)].

Section 11.19 addresses laboratory requirements for reporting test results. The Department made a change to wording in Section 11.19(a), deleting the requirement for laboratories to report results directly to the MRO, to allow the use of external service providers. Providing test results electronically to MROs can be timely and cost-effective, and is expected to increase following implementation of the Federal Custody and Control Form (CCF) as an electronic document. Section 11.19(n) was revised to require HHS-certified laboratories and external service providers to maintain the confidentiality, integrity, and availability of the data, which includes test results and donor personal identifying information (PII), and to limit access to any data transmission, storage, and retrieval system. Changes have been made to the criteria for reporting a specimen as adulterated or as invalid based on low pH [*i.e.,* Sections 11.19(d) and 11.19(h)(2)] to reflect the proposed change to the low pH cutoff for adulteration [*i.e.,* raising the pH 3 cutoff to 4; Section 3.6(a)]. In Section 11.19(p), the Department has added the requirement for the laboratory to send a legible image or copy of the Federal CCF for rejected specimens to the MRO, as is current practice.

The Department revised Section 11.21(a) to allow hardcopy records to be discarded 6 months after conversion to electronic records. This change ensures the availability of the records while reducing the recordkeeping burden, and is consistent with the Paperwork Reduction Act.

Section 11.22 describes the semiannual statistical summary report that a laboratory must provide to a federal agency for urine testing. The Department is proposing to require the laboratory to submit a copy (paper or electronic) of each statistical summary report to the Secretary or designated HHS representative.

Section 11.23 is a new section addressing the laboratory information to be made available to a federal agency and describes the contents of a standard laboratory documentation package, which are the same as in the current Guidelines. The Department is proposing that a federal agency may obtain laboratory information related to a positive, adulterated, or substituted drug test reported for a federal employee tested in its workplace program, as well as any relevant certification, review, or revocation of certification records for the laboratory.

Section 11.24 was modified to clarify that specimens are not a part of the information package that donors can receive from HHS-certified laboratories.

Subpart L—Instrumented Initial Test Facility (IITF)

This subpart addresses requirements for IITFs. Most requirements remain the same as the current Guidelines. The proposed revisions, detailed below, are consistent with the proposed revisions for laboratories in Section 11.

Section 12.9 addresses initial drug test requirements for IITFs. The Department is proposing to allow IITFs to use technologies other than immunoassay (*i.e.,* alternate initial test technologies). In recent years, technological advances have been made to techniques (*e.g.,* methods using spectrometry or spectroscopy) that enable their use as efficient and cost-effective alternatives to the immunoassay techniques for initial drug testing while maintaining the required degree of sensitivity, specificity, and accuracy.

Section 12.10 describes validation requirements for initial drug tests. The Department has included a requirement in Paragraph 12.10(a)(5) for IITFs to assess potential interferences during assay validation. The revision is consistent with current requirements for HHS-certified IITFs. In Paragraphs 12.10(a)(6) and 12.10(c), the Department is proposing additional requirements for alternate technology initial drug tests based on the characteristics of these technologies.

In Section 12.13, the Department added the requirement for IITFs to verify each new lot of reagent for specimen validity testing prior to placement into service, consistent with current requirements for HHS-certified IITFs.

Section 12.15 addresses IITF requirements for reporting test results. The Department made a change to wording in Section 12.15(a), deleting the requirement for IITFs to report results directly to the MRO, to allow the use of external service providers. Providing test results electronically to MROs can be timely and cost-effective, and is expected to increase following implementation of the Federal Custody and Control Form (CCF) as an electronic document. Section 12.15(e) was revised to require HHS-certified IITFs and external service providers to maintain the confidentiality, integrity, and availability of the data, which includes test results and donor PII, and to limit access to any data transmission, storage, and retrieval system. In Section 12.15(g), the Department has added the requirement for the IITF to send a legible image or copy of the Federal CCF for rejected specimens to the MRO.

The Department revised Section 12.18(a) to allow hardcopy records to be discarded 6 months after conversion to electronic records. This change ensures the availability of the records while reducing the recordkeeping burden, and

is consistent with the Paperwork Reduction Act.

Section 12.19 describes the semiannual statistical summary report that an IITF must provide to a federal agency for urine testing. The Department is proposing to require the IITF to submit a copy of each semiannual statistical summary report (paper or electronic) to the Secretary or designated HHS representative.

Section 12.20 is a new section addressing the IITF information to be made available to a federal agency and describes the contents of a standard IITF documentation package, which are the same as in the current Guidelines. The Department is proposing that a federal agency may obtain IITF information related to a positive, adulterated, or substituted drug test reported by a laboratory for a federal employee tested in its workplace program, as well as any relevant certification, review, or revocation of certification records for the IITF.

Subpart M—Medical Review Officer (MRO)

Section 13.1 describes who may serve as an MRO. With the inclusion of additional Schedule II prescription medications in the Guidelines and the ever-changing field of drug testing, medical review of drug test results is more complex today than before. Therefore, the Department proposes to incorporate MRO requalification training and reexamination on a regular basis (at least every five years). The UrMG and OFMG do not include a requirement for MROs to obtain continuing education units (CEUs). The Department understands that it would be difficult to determine whether CEUs obtained are related to federal agency drug testing. The requalification requirement every five years will assure agency auditors and inspectors and regulated employers that MROs are appropriately qualified. This requirement is not expected to increase costs to MROs. Current practices for MRO requirements have equivalent standards but vary among MRO training entities. These requirements will standardize the length of time each MRO is required to take a requalification examination. Currently, some MRO requalification periods are longer than five years, while others are less than five years. The Department assumes that the costs to those MROs that have requalification periods over five years will be offset by the cost savings to MROs that have periods shorter than five years. Thus, the Department has not estimated any costs associated with this provision, but it welcomes comment on this assumption.

The Department anticipates that MROs will continue to obtain CEUs by virtue of maintaining their medical licensure requirements. In addition, the MRO certification/training entities provide MRO manuals and periodic newsletters with updates on federal drug testing program requirements. However, the Department is seeking comments on requiring MRO requalification CEUs and on the optimum number of credits and the appropriate CEU accreditation bodies should CEUs be required as part of MRO requalification.

MROs play a key role in the federal safety program and maintain the balance between the safety and privacy objectives of the program. The MRO's role in gathering and evaluating the medical evidence and providing due process is imperative. These are duties that must be carried out by the MRO, and cannot be delegated to other personnel who are not certified by an MRO entity.

The MRO is charged with certain important medical and administrative duties. The MRO must have detailed knowledge of the effects of medications and other potential alternative medical explanations for laboratory reported drug test results. He or she is responsible for determining whether legitimate medical explanations are available to explain an employee's drug test result. This medical review process has become far more complex as a result of specimen validity testing and the myriad of donor explanations for adulterated, substituted, and invalid laboratory test results.

In addition, MROs confer with prescribing physicians in making decisions about prescription changes so that alternative medications can be used that will not impact public safety. Similarly, the MRO is required to report to employers the employees' prescription and over-the-counter medication use (or dangerous combinations of use) that the MRO believes will negatively affect duty performance. In addition, the MRO is required to medically assess referral physician examinations and evaluations in certain positive and refusal-to-test situations. These, too, have become more complex over time.

Section 13.2 describes how nationally recognized entities or subspecialty boards that certify MROs are approved. The Department is proposing to extend the due date for resubmission of qualifications for HHS approval from each year to every two years and to publish the list of approved entities at least every two years, rather than annually. The revised time periods appear sufficient to ensure that educational material is updated at least every two years and the Department requiring the nationally recognized entities that approves MROs ensures the qualifications are being met. The Department has also revised this section to require submission of the certification examination delivery method along with other documentation for review.

Section 13.3 describes the training that is required before a physician may serve as an MRO. With the issue of prescription drug abuse and the inclusion of additional opiates to the federal drug-testing panel, MROs have the difficult task of interpreting positive drug test results from prescription drugs. Further guidance on these drug test results will be included in the MRO manual. The Department has added a requirement for MRO training to include information about how to discuss substance misuse and abuse and how to access those services. MROs performing the review of federal employee drug test results should be aware of prevention and treatment opportunities for individuals and can provide information to the donor.

The Department also revised Section 13.4 to allow the MRO to discard hardcopy records 6 months after conversion to electronic records. This change ensures the availability of the records while reducing the recordkeeping burden, and is consistent with the Paperwork Reduction Act.

Section 13.5 describes MRO actions when reviewing a urine specimen's test results. Section 13.5(d) contains the same procedure as the current Guidelines: 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. If the donor provides a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency. The Department added a new Section 13.5(c) to address multiple test results for one specimen and added Section 13.5(h) to address MRO procedures for multiple specimens from the same testing event (*e.g.,* when the collector forwarded to the laboratory a urine specimen with temperature out of range and the subsequently collected specimen—urine or another authorized specimen type). In Paragraphs 13.5(b) and 13.5(g), the Department added instructions for handling recollected negative/dilute or invalid specimens that provide the same results as the first specimen (*i.e.,* when another specimen

was collected from a donor because of a negative/dilute or invalid result, and the recollected specimen provides the same result as the first specimen). The proposed revisions provide a final resolution to report such drug tests, which were not adequately addressed in the current Guidelines. The Department revised Section 13.5(i) to specify the type of specimen (*i.e.,* urine) to be collected from the donor following a cancelled test for a rejected specimen.

Section 13.6 describes what an MRO must do when the collector reports that a donor did not provide a sufficient amount of urine for a drug test. For those instances in which the donor did not provide an adequate urine specimen and the federal agency authorized collection of another specimen type (*e.g.,* oral fluid), the Department is proposing that the MRO review and report those results. If the federal agency did not authorize collection of another specimen type, the current Guidelines procedures remain in effect (*i.e.,* medical evaluation). The Department revised this section to address collection of an alternative specimen for any subsequent tests when the donor has a permanent or long-term medical condition that prevents provision of a sufficient volume of urine for the drug test. As noted previously, a federal agency may authorize collection of oral fluid only when the OFMG are effective and HHS has certified laboratories to perform oral fluid testing under the Guidelines.

Section 13.7 describes what an MRO must do when a donor has a permanent or long-term medical condition that prevents him or her from providing a sufficient amount of urine, a negative test is required (*i.e.,* for a federal agency applicant/pre-employment, follow-up, or return-to-duty test), and the federal agency did not authorize collection of another specimen type (*e.g.,* oral fluid). As noted previously, a federal agency may authorize collection of oral fluid only when the OFMG are effective and HHS has certified laboratories to perform oral fluid testing under the Guidelines.

Section 13.9 describes how an MRO reports a primary (A) specimen result to an agency. The Department revised Section 13.9(a) to address MRO use of external service providers. The revised section requires MROs and external service providers to maintain the confidentiality, integrity, and availability of the data, which includes donor PII, and to limit access to any data transmission, storage, and retrieval system. The Department is also proposing to delete the requirement in Paragraph 13.9(c) for the MRO to send a paper copy of the Federal CCF or separate letter/memorandum. The MRO may report results electronically.

Subpart N—Split Specimen Tests

The Department is proposing to revise Section 14.1(c) to clarify that, in a case where a B specimen is not available for testing, the MRO reports only to the federal agency and not to the donor. This is consistent with the requirement in the next sentence that no notice be given to the donor until immediately before the observed recollection.

Section 14.3(a) addresses criteria for reconfirming an adulterated result. The low pH cutoff in Section 14.3(a)(1) has been changed to reflect the proposed change to the low pH cutoff for adulteration [*i.e.,* raising the pH 3 cutoff to 4; Section 3.6(a)].

Section 14.5 describes who receives the split specimen report from the laboratory. The Department reworded this section to address MRO use of external service providers, similar to the change made to Section 11.19(a) for primary specimen reports.

Section 14.7 describes how an MRO reports a split (B) specimen result to an agency. The Department revised Section 14.7(a) to address MRO use of external service providers. The revised section requires MROs and external service providers to maintain the confidentiality, integrity, and availability of the data, which includes donor PII, and to limit access to any data transmission, storage, and retrieval system. The Department revised Section 14.7(c) to clarify that MRO must use the Federal CCF or separate letter/memorandum to report all split specimens (*i.e.,* not just positive, adulterated, or substituted specimens), and deleted the requirement for the MRO to send paper copies of these documents. The MRO may report results electronically.

Subpart O—Criteria for Rejecting a Specimen for Testing

In Section 15.1, the Department is proposing a new Paragraph 15.1(e) requiring specimen rejection if the accessioner has not documented the primary (A) seal condition at the time of accessioning and the split (B) specimen cannot be redesignated as the primary (A) specimen. This is consistent with current practice. The Department maintains that relying on the accessioner's recall of a particular specimen's bottle seal condition is not a forensically acceptable practice.

Subpart P—Laboratory or IITF Suspension/Revocation Procedures

This subpart includes procedures to revoke or suspend the HHS-certification of laboratories and IITFs. These are the same as in the current Guidelines.

Impact of These Guidelines on Government Regulated Industries

The Department is aware that these proposed new Guidelines may impact the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) regulated industries depending on these agencies' decisions to incorporate the final UrMG revisions into their programs under their own authority.

Topics of Special Interest

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

Section 3.4 lists the proposed new analytes oxycodone, oxymorphone, hydrocodone, and hydromorphone and their cutoff concentrations. The Department is specifically requesting comments on these revisions.

Section 13.1 describes proposed requirements for MRO requalification training and reexamination on a regular basis (*i.e.,* every five years) but does not require MROs to obtain continuing education units (CEUs). The Department is seeking comments on requiring MRO CEUs and on the optimum number of credits and the appropriate CEU accreditation bodies should CEUs be required.

Regulatory Impact and Notices

The Department welcomes public comment on all figures and assumptions used for the regulatory impact assessment described in this section.

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 proposes 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 proposed 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 proposed 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: 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.

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 and MDEA since the current immunoassays can be adapted to test for these analytes. 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 is proposing criteria for calibrating initial tests for grouped analytes such as opiates and amphetamines, and specifying the cross-reactivity of the immunoassay to the other analytes(s) within the group. These proposed Guidelines allow the use of methods other than immunoassay for initial testing. In addition, these proposed Guidelines include an alternative for laboratories to continue to use existing FDA-cleared immunoassays which do not have the specified cross-reactivity, by establishing a decision point with the lowest-reacting analyte. 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 are 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.

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%. This 3% cost increase is expected to occur gradually 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 for federal agencies of $83,700 to $188,325 in the urine testing program.

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 $54,000 and $69,000 (*i.e.,* assuming 8 hours of time multiplied by a GS 12/13 wage).

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	54,000	69,000
Total	81,900.00	124,800.00

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 proposed 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, an initial regulatory flexibility analysis is not required for this notice.

The Secretary has determined that the proposed 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 proposed 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 proposed 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 proposed 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 is proposing to revise 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 proposed 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. 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 has submitted the information collection and recordkeeping requirements contained in the proposed Guidelines to OMB for review and approval.

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 proposed 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 proposed 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, 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 until final Guidelines including the use of another specimen matrix are issued.

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, 5 IITFs, 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 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 submits qualifications of RT to HHS.	.....	.....	.....	.....
12.4(c)	IITF submits information to HHS on new RT or alternate RT.	.....	.....	.....	.....
12.19	Specifications for IITF semi-annual statistical report of test results to each federal agency.	.....	.....	.....	.....
13.9 and 14.7	Specifies that MRO must report all verified primary and split specimen test results to the federal agency.	100	5	*0.05	25
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	.....	.....	247

*3 min.

The following reporting requirements are also in the proposed Guidelines, but have not been addressed in the above reporting burden table: Collector must report any unusual donor behavior or 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)]; 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.

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	5
11.23, 11.24	Information on drug test that laboratory must provide to federal agency upon request or to donor through MRO.	10	10	3	1,500

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
12.20, 12.21	Information on drug test that IITF must provide to federal agency upon request or to donor through MRO.				
13.8(b)	MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported.	100	5	3	1,500
Total		210			3,505

* 3 min.

The following disclosure requirements are also included in the proposed Guidelines, but have not been addressed in the above disclosure burden table: The collector must explain the basic collection procedure to the donor and answer any questions [Section 8.3(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	2,534
8.8(d) & (f)	Donor initials specimen labels/ seals and signs statement on the Federal CCF.	38,000	1	** 0.08	3,167
11.8(a) & 11.19	Laboratory completes Federal CCF upon receipt of specimen and before reporting result.	10	3,800	*** 0.05	1,900
12.8(a) & 12.15	IITF completes Federal CCF upon receipt of specimen and before reporting result.				
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	1,900
14.1(b)	MRO documents donor's request to have split specimen tested.	300	1	*** 0.05	15
Total		38,510			9,516

* 4 min.
** 5 min.
*** 3 min.

The proposed Guidelines contain a number of recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector [Section 4.3(a)(3)] and the documentation must be maintained in the collector's training file [Section 4.3(c)]. 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 13,268 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 has submitted a copy of these proposed Guidelines to OMB for its review. Comments on the information collection requirements are specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

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

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building, 725 17th Street NW., Washington, DC 20502, Attn: Desk Officer for SAMHSA. Because of delays in receipt of mail, comments may also be sent to 202–395–6974 (fax).

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Dated: May 4, 2015.

Pamela S. Hyde,

Administrator, SAMHSA.

Dated: May 7, 2015.

Sylvia M. Burwell,

Secretary.

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

MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS USING URINE SPECIMENS

Subpart A—Applicability

1.1 To whom do these Guidelines apply?
1.2 Who is responsible for developing and implementing these Guidelines?
1.3 How does a federal agency request a change from these Guidelines?
1.4 How are these Guidelines revised?
1.5 What do the terms used in these Guidelines mean?
1.6 What is an agency required to do to protect employee records?
1.7 What is a refusal to take a federally regulated drug test?
1.8 What are the potential consequences for refusing to take a federally regulated drug test?

Subpart B—Urine Specimens

2.2 Under what circumstances may a urine

specimen be collected?
2.3 How is each urine specimen collected?
2.4 What volume of urine is collected?
2.5 How does the collector split the urine specimen?
2.6 When may an entity or individual release a urine specimen?

Subpart C—Urine Specimen Tests

3.1 Which tests are conducted on a urine specimen?
3.2 May a specimen be tested for additional drugs?
3.3 May any of the specimens be used for other purposes?
3.4 What are the drug test cutoff concentrations for urine?
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)?
3.6 What criteria are used to report a urine specimen as adulterated?
3.7 What criteria are used to report a urine specimen as substituted?
3.8 What criteria are used to report a urine specimen as dilute?
3.9 What criteria are used to report an invalid result for a urine specimen?

Subpart D—Collectors

4.1 Who may collect a specimen?
4.2 Who may not collect a specimen?
4.3 What are the requirements to be a collector?
4.4 What are the requirements to be an observer for a direct observed collection?
4.5 What are the requirements to be a trainer for collectors?
4.6 What must a federal agency do before a collector is permitted to collect a specimen?

Subpart E—Collection Sites

5.1 Where can a collection for a drug test take place?
5.2 What are the requirements for a collection site?
5.3 Where must collection site records be stored?
5.4 How long must collection site records be stored?
5.5 How does the collector ensure the security and integrity of a specimen at the collection site?
5.6 What are the privacy requirements when collecting a urine specimen?

Subpart F—Federal Drug Testing Custody and Control Form

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?

Subpart G—Urine Specimen Collection Containers and Bottles

7.1 What is used to collect a urine specimen?
7.2 What are the requirements for a urine collection container and specimen bottles?
7.3 What are the minimum performance requirements for a urine collection container and specimen bottles?

Subpart H—Urine Specimen Collection Procedure

8.1 What privacy must the donor be given when providing a urine specimen?
8.2 What must the collector ensure at the collection site before starting a urine specimen collection?
8.3 What are the preliminary steps in the urine specimen collection procedure?
8.4 What steps does the collector take in the collection procedure before the donor provides a urine specimen?
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 he or she is unable to provide a urine specimen?
8.7 If the donor is unable to provide a urine specimen, may another specimen type be collected for testing?
8.8 How does the collector prepare the urine specimens?
8.9 When is a direct observed collection conducted?
8.10 How is a direct observed collection conducted?
8.11 When is a monitored collection conducted?
8.12 How is a monitored collection conducted?
8.13 How does the collector report a donor's refusal to test?
8.14 What are a federal agency's responsibilities for a collection site?

Subpart I—HHS Certification of Laboratories and IITFs

9.1 Who has the authority to certify laboratories and IITFs to test urine specimens for federal agencies?
9.2 What is the process for a laboratory or IITF to become HHS-certified?
9.3 What is the process for a laboratory or IITF to maintain HHS certification?
9.4 What is the process when a laboratory or IITF does not maintain its HHS certification?
9.5 What are the qualitative and quantitative specifications of performance testing (PT) samples?
9.6 What are the PT requirements for an applicant laboratory?
9.7 What are the PT requirements for an HHS-certified urine laboratory?
9.8 What are the PT requirements for an applicant IITF?
9.9 What are the PT requirements for an HHS-certified IITF?
9.10 What are the inspection requirements for an applicant laboratory or IITF?
9.11 What are the maintenance inspection requirements for an HHS-certified laboratory or IITF?
9.12 Who can inspect an HHS-certified laboratory or IITF and when may the inspection be conducted?
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?
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?
9.15 What factors are considered in determining whether revocation of a laboratory's or IITF's HHS certification is necessary?
9.16 What factors are considered in determining whether to suspend a laboratory's or an IITF's HHS certification?
9.17 How does the Secretary notify an HHS-certified laboratory or IITF that action is being taken against the laboratory or IITF?
9.18 May a laboratory or IITF that had its HHS certification revoked be recertified to test federal agency specimens?
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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.

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,

[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.

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 when the laboratory determines that it cannot complete testing or obtain a valid drug test result.

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.

Non-Medical Use of a Drug: The use of a prescription drug, whether obtained by prescription or otherwise, other than in the manner or for the time period prescribed, or by a person for whom the drug was not prescribed.

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. A sample 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.

In addition, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR parts 160 and 164, Subparts A and E, is 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);

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

(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 13.5;

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

(11) Admit to the collector or MRO that you have adulterated or (for urine) 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, the collector must terminate that portion of the collection process and take action as described in Section 8.9; immediately notify 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, document the refusal on the Federal CCF, sign and date the Federal CCF, and send 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 opiates, 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 (other than the drugs listed in Section 3.1, or when used pursuant to a valid prescription or when used as otherwise authorized by law). 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 (ng/mL)	Confirmatory test analyte	Confirmatory test cutoff concentration (ng/mL)
Marijuana (THCA) [1]	50	THCA	15
Benzoylecgonine	150	Benzoylecgonine	100
Codeine/Morphine	[2] 2000	Codeine	2000
		Morphine	2000
Hydrocodone/Hydromorphone	[2] 300	Hydrocodone	100
		Hydromorphone	100
Oxycodone/Oxymorphone	[2] 100	Oxycodone	50
		Oxymorphone	50
6-Acetylmorphine	10	6-Acetylmorphine	10
Phencyclidine	25	Phencyclidine	25
Amphetamine/Methamphetamine	[2] 500	Amphetamine	250
		Methamphetamine	250
MDMA [3]/MDA [4]/MDEA [5]	[2] 500	MDMA [3]	250
		MDA [4]	250
		MDEA [5]	250

[1] Δ-9-Tetrahydrocannabinol-9-carboxylic acid (THCA)

[2] *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.

[3] Methylenedioxymethamphetamine (MDMA).

[4] Methylenedioxyamphetamine (MDA).

[5] Methylenedioxyethylamphetamine (MDEA).

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 as necessary to provide information that the MRO would use to report a verified drug test result (*e.g.,* d,l-stereoisomers determination for methamphetamine, tetrahydrocannabivarin, and other specimen validity tests using biomarkers). All tests must meet appropriate validation and quality control requirements.

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 or equal to 5 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 immunoassay or alternate technology 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.

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 his or her 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 he or she fulfills 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, 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 his or her training and provide that documentation to a federal agency when requested.

(d) An individual may not collect specimens for a federal agency until his or her 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 observer must be the same gender as the donor.

(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 his or her 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 8.11.

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 six 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 for a urine specimen?

(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 uses an incorrect form, 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 an incorrect form was used by the collector, 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 HHS-certified laboratory or IITF must wait at least 5 business days before the laboratory or IITF reports a rejected for testing result to the MRO and the MRO cancels the test.

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 observer for a direct observed collection (*i.e.,* as described in Section 8.10) must be the same gender as the donor. The monitor for a monitored collection (*i.e.,* as described in Section 8.11) must be the same gender as the donor, 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 he or she is 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 his or her wallet.

(2) The collector asks the donor to empty his or her pockets and display any items 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 his or her 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 or substitute the specimen, a direct observed collection procedure is used in accordance with Section 8.9. 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 his or her 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 his or her hands prior to urination. After washing his or her 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 his or her 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 his or her 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 8.11), 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 conduct an immediate collection under direct observation in accordance with Section 8.10. The collector must note the conduct and the fact that the collection was observed on the Federal CCF.

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 his or her 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 will 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.

(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 will forward both specimens (*i.e.,* from the first and second collections) to an HHS-certified laboratory for testing and records a comment on the Federal CCF.

(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. 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 he or she is unable to provide a urine specimen?

(a) If the donor states that he or she is 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 his or her 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 he or she 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 he or she is 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. 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?

No, unless 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 him or her. 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 his or her 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. The collector must also send a copy of the Federal CCF to the HHS-certified laboratory or IITF.

(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;

(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);

(3) The collector observes conduct by the donor that indicates a possible attempt to adulterate or substitute the specimen; or

(4) The collector observed materials brought by the donor to the collection site for the purpose of adulterating, substituting, or diluting the specimen.

(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 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 must be the same gender as the donor with no exception to this requirement. If there is no collector available of the same gender as the donor, 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.

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:

(a) The observer enters the restroom with the donor;

(b) 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);

(c) The observer must not touch or handle the collection container unless the observer is also serving as the collector;

(d) After the donor has completed urinating into the collection container:

(1) If the same person serves as the observer and collector, he or she may receive the collection container from the donor while they are both in the restroom;

(2) 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.

(e) 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

(f) 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 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, he or she 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 less than 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 he or she satisfies the following criteria:

(1) Has experience and an educational background similar to that required for either the responsible person or the certifying scientist as described in Subpart K for an HHS-certified laboratory or as a responsible technician 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 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 he or she is 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 specimen validity test result must be based on performing an initial specimen validity test on one aliquot and a second or confirmatory 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.

(4) 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) 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 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 one 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 one-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 two years. The laboratory 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 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 two-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 his or her 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 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 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 he or she is 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 than 1.003) or dilute (equal to or greater than 1.002 and less than 1.003). 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 his or her 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 and nonmedical use of prescription 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, 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 and/or train physicians as MROs for federal workplace drug testing programs must submit their qualifications and, if applicable, a sample examination. Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, the course syllabus and materials, documentation that the continuing education courses are accredited by a professional organization, and, if applicable, the delivery method and content of the examination. Each approved MRO training/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;

(5) Procedures for interpretation, review (*e.g.,* donor interview for legitimate medical explanations), and reporting of results specified by any federal agency for which the individual may serve as an MRO; and

(6) Training in Substance Abuse including information about how to discuss substance misuse and abuse, and how individuals that test positive can access services.

(b) Nationally recognized entities or subspecialty boards that train or certify physicians as MROs should make the MROs aware of prevention and treatment opportunities for individuals after testing positive.

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 (g) 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 (g) 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 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 Section 13.5(b)(1) or (2) for the recollected specimen.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a positive result to the agency. If the laboratory also reports that the urine specimen is dilute, the MRO may choose not to report the dilute result.

(e) When the HHS-certified laboratory reports a positive result for opiates for the primary (A) urine specimen, the MRO must determine if there is clinical evidence (in addition to the test result) of illegal use of any opium, or opiates, listed in Schedule I or II of the Controlled Substances Act. However, this requirement does not apply if the laboratory confirms the presence of 6-acetylmorphine (*i.e.,* the presence of this metabolite is proof of heroin use) or the morphine or codeine concentration is equal to or greater than 15,000 ng/mL and the donor does not present a legitimate medical explanation for the presence of morphine or codeine at or above this concentration. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

(f) When an 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.

(g) 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 Section 13.5(a) through (f).

(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).

(h) 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.

(i) 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, if ever. 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 genitor-urinary 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.

Section 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 him or her 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 his or her 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 he or she 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 verbally request 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 verbal request after being informed of the result by the MRO. The MRO must document in his or her 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 official responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(g) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and substituted.* The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [(specify drug(s)]). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and found that the specimen was substituted. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(h) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and not adulterated or substituted.* The MRO reports a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(i) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs,*

and invalid result. The MRO reports to the agency a reconfirmed result [specify drug(s)] and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and reported an invalid result. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(j) *Failed to reconfirm substitution or adulteration.* The MRO reports to the agency a failed to reconfirm result (specify adulterant or not substituted) and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

(k) *Failed to reconfirm a single or all drug positive results and reconfirmed an adulterated or substituted result.* The MRO reports to the agency a reconfirmed result (adulterated or substituted) and a failed to reconfirm result [specify drug(s)]. The MRO tells the agency that it may take action based on the reconfirmed result (adulterated or substituted) although Laboratory B failed to reconfirm the drug(s) result.

(l) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterated or substituted result.* The MRO reports to the agency a failed to reconfirm result [specify drug(s) and specify adulterant or substituted] and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

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

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

(o) *Failed to reconfirm an adulterated result and failed to reconfirm a substituted result.* The MRO reports to the agency a failed to reconfirm result [(specify adulterant) and not substituted] and cancels both tests. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

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

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

Section 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 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 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; or

(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.

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 are considered insignificant and 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 SSN;

(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 he or she 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 are considered insignificant and should not cause an MRO to cancel a test:

(1) The testing laboratory or IITF fails to indicate the correct name and address in the results section when a different laboratory or IITF name and address is printed at the top of the Federal CCF;

(2) The accessioner fails to print his or her name;

(3) The certifying scientist or certifying technician fails to print his or her 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 are considered insignificant only when they 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 he or she 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 his or her employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Section 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 his or her discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) *Time and Place of 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 his or her employees or consultants in conducting

the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

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

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

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

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

Section 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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