



Billing Code: 4162-20-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Chapter I

#### Mandatory Guidelines for Federal Workplace Drug Testing Programs

**AGENCY:** Substance Abuse and Mental Health Services Administration (SAMHSA), HHS.

**ACTION:** Notification of mandatory guidelines.

**SUMMARY:** The Department of Health and Human Services (“HHS” or “Department”) is proposing to establish scientific and technical guidelines for the inclusion of hair specimens in the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines).

**DATES:** Submit comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

**ADDRESSES:** In commenting, please refer to file code [SAMHSA-2020-0001]. 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: SAMHSA, Center for Substance Abuse Prevention (CSAP), Division of Workplace Programs (DWP), 5600 Fishers Lane, Room 16N02, 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: SAMHSA, CSAP, DWP, 5600 Fishers Lane, Room 16N02, Rockville, MD 20857.

•*By hand or courier.* You may deliver your written comments by hand or courier to the following address prior to the close of the comment period: SAMHSA, CSAP, DWP, 5600 Fishers Lane, Room 16N02, Rockville, MD 20857. If you intend to deliver your comments to the Rockville address, please call (240) 276-2600 in advance to schedule your arrival with one of our staff members. Because access to the SAMHSA building is secure, persons without federal government identification are encouraged to schedule their delivery or to leave comments with the security guard at the front desk located in the main lobby of the building.

All comments received before the close of the comment period will be 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 the comment. SAMHSA will post all comments before the close of the comment period on the following website:

<http://www.regulations.gov>. Use the website's search function to view the associated 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 SAMHSA, CSAP, DWP, 5600 Fishers Lane, Rockville, MD 20857, Monday through Friday of each week, excluding federal holidays, from 8:30 a.m. to 4:00 p.m. To schedule an appointment to view public comments, please call (240) 276-2600.

**FOR FURTHER INFORMATION, CONTACT:** Eugene D. Hayes, PhD, MBA, SAMHSA, CSAP, DWP; 5600 Fishers Lane, Room 16N02, Rockville, MD 20857, by telephone (240) 276-1459 or by e-mail: [Eugene.Hayes@samhsa.hhs.gov](mailto:Eugene.Hayes@samhsa.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Executive Summary**

This notice of proposed Mandatory Guidelines for Federal Workplace Drug Testing

Programs using Hair (HMG) will allow federal executive branch agencies to collect and test a hair specimen as part of their drug testing programs with the limitation that hair specimens be used for pre-employment (i.e., for applicants applying for federal testing designated positions) and random testing. A federal agency choosing to test hair specimens must authorize collection and testing of at least one other specimen type (e.g., urine or oral fluid) that is authorized under the Mandatory Guidelines for Federal Workplace Drug Testing Programs, and provide procedures whereby the alternate specimen is used in the event that a donor is unable to provide a sufficient amount of hair for faith-based or medical reasons, or due to an insufficient amount or length of hair. The proposed HMG require collection of an alternate authorized drug testing specimen in addition to the hair specimen, either simultaneously (i.e., at the same collection event) or when directed by the Medical Review Officer (MRO) after review and verification of laboratory-reported results for the hair specimen. This alternate specimen would be tested and reported in place of a donor's positive hair specimen only in certain circumstances, as described below.

These proposed HMG establish standards and technical requirements for hair collection and collection materials, initial hair drug test analytes and methods, confirmatory hair drug test analytes and methods, processes for review by an MRO, standards for certification of laboratories engaged in hair drug testing for federal agencies' drug-free workplace programs, and requirements for federal agency actions that are covered by these Guidelines. The HMG provide flexibility for federal agency workplace drug testing programs to address testing needs by allowing hair as an alternative specimen type.

The Department of Health and Human Services, pursuant to the Department's authority under Section 503 of Public Law 100-71, 5 U.S.C. Section 7301, and Executive Order No.

12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in drug testing for federal agencies.

### **Summary of the Major Provisions of the Proposed HMG**

The promulgation of the HMG allows federal agencies to collect and test hair specimens in their workplace drug testing programs. The collection process provides that the specimen will be collected by a trained collector under direct observation. The HMG collection procedure requires that a single hair specimen be obtained from the donor's head and divided into two specimens (A and B). The collector places the A and B specimens into separate specimen collection containers. Unlike the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG), the HMG do not allow Instrumented Initial Test Facilities (IITFs), primarily because of the limited amount of hair collected from the donor.

The Department is proposing that an alternate authorized drug testing specimen be collected (i.e., simultaneously collected or collected and tested at the direction of the MRO after verification of a positive hair test result). As described in greater detail below, this two-test approach is intended to protect federal workers from issues that have been identified as limitations of hair testing, and related legal deficiencies identified in Jones v. City of Boston, 845 F.3d 28 (1st Cir. 2016) and Thompson v. Civil Service Com'n, 90 Mass.App.Ct. 462 (Oct. 7, 2016). Both cases indicate that an employment action taken on the basis of a positive hair test alone, without other corroborating evidence, may be vulnerable to legal challenge. The Department is specifically requesting comments, including support from recent peer-reviewed scientific literature, on advances in the science of hair testing that adequately address these limitations and elucidate the

extent to which hair color, external contamination and other factors (e.g., hair treatments, hygiene) will affect hair tests and the interpretation of hair drug test results. The Department will continue to monitor the science of hair testing and will carefully review peer-reviewed literature and other valid scientific information submitted by federal agencies and the public for scientific support of hair testing. Based on this evaluation, the Department will decide whether performance standards can be established to mitigate identified limitations and obviate the requirement to collect an alternate authorized specimen. The Department is also soliciting public comment on the potential added burden to federal agencies and specimen donors should an alternate specimen be necessary. As noted under *Executive Orders 13563 and 12866* in the Regulatory Impact and Notices section of this Notice, the Department does not find these proposed mandatory guidelines to be a significant burden for federal agencies or incur a significant cost. In addition, a federal agency is not required to adopt hair testing in their Drug-free Workplace Programs. However, comments provided by the public on the subject of potential added burden could be useful to federal agencies deciding whether to test hair in addition to other specimen types in their federal workplace drug testing programs.

In addition, the Department is specifically requesting comments, including support from the recent scientific literature, on whether hair tests that are positive for the marijuana analyte, delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA), should be excluded from the requirement to test an alternate authorized specimen (i.e., MROs would report verified positive THCA hair results to the federal agency).

## **Costs and Benefits**

Using data obtained from the Federal Workplace Drug Testing Programs and HHS-certified laboratories, the Department estimates that 275,000 urine specimens are tested annually by federal agencies. HHS projects that approximately 1% (or 2,750) of the 275,000 specimens tested per year will be hair specimens and 89% (or 244,750) will be urine specimens, with the remaining approximately 10% being oral fluid specimens (27,500). The approximate annual numbers of regulated specimens for the Department of Transportation (DOT) and the Nuclear Regulatory Commission (NRC) are 6.1 million and 150,000, respectively. It should be noted that the NRC-related information in this notice only 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). Should DOT and NRC allow hair testing in their regulated workplace programs, the estimated annual numbers of specimens for DOT would be 50% (3,050,000) hair specimens for pre-employment testing, 7% (427,000) oral fluid specimens, and 43% (2,623,000) urine specimens; and numbers of specimens for NRC would be 10% (15,000) hair, 7% (10,500) oral fluid, and 83% (124,500) urine. These projected numbers are based on existing annual pre-employment testing in the regulated industries and hair testing currently conducted in the private sector for commercial drivers.

An HHS-certified laboratory may group analytes for initial testing as shown in the table in Section 3.4 (i.e., use a single test for two or more analytes that are in the same drug class and have the same initial test cutoff), or may use multiple tests. In Section 3.4, the Department is proposing criteria for calibrating initial tests for grouped analytes and is specifying the minimum cross-reactivity of the immunoassay to the non-target analytes(s) within the group (i.e., those not used for calibration). An immunoassay manufacturer may incur costs if they choose to alter their

existing product and resubmit the immunoassay for Food and Drug Administration (FDA) clearance.

Costs associated with hair testing are greater than for urine or oral fluid testing based on information from commercial laboratories currently testing hair specimens. Costs of initial testing will not pose a significant increase for laboratories currently testing hair if the laboratory can use currently available immunoassay testing kits cleared by the FDA for hair testing. All confirmatory testing can be achieved using commercially available instrumentation. Prior to testing regulated hair specimens, laboratories must be specifically certified for hair testing by the Department through the National Laboratory Certification Program (NLCP). Laboratories choosing to apply for HHS certification may incur additional costs associated with adding the matrix and/or validating and implementing assays using different cutoffs and analytes. The estimated laboratory cost to complete and submit a certification application is \$3,000 and the estimated cost for the Department to process the application is \$10,200. The initial HHS hair testing certification includes the requirement for the laboratory to demonstrate that their performance meets Guidelines analytical requirements by testing three (3) sets of performance testing (PT) hair samples. The Department will provide the three groups of PT samples through the NLCP at no cost to laboratories participating in the NLCP Pilot Proficiency Testing Program for hair. This pilot PT program is described in the History and Proposed Changes to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs section below. Based on estimated fees charged for hair specimen testing, laboratory costs to conduct the PT testing would range from \$3,000 to \$3,375 for each applicant laboratory.

Based on information from current commercial hair testing laboratories, once hair testing is implemented, the average cost per specimen will range from \$40.00 to \$45.00. Information

from current HHS-certified laboratories indicates that the average cost of testing a urine specimen ranges from approximately \$6.50 to \$11.00 per specimen. Once hair testing is implemented, the estimated cost per specimen for each initial test will range from \$2.50 to \$6.00 including costs for initial test reagents and sample preparation (e.g., washing, digestion). Estimated additional costs for each confirmatory test will range from \$20.00 to \$35.00, primarily due to the costs of sample preparation (including decontamination procedures as defined in Section 1.5) and analysis. Therefore, the estimated cost of a commercial hair testing laboratory using both initial testing with confirmation will range from \$40.00 to \$80.00 per specimen. These costs for the laboratories or federal agencies choosing to use hair in their drug testing programs will be incorporated into the overall testing cost for the federal agency submitting the specimen to the laboratory.

As described earlier, a federal agency choosing to use hair for pre-employment and/or random testing may collect an alternate specimen type at the same collection event or later, at the direction of the MRO. Agencies choosing not to collect an alternate specimen at the same time as hair would save upfront collection and handling costs, and would pay for alternate specimen collection and testing only when directed by the MRO (i.e., when the donor has no legitimate medical explanation for a positive hair test, when the hair specimen was reported by the laboratory as invalid or rejected, or when the donor requests testing of the split specimen and the split specimen cannot be tested). A federal agency that chooses to collect an alternate specimen type at the same time as hair for a pre-employment or random test would incur additional upfront costs for collection and handling of the alternate specimen, but would only pay for testing of those alternate specimens when directed by the MRO, and would save time on recollection in

those instances. Agencies choosing to use hair in their drug testing programs may also incur some costs for training of federal employees such as drug program coordinators.

As explained in more detail below, hair testing potentially offers several benefits when compared to urine, including directly observed collections, ease of transport and storage, increased specimen stability, and a longer window of drug detection. The Department believes these benefits justify pursuing hair testing in federal workplace programs.

## **Background**

The Department of Health and Human Services, pursuant to the Department's authority under Section 503 of Public Law 100-71, 5 U.S.C. Section 7301, and Executive Order No. 12564, establishes the scientific and technical guidelines for federal workplace drug testing programs and establishes standards for certification of laboratories engaged in drug testing for federal agencies. As required, HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Guidelines) in the Federal Register [FR] on April 11, 1988 [53 FR 11979]. The Substance Abuse and Mental Health Services Administration (SAMHSA) subsequently revised the Guidelines on June 9, 1994 [59 FR 29908], September 30, 1997 [62 FR 51118], November 13, 1998 [63 FR 63483], April 13, 2004 [69 FR 19644], and November 25, 2008 [73 FR 71858]. SAMHSA published the revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) on January 23, 2017 [82 FR 7920] and published the proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) on May 15, 2015 [80 FR 28054].

On December 4, 2015, the President signed the Fixing America's Surface Transportation (FAST) Act, which required HHS to "issue scientific and technical guidance for hair testing as a

method of detecting the use of a controlled substance for purposes of section 31306 of title 49, United States Code.” Public Law 114–94, section 5402(b).

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

A focus of the HHS mission is to maintain the integrity and ensure the quality of federal drug-free workplace programs by a commitment to identify and mandate the use of the most accurate, reliable drug tests and testing methods available. To accomplish these goals, the Department implements ongoing scientific reviews and program collaboration with federal regulators, researchers, drug testing laboratories, and public and private sector employers. As the use of alternative specimens (other than urine) and new analytical test technologies increased over the previous years, the Department, through SAMHSA’s Center for Substance Abuse and Prevention (CSAP) Drug Testing Advisory Board (DTAB), responded by reviewing new technologies and assessing drug testing using other specimen types, such as oral fluid (saliva), hair, and sweat for possible use in federal agency workplace testing programs.

The proposed HMG are the result of a directed Departmental assessment that began in 1997 with a 3-day scientific meeting of the DTAB. During that public meeting, DTAB members discussed drug testing using alternative specimens and the use of new and developing drug testing technologies with potential applicability to workplace drug testing programs. Following the initial meeting, members of the DTAB continued to review and analyze all available information on alternative specimens and testing technologies. These efforts identified specific scientific, administrative, and procedural requirements necessary for a comprehensive federal workplace drug testing program that included alternative specimens and technologies.

The first working draft of new Guidelines that included the testing of alternative specimens including hair was presented at the June 2000 DTAB meeting. These “work-in-progress” draft Guidelines were placed on the SAMHSA website and the public was invited to submit information and comments to improve the draft document and further SAMHSA’s knowledge of the analysis of alternative specimens. Twenty-eight separate comments were received. Those comments were summarized, incorporated into the draft Guidelines and the updated document was presented at the DTAB meeting in September 2000. Again, comments were requested from all interested parties. At the December 2000 DTAB meeting, a third working draft of the Guidelines was presented that included public comments resulting from the September meeting. SAMHSA, in consultation with subject matter experts including researchers and drug testing industry professionals, continued to assess the scientific supportability of testing alternative specimens in the Drug-Free Workplace Program (DFWP). Areas of specimen collection, specimen validity, initial testing, confirmation, medical review, and performance testing were examined to evaluate the integrity, reliability, and defensibility of drug testing using alternate matrices.

To assess laboratory performance and utility of alternative specimen testing in federal drug-free workplace programs, the Department initiated a voluntary pilot proficiency testing (PT) program for hair. The Hair Pilot PT program ran from 2000 to 2007 and resumed in 2014 based on DTAB’s recommendation. The program was developed, and the samples were prepared using government funding. This pilot PT program was established to determine if it was possible to prepare stable and accurate hair PT samples, and to develop criteria for the PT program. Participating laboratories used their established procedures to test the PT samples and shared their results with SAMHSA. Based on data obtained from the pilot PT program, it

appeared that valid and stable hair PT samples could be prepared. The results of the pilot PT program showed that the technology used by participant laboratories for confirmatory testing could meet requirements for sensitivity and specificity. Also, inter-laboratory precision improved during the pilot PT program for most drug analytes.

Based on the pilot PT results from 2000 to 2003 and input from subject matter experts for all alternate matrices, the Department issued a Federal Register notice [69 FR 19673] on April 13, 2004 proposing inclusion of oral fluid, hair, and sweat specimens in federal workplace drug testing programs. Following publication of the proposed Guidelines, the public and federal agencies identified significant scientific, legal, and public policy concerns about the use of the alternative specimens. As a result of the review, the Department issued a Final Notice of Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs on November 25, 2008 [73 FR 71858] that concluded the scientific, technical, and legal information for the testing of alternative specimens (oral fluid, hair, and sweat) was insufficient to include these specimens in the federal programs at that time. As noted above, the purposes of the Hair Pilot PT Program were to determine if it was possible to prepare stable and accurate hair PT samples, and to develop criteria for the PT program. Many of the issues raised by commenters (e.g., concerns over external contamination) were not addressed in the pilot PT program. The Department committed to monitoring developments in alternative specimen testing and has continued to do so since 2008.

The complexity of responses to the 2004 notice made it clear that if the Department were to subsequently authorize alternative specimens for the Mandatory Guidelines for Federal Workplace Drug Testing Programs, each specimen matrix would need a separate set of Guidelines. Additionally, the Department proposed to stagger the timeline for the review and

potential incorporation of alternative specimens, and to begin with oral fluid. The decision to begin with oral fluid was supported by fewer legal and policy concerns, and current peer-reviewed literature that existed with oral fluid. The Department published the proposed OFMG on May 15, 2015 [80 FR 28054].

Since 2004, methodology developed for non-regulated private sector workplace alternate matrix testing has evolved, leading to enhanced analytical sensitivity and specificity for hair testing. The scientific literature for hair testing and interpretation of results has grown. Many non-regulated private sector organizations have incorporated hair testing into their workplace drug testing programs.

At the open session of the January 2012 DTAB meeting, SAMHSA shared updated information on hair testing with DTAB and the public. During the meeting, experts made scientific presentations concerning hair specimens for workplace drug testing, including physiological composition of hair, tested drugs and cutoffs, wash procedures, decontamination procedures, hair testing results and best practices in laboratory methodologies (initial and confirmatory testing). Wash procedures consisted of a rinse with organic solvents to remove oils and residue on the hair prior to initial testing. Decontamination procedures were more extensive methods (e.g., multiple organic and aqueous washes) designed to remove drug present due to environmental contamination prior to confirmatory testing.

In May 2015, SAMHSA solicited comments regarding the science and practice of hair testing via a Request for Information (RFI) [80 FR 30689], and subsequently extended the due date for comments [80 FR 34921]. The notice requested comments from the public and industry stakeholders regarding a variety of hair testing issues (e.g., specimens, collection, specimen preparation, analytes/cutoffs, specimen validity, and testing methods). The RFI gave the public

and industry stakeholders an opportunity to provide information and comments for consideration during the development of the proposed Guidelines for hair testing. The Department received 37 comments from drug testing laboratories, MROs, manufacturers, drug testing industry associations, and the public. All submitted comments were reviewed and were presented to the DTAB members for consideration during SAMHSA's continuing assessment of hair as an alternative specimen.

Following the August 2015 meeting of the DTAB, the Board submitted the following recommendation to SAMHSA: "Based on the review of the science, DTAB recommends that SAMHSA pursue hair as an alternative specimen in the Mandatory Guidelines for Federal Workplace Drug Testing Programs, including performance standards that sufficiently address external contamination and hair color impact."

Thereafter, SAMHSA continued to critically review the state-of-the-science and technology for forensic drug testing of hair and the utility of hair as a specimen in federal workplace drug testing programs. SAMHSA also consulted subject matter experts with expertise in biochemistry, toxicology, laboratory operations, MRO practices and workplace policy. The input of these experts was considered along with Department officials at quarterly DTAB meetings.

### **Rationale for Pursuing Hair Testing in the Mandatory Guidelines for Federal Workplace Drug Testing Programs**

Hair has been used in non-regulated testing programs including the transportation and casino industries (i.e., for pre-employment and random testing), and other situations when longer detection periods may be needed. Corresponding developments have led to analytical

technologies that provide the needed sensitivity and accuracy for testing hair specimens at the levels required to determine a positive test result, as demonstrated in the Hair Pilot PT Program.

Hair and urine pre-employment test results have been shown to be somewhat dissimilar because each matrix has a different time window of drug detection. Typically, positivity rates are higher in hair due to hair's longer window of detection.<sup>1</sup> Hair is easily collected, transported and stored, and is also more difficult to substitute and/or adulterate than urine since collections are performed under direct observation. Separation, detection, and identification techniques have improved such that scientists are now able to detect and quantify drugs and/or metabolites in hair at picogram per milligram (pg/mg) concentrations. A forensic workplace testing program for hair can be modeled after the existing federal program: specimens are first tested using an initial test (e.g., immunoassay or an alternate technology), and specimens with positive initial test results are confirmed using mass spectrometric identification.

#### *What is hair?*

Unlike urine and oral fluid, hair is a solid, heterogenous matrix that is exposed to the environment. Hair color and structure differ by individual and within the same individual. Hair consists of a hair follicle and hair shaft. At the base of the follicle (bulb) are highly vascularized matrix cells. As matrix cells in the dermis of the skin move outward during growth, they form layers of a hair shaft that include the outer protectant cuticle, central cortex and inner medulla. Hair grows in three stages: about 85 percent of hair follicles in the posterior vertex region of the head are in active growth phase (anagen), while the others are in a transition phase (catagen) before the resting phase (telogen). At the vertex region of the scalp, the average growth rate of hair is about 0.4 millimeters per day or approximately 1 centimeter per month.<sup>2-5</sup> The Department is proposing to permit agencies as part of their federal drug-free workplace programs

to test head hair specimens between 0.5 and 1.0 inches (approximately 2.5 cm) long, representing a detection time period of approximately 30-60 days, for pre-employment and random testing.

*What is the mechanism of drug disposition in hair?*

Drugs and drug metabolites may be incorporated into hair by several pathways.<sup>6-10</sup> As drugs and their metabolites travel through the body in blood, they diffuse from the bloodstream into the base of the hair follicle. The amount of drug in the hair is related to the drug concentration in the blood when the hair was formed and depends on the chemical structure of the drug or metabolite. Drugs and/or metabolites may also be incorporated into hair via secretions of the sweat glands and sebaceous glands, which are in close contact with hair as it develops and emerges from the skin. Sweat and sebum can deposit drugs and/or metabolites on the hair shaft that are absorbed into the hair during and after its formation. As hair grows and emerges from the skin, the location of drug and metabolite in the hair shaft can be used to generally assess the timeframe of drug use. However, sweat can contribute to drug and/or metabolite incorporation across the entire length of the hair. Therefore, segmental analysis (i.e., analysis of multiple short longitudinal segments to determine a time profile of use) must be done with caution and is not recommended for workplace drug testing.<sup>6-10</sup>

*What are some of the known issues with drug testing using hair?*

Numerous factors influence the amount of drug incorporated into hair (e.g., drug dose, length of exposure, physical and chemical properties of hair, and factors associated with the chemical structure of the drug). Of concern are environmental contamination, the impact of natural hair color on drug incorporation, and the effects of hygiene and cosmetic hair treatments. These issues may confound the results and interpretation of hair tests as explained in more detail below.

*Environmental contamination and decontamination*

Concerns have been raised over environmental contamination of hair.<sup>2, 4, 11-15</sup> There can be opportunities for hair to be contaminated from drugs in the environment.<sup>14</sup> For example, a donor may claim they tested positive for a drug because they were in the presence of others using the drug, or were in an environment in which drug particulates were in the air or on contaminated surfaces.

Effective decontamination procedures are a key issue in hair testing, because the inability to rule out external contamination presents legal challenges. In one relevant case, a state court upheld a state commission's finding that hair testing did not adequately rule out the possibility of a false positive drug test resulting from external contamination such that an employer could rely on hair testing as the sole basis for an employee's termination. See Thompson v. Civil Service Com'n, 90 Mass.App.Ct. 462 (Oct. 7, 2016). Notably, the court in Thompson v. Civil Service Com'n stated the following regarding the reliability of hair testing:

A threshold issue before the commission was the scientific reliability of the hair testing, and its ability to distinguish between voluntary ingestion and environmental exposure.

The ten officers and the department held competing views as to whether the testing alone was reliable enough to establish just cause supporting the officers' terminations ....

Ultimately, the commission found that the hair testing methodology was not sufficiently reliable to be the sole basis for an officer's termination, concluding that "[a] reported positive test result ... is not necessarily conclusive of ingestion and, depending on the preponderance of evidence in a particular case, may or may not justify termination or other appropriate discipline of a tenured [department] officer." Nonetheless, the commission found that hair testing is an appropriate tool to enforce the department's

substance abuse policy and that hair test results could be used as some evidence of drug use.

Id. at 465 - 466 (internal citations omitted) (emphasis added). The Thompson court also stated that:

Here, after an exhaustive inquiry on the scientific reliability of the . . . hair testing methodology, the commission reached the conclusion that a positive test was not conclusive on the question of voluntary ingestion, as the positive test may also represent sample contamination by environmental exposure. In other words, the commission found that the risk of a false positive test was great enough to require additional evidence to terminate an officer for just cause. That conclusion is well supported by the record, which includes evidence of shifting cutoff levels through the years since the testing had been implemented, a lack of general acceptance in the scientific and law enforcement communities, and a lack of universally recognized industry standards.

Id. at 467 - 468. The Thompson court went on to hold that, “the evidence amply supported the commission decision.” Id. at 470.

Many laboratories use wash procedures to remove oils and residue on the hair prior to initial testing. Approximately 90% of specimens are negative upon initial testing, and are subsequently reported negative.<sup>16</sup> Depending upon the analyte, external contamination is of the most concern for the remaining 10% of hair specimens submitted for confirmation testing. Therefore, some laboratories use decontamination procedures designed to remove drug present due to environmental contamination prior to performing confirmatory testing.

Decontamination procedures that adequately remove externally deposited drug and drug metabolites prior to confirmation testing are the subject of much scientific inquiry. It is likely that

hair from individuals who use drugs is also externally contaminated.<sup>6,17</sup> In other words, drugs and some drug metabolites (e.g., benzoylecgonine) detected during testing of a drug user's hair can be from drug ingestion and/or external contamination. This is mainly because of drug users' exposure to drugs in their environment as well as drugs and/or metabolites in the individual's own sweat and sebum coming into contact with their hair.

A variety of decontamination procedures have been reported in the literature with varying effectiveness.<sup>11-13</sup> Decontamination procedures employing multiple washes with analysis of the final wash solution may be a useful tool to identify external contamination.<sup>11,12,15</sup> However, it has been shown that some externally deposited drug may remain, even after extensive washing.<sup>11</sup> To address this issue, some laboratories have developed procedures employing a wash "factor" for some drugs (e.g., cocaine), whereby the concentration of the final wash solution is multiplied by a factor to simulate the effect of additional washes and the product is subtracted from the concentration of the drug measured in the hair.<sup>12</sup> The factor used in these calculations varies and is dependent upon the drug and the laboratory. For some drugs (e.g., cocaine), the factor alone was not found to be effective at discriminating external contamination from drug use, so laboratories have employed additional criteria (e.g., presence of multiple metabolites, metabolite to parent drug ratios).<sup>12</sup> One study proposed using a wash-to-hair concentration ratio to designate results as either indicative of drug use, indicative of drug use in combination with external contamination or indicative that the source of the drug was external contamination and inconclusive as to drug use.<sup>15</sup> In that study, 11% of all test results had ratios indicative of external contamination and inconclusive for drug use. While the use of wash factors or ratios has shown promise in mitigating the effect of external contamination on hair drug testing, the Department is not proposing that such procedures be used in federal agency testing programs, in part because of the difficulty in

development of performance testing samples to assess their effectiveness in the certified laboratories.

Laboratories that have researched the validity and efficacy of decontamination procedures recommend utilizing aqueous and organic solvents in these decontamination procedures.<sup>11</sup> Both the Society of Hair Testing and United Nations Office of Drugs and Crime recommend a hair decontamination procedure that includes both an organic and aqueous washing step, whereas the European Workplace Drug Testing Society recommends an organic and/or aqueous wash. The proposed inclusion of both organic and aqueous solvent wash steps is in accordance with current peer reviewed literature. As opposed to requiring a single method for decontamination to be used by all testing laboratories, SAMHSA proposes that minimum performance standards be established for the efficacy of decontamination procedures that are followed in all HHS-certified hair drug testing laboratories.

However, although there is scientific evidence that suggests that wash and decontamination procedures may be effective in ensuring that the outer protectant cuticle and inner medulla portions of the hair shaft are decontaminated, there are no published studies that prove that external contamination cannot reach the central cortex of the hair. Further, one published study concludes that drug-contaminated hair when washed with water and methanol is indistinguishable from drug user hair because the drug migrates into the cortex and medulla due to swelling effects of these solvents.<sup>13</sup> If this issue is not addressed, a donor may claim that, even if hair is washed and decontaminated in accordance with the most vigorous washing methodologies utilized by laboratories, a hair test result could remain influenced by contamination and potentially result in a false positive test. Therefore, more time and research are needed for the development of performance standards that address this and other issues. The Department is currently in the

process of developing performance standards for decontamination of hair and is seeking public comment on what such standards should be and how performance test samples could be developed to assess these standards. When the decontamination performance standards are fully developed, it is the Department's intention to add them to the HMG through the notice and comment process rather than delay publishing of the proposed HMG until such standards are developed. Compliance with these mandatory minimum standards, when fully developed and included in these Guidelines, will be evaluated through the NLCP Performance Testing (PT) program.

After relevant performance testing standards are developed, the HMG require laboratories to perform a valid and effective decontamination procedure prior to confirmatory drug testing in order to address the external contamination issue. The Department is requesting comments and information about decontamination procedures that remove drug present as a result of external contamination. All decontamination and test methods must meet the validation, quality control, and review requirements specified by the HMG. Furthermore, the NLCP Performance Testing (PT) program would challenge those methods using drug user hair, hair contaminated with drug analytes, hair subjected to cosmetic treatments, and blind quality controls. The laboratories will also be required to prepare decontamination controls that challenge their decontamination procedures and are analyzed with each confirmatory drug analysis. The Department is specifically requesting comments on the types of samples to be included in the hair PT program and procedures used to prepare decontamination controls.

#### *Identification of unique metabolites*

Identification of a unique drug metabolite would distinguish drug use from environmental contamination as long as strict criteria for defining a unique metabolite are established.<sup>11</sup> The proposed HMG define a unique metabolite as “a drug metabolite present in a hair specimen only

as a result of biotransformation following drug use” and which “does not occur as a contaminant in licit and illicit drug products and is not produced from the drug as an artifact.”

To date, only one unique metabolite (i.e., THCA) meets the above definition and has been included for the proposed drugs. However, while the use of a unique metabolite addresses the external contamination issue, the Department is not aware of any controlled dosing studies that demonstrate the lack of a hair color impact on THCA results. See additional discussion on the impact of hair color on hair test results below. Accordingly, the Department is requesting comments including support from the scientific literature on whether THCA positive hair tests can be excluded from the requirement to test an alternate authorized specimen (i.e., MROs would report verified positive THCA hair results to the federal agency).

The Department is also requesting information including, at a minimum, support from the scientific literature about unique metabolites that can be analyzed on a stand-alone basis for the other proposed drugs listed in Section 3.4. For example, one recent study analyzing opioids in hair indicates that unique glucuronide metabolites of opioid drugs may be reliably detected in hair.<sup>18</sup> In addition, although hydroxylated metabolites of cocaine and benzoylecgonine do not meet the Guidelines definition of a unique metabolite for hair, these analytes have been touted in the literature as being diagnostic of cocaine use when ratio criteria are applied to the quantitative results.<sup>12,19-22</sup> Hydroxy-metabolites of cocaine were originally thought to be unique metabolites as defined in the HMG, until these compounds were identified in street cocaine samples and found to be produced during hair treatment experiments.<sup>21,22</sup> More recently, hydroxy-metabolites of benzoylecgonine were identified in hair and thought to represent a new opportunity to reliably identify cocaine use.<sup>19-21</sup> However, these analytes also have been detected in a limited study of street cocaine samples, and were found to form and increase in

concentration over a period of eight weeks after contamination of seven subjects' hair with cocaine.<sup>20</sup> To compensate for these issues, researchers have proposed the use of ratios and criteria schemes (i.e., detection of multiple metabolites at or above proposed cutoff concentrations and within certain ratios to each other).<sup>20, 21</sup> These schemes require the analysis of cocaine and multiple hydroxylated metabolites to be effective, thereby increasing the costs of testing and the NLCP performance testing used to monitor the accuracy and reliability of laboratory results.

#### *Impact of hair color on hair test results*

The natural color of human hair ranges from shades of black, brown, red, yellow, gray and white. Hair color is controlled, in part, by the biochemistry of two major groups of melanin pigments. The eumelanins are black to brown and the pheomelanins are reddish in color.<sup>23</sup> The presence of eumelanin appears to be the major determinant of drug binding and incorporation of drug into the hair shaft. One of the postulated mechanisms for drug uptake in hair is ionic binding of drugs containing basic nitrogen moieties in their molecular structure (e.g., amphetamines, cocaine, opioids, and phencyclidine) with melanins.<sup>24</sup> Neutral and acidic drugs appear to bind to hair by other poorly understood means. Direct evidence of binding of various drugs with melanin and with human hair has been demonstrated.<sup>25-27</sup> In one *in vitro* study, cocaine binding experiments with black, brown, and blonde human hair demonstrated up to 34-fold differences in cocaine binding with dark hair as compared to blonde hair.<sup>26</sup> These findings have raised concerns that selective drug binding with the wide variation of color pigments distributed amongst the population may introduce bias in drug test results.

A number of laboratory animal studies indicate that some drugs are differentially incorporated into hair based on color. Following administration of the same dose, higher drug

concentrations were demonstrated in dark hair versus light hair in animals administered amphetamine<sup>28</sup>, methamphetamine<sup>29</sup>, methadone<sup>30</sup>, and phencyclidine.<sup>31</sup> Several controlled dosing studies in humans are consistent with the findings in animals.

In one human study, administration of the same dose of isotopically labeled cocaine to Caucasians (hair color primarily brown) and non-Caucasians (hair color primarily black) resulted in approximately 2.7 times more cocaine being incorporated into non-Caucasian hair than Caucasian hair.<sup>32</sup> In another study, codeine was administered to male and female participants with black (Caucasians, non-Caucasian, American Indian, Hispanic, Asian), brown (Caucasians), blond (Caucasians) and red hair (Caucasians).<sup>33</sup> Codeine concentrations in black hair were seven-fold higher than those in brown hair and 14-15-fold higher than those in blond hair. Using the proposed confirmatory cutoff of 200 pg/mg, 100% of subjects with black hair and 50% subjects with brown hair in this study would have been reported as positive. In contrast, subjects with blond or red hair would have tested negative. The authors suggested a direct relationship between codeine concentration and melanin concentration in hair. In another study of codeine administration to participants with different hair colors, a strong correlation was observed between codeine concentrations in hair and melanin concentrations.<sup>34</sup>

Some of these investigators conducting controlled drug dosing studies measured melanin pigments as well as the amount of drug incorporation in hair and suggested that normalization of drug concentration to pigment content would effectively reduce potential bias in test results.<sup>33,34</sup>

However, it remains unclear how the effect of pigmentation differences on drug amount in hair translates to a broader population as a whole, given the many other sources of variability (e.g., individual differences in amount and frequency of drug use and rates of drug metabolism and disposition). Epidemiology studies have suggested no significant hair color impact exists for

THCA<sup>35</sup>, heroin, cocaine, and amphetamines.<sup>36</sup> The THCA result is consistent with studies of other acidic and neutral drugs and metabolites in hair. However, the Department is unaware of any controlled dosing studies that evaluated THCA in hair and therefore without this objective data the question of whether THCA exhibits a hair color impact remains. As noted earlier, the Department is requesting comments including support from the recent scientific literature on whether THCA positive hair tests should be excluded from the requirement to test an alternate authorized specimen (i.e., MROs would report verified positive THCA hair results to the federal agency). It is unknown for the other drugs whether the absence of an objective and scientific measure of hair color and differences in how hair color was categorized between these epidemiological and controlled human dosing studies played a role in the lack of concordance in results. Another study found that black arrestees tested positive for cocaine more often than white arrestees in both urine and hair.<sup>37</sup> The authors suggested that, given the consistency between self-reported cocaine use and test outcome, there was no bias in the hair or urine tests based on racial group. A recent prepublication article by researchers from the University of Arkansas was provided to the Department for review. Similar to the Mieczkowski studies referenced above, the article attempts to consider hair pigmentation difference by dividing donors into ethnic groups and comparing urine and hair specimen testing results. The authors suggest that ethnic groups are significantly different irrespective of testing procedure. As noted, the Department wishes to solicit feedback on scientific studies comparing drug results and hair color and results comparing urine to hair.

In addition, *in vitro* binding studies, animal studies, and controlled human dosing studies for certain drug classes (i.e., amphetamines, cocaine, opioids, and phencyclidine) provide scientific evidence that melanin pigments may influence the amount of drug incorporated into

hair. However, it is unclear whether this influence would lead to significant bias in different populations of workers undergoing drug tests, given variabilities described herein, that could be introduced into test results from other sources and within the time frame of 30-60 days based on a 0.5 to 1.0 inch hair test. The Department is requesting information, including support from the recent scientific literature to address the impact of hair color on drug test results.

The hair color impact/bias issue also presents legal challenges. It should be highlighted in this regard that the United States Court of Appeals for the First Circuit found that certain African-American police officers who were terminated from their positions on the basis of hair testing results were able to prove a “prima facie case of disparate impact under Title VII.” See Jones v. City of Boston, 752 F.3d 38, 60 (1st Cir. 2014).) The First Circuit reiterated this finding in a subsequent 2016 proceeding and remanded the matter to the district court for further proceedings on the remaining prongs of the disparate impact analysis. See Jones v. City of Boston, 845 F.3d 28 (1st Cir. 2016). The First Circuit held that:

[t]he record contains sufficient evidence from which a reasonable factfinder could conclude that hair testing plus a follow-up series of random urinalysis tests for those few officers who tested positive on the hair test would have been as accurate as the hair test alone at detecting the non-presence of cocaine metabolites while simultaneously yielding a smaller share of false positives in a manner that would have reduced the disparate impact of the hair test. We also think that, on the present record, a reasonable factfinder could conclude that the [Boston Police] Department in 2003 refused to adopt this alternative.

Jones v. City of Boston, 845 F.3d 28, 38 (1st Cir. 2016).

Thus, the First Circuit characterized “a follow-up series of random urinalysis tests” for officers who tested positive using hair as being just “as accurate as the hair test alone at detecting

the non-presence of cocaine metabolites while simultaneously yielding a smaller share of false positives in a manner that would have reduced the disparate impact of the hair test.” Id.

Accordingly, the Department is proposing to include testing using an alternate specimen when directed by the MRO for individuals who test positive on a hair test, unless the donor has a legitimate medical explanation for the positive test or the MRO has corroborating evidence to support the positive hair test (i.e., donor admission of illicit drug use). In addition, testing of an alternative matrix could also prove to be an effective measure to mitigate the external contamination issue because it would supply additional evidence to support an adverse action when premised on a positive drug test, which the Thompson court found to be needed when hair specimens are used for drug testing. As noted earlier, the Department is specifically requesting comments, including support from recent peer-reviewed scientific literature, on advances in the science of hair testing that may mitigate the requirement for an alternate authorized specimen in place of a donor’s positive hair specimen in certain circumstances. The Department is also seeking comments from the public on the potential for added burden should the alternate specimen requirement be necessary. Specifically, the Department is soliciting comments on potential burden that this approach could place on the federal agency employers and specimen donors. Information from the public could be useful to federal agencies evaluating hair testing as compared to using urine or oral fluid testing in their workplace drug testing programs.

#### *Effects of cosmetic hair treatments*

Hair treatments such as bleaching, straightening, relaxing, frequent washing, and vigorous brushing may; 1) decrease the hair concentrations of incorporated drug, 2) have effects that are drug, metabolite, target marker and profile dependent, and 3) because of the physical and chemical damage caused by these processes, they may increase the susceptibility of the hair to

environmental contamination.<sup>38-42</sup> The Department is proposing that each laboratory have a scientifically validated method to identify hair that has been damaged to the extent a drug test may be affected. One method for identification of damaged or porous hair has been published in the scientific literature but further information on this topic is needed.<sup>43</sup> Therefore, the Department is requesting information including, at a minimum, support from the scientific literature to address these issues. Examples of requested information might include published scientific studies, internal laboratory study procedures or protocols, or reviews conducted by outside stakeholders to identify damaged hair. The Department is also requesting comments on whether this testing should be performed routinely on all specimens, or only on certain specimens (e.g., based on initial test results). The Department is also seeking comment on the extent to which (based upon scientific studies) hair specimens can be impacted by hair treatments and whether such specimens should be reported as invalid and an alternate specimen be collected and tested.

*Rationale for hair for pre-employment and random testing*

The Department is proposing the use of hair for pre-employment and random drug testing. Because drugs/metabolites are not detected in hair for 5 to 7 days after ingestion, it is not an appropriate specimen to detect recent use. Thus, hair is not an appropriate specimen for post-accident and reasonable suspicion testing. The Department is requesting comments on whether hair may be used for follow-up or return to duty testing.

*How were analytes and cutoffs selected?*

The selection of analytes for testing was based on known drug disposition patterns in hair. Analytes for the regulated drugs tested in hair are marijuana metabolite (delta-9-tetrahydrocannabinol-9-carboxylic acid, THCA), cocaine (parent drug and metabolite, benzoylecgonine), phencyclidine (PCP), opioids (codeine, morphine, hydrocodone,

hydromorphone, oxycodone, oxymorphone), heroin metabolite (6-acetylmorphine, 6-AM), and amphetamines (amphetamine, methamphetamine, methylenedioxyamphetamine [MDMA], and methylenedioxyamphetamine [MDA]).

Cutoffs were based on those proposed by the Department in 2004 (69 FR 19673). The Department has added the same prescription opioids (i.e., hydrocodone, hydromorphone, oxycodone, and oxymorphone) specified in the UrMG and OFMG, with the same hair cutoffs as proposed for codeine and morphine. The codeine and morphine cutoffs are consistent with those recommended by the European Workplace Drug Testing Society and the Society of Hair Testing.<sup>44, 45</sup>

*Will there be specimen validity tests for hair?*

The Department is not aware of any objective methods in use to assess hair specimen validity (e.g., to distinguish synthetic from human hair or to identify hair that has been damaged to the extent a drug test result may be affected). As noted earlier, the Department is proposing that each laboratory use a validated method to identify damaged hair; therefore, the Department is seeking information on such methods and comments on whether all or only certain hair specimens should be subjected to such testing. The Department is also seeking comments on whether other validity testing is necessary for hair and, if so, what tests could be used.

**National Laboratory Certification Program (NLCP)**

The functions of the National Laboratory Certification Program include maintaining laboratory inspection and PT programs as described in these Guidelines. Activities within these functions also include, but are not limited to, reviewing inspection reports and PT results,

preparing summary reports of inspection and PT results, and making decisions regarding laboratory certification, suspension or revocation.

### **Organization of Proposed Guidelines**

This preamble describes the differences between the UrMG and the proposed HMG. In addition, it provides the rationale for the differences between the two Guidelines. The preamble also presents a number of issues raised during the development of the HMG. These issues are presented first in summary form as they appear in the proposed HMG and second as issues for which the Department is seeking specific public comment.

References to Instrumented Initial Test Facilities (IITFs) have been removed in multiple sections, because IITFs are not practical for hair testing and will not be allowed to test hair specimens (see discussion under Subpart L, section 12.1 below).

### **Subpart A – Applicability**

Section 1.1 contains the same policies as described in the UrMG regarding who is covered by the Guidelines, except that instrumented initial test facilities will not be allowed to test hair specimens.

Sections 1.2, 1.3, and 1.4 contain the same policies as described in the UrMG regarding who is responsible for the development and implementation of the Guidelines, how a federal agency requests a change from these Guidelines, and how these Guidelines are revised.

In Section 1.5, where terms are defined, the Department proposes to add terms that apply specifically to hair (e.g., artificial hair, false hair, wash procedures, decontamination, unique metabolite).

Section 1.6 contains the same policies as described in the UrMG regarding what an agency is required to do to protect federal applicant and employee records.

Section 1.7 contains the conditions that constitute a refusal to take a federally regulated drug test. The Department has removed UrMG items that are not applicable to hair (e.g., situations involving observed or monitored urine collections) and is proposing conditions specific to hair. For example, in the event a donor is unable to provide a sufficient amount of hair for faith-based or medical reasons, or due to an insufficient amount or length of hair, the federal agency would be required to collect another authorized specimen type (e.g., urine, oral fluid). In addition, the Department is proposing in Section 8.4 that the collector ask the donor whether the donor is wearing false hair (i.e., artificial or natural hair that is not the donor's own such as a wig, weave, or extensions). If the donor states that they are wearing false hair, or the collector otherwise identifies its presence, this does not constitute a refusal to test. If the collector can collect a sufficient amount of the donor's own hair, the collector will proceed with the hair test. If the donor is unable to provide a sufficient amount of hair because of the false hair or for faith-based or medical reasons, or due to an insufficient amount or length of hair, the collector will collect an alternate authorized specimen.

Section 1.8 contains the same policies as described in the UrMG with regard to the consequences of a refusal to take a federally regulated drug test.

## **Subpart B – Hair Specimen**

In section 2.1, the Department proposes to expand the drug testing program for federal agencies to permit the use of hair specimens. There is no requirement for federal agencies to use hair as part of their program. A federal agency may choose to use urine, oral fluid, hair, or any

combination of authorized specimen types in their drug testing program. However, any agency choosing to use hair is required to follow the HMG. For example, for pre-employment or random drug tests, an agency program can randomly assign individuals for urine, oral fluid, or hair collection. The Department is proposing to allow federal agencies the option to collect an alternate authorized specimen (e.g., urine, oral fluid) either: 1) at the same time as the hair specimen or 2) at the direction of the MRO, following verification of a hair test as positive or invalid, or when the laboratory rejected the hair specimen. Under both options, the MRO would direct testing of the alternate specimen after completing the review and verification of the hair test results. Under these procedures, MROs would only be authorized to report a positive result for a hair test when the donor admits illicit use of the drug(s) that caused the positive test. To be clear, the results of a positive hair test cannot be reported to a federal agency without this corroborating evidence to support the positive test result. This hair testing approach best addresses the current disparate impact and external contamination legal issues discussed in the Jones v. City of Boston and Thompson v. Civil Service Com'n. cases. As noted earlier, the Department is specifically requesting comments including support from the scientific literature on advances in the science of hair testing that address these issues and obviate the need for the alternate specimen collection, as well as whether THCA should be excluded from this requirement (i.e., MROs would report verified positive THCA hair results to the federal agency). In the event a donor was unable to provide a sufficient amount of head hair for faith-based or medical reasons, or due to an insufficient amount or length of hair, the federal agency would be required to collect an alternate authorized specimen.

Section 2.2 describes the circumstances under which a hair specimen may be collected. The Department proposes that hair tests be used in the pre-employment and random drug testing

contexts only. Because drug analytes do not appear in hair for 5-7 days after use, hair is not an appropriate specimen to detect recent use. The Department is proposing to allow hair testing for pre-employment and random testing, and is requesting comments on whether hair may be used for follow-up or return to duty testing. In addition, due to different growth rates and drug detection windows based on the location of hair on the body, as well as privacy concerns, the Department is proposing to limit collection to head hair only and require federal agencies to authorize another specimen type for collection when head hair cannot be collected.

Section 2.3 describes how each hair specimen is collected for testing. This section is consistent with the established requirement for all specimens to be collected as a split specimen. The Department proposes that the collector subdivide the collected hair specimen into the primary (A) and split (B) specimens.

Section 2.4 establishes the amount of hair that must be collected for each specimen.

Section 2.5 describes how a hair specimen is split.

Section 2.6 includes the same requirement as the UrMG, 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 the HMG do not authorize the release of specimens, or portions thereof, to donors, the Guidelines afford donors 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 donors to request the retesting of their specimen (for drugs or adulteration) at a different certified laboratory. Furthermore, the Guidelines grant donors 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 Custody and Control Form (CCF) with any attachments, internal chain of custody records for the specimen, and any memoranda generated by the laboratory regarding the donor's drug test.

Therefore, the procedures in these 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 to access the specimen itself or a portion thereof. The reason for this prohibition is that specimens collected under the Guidelines are for the purpose of drug testing only. They are not intended or designed to be used 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- Hair Specimen Tests**

Section 3.1 describes the tests to be performed on each hair specimen. This is the same policy that is in the UrMG regarding which drug tests must be performed on a specimen. A federal agency is required to test all specimens for marijuana and cocaine and is authorized to also test specimens for opioids, amphetamines, and phencyclidine. The Department realizes that most federal agencies typically test for all five drug classes authorized by the existing Guidelines, but has not made this a mandatory requirement, and will continue to rely on the individual agencies and departments to determine their testing needs above the required minimum. The Department is not aware of any currently used hair tests for a biomarker or specific adulterant. However, the HMG authorize specimen validity testing (e.g., for a

biomarker, for a specific adulterant) upon request of the MRO as is allowed in the URMG. All tests must be properly validated and include appropriate quality control samples in accordance with these Guidelines. Specimen validity testing methods must be reviewed and approved by SAMHSA prior to use with federally regulated specimens. The Department is seeking comments on whether validity testing is necessary for hair and, if so, what tests could be used.

The policy in Section 3.2 does not differ from that for urine testing in that an agency may test a donor's hair specimen for additional drugs on a case-by-case basis. For reasons outlined above, hair may be used for pre-employment and random testing purposes but cannot be used for other reasons (e.g., reasonable suspicion and post-accident testing). A federal agency must consider collecting another authorized specimen type (e.g., urine or oral fluid) in such cases.

The Department has included the same policy as the UrMG for a federal agency that wishes to routinely test its specimens for any drug not included in the Guidelines, in that the agency must obtain approval from the Department before expanding its program. The HHS-certified laboratory performing such additional testing must validate the test methods and meet the quality control requirements as described in the Guidelines for the other drug analyses.

Section 3.3 states that specimens must only be tested for drugs and to determine their validity in accordance with Subpart C of these Guidelines. Additional explanation is provided above, in the description of Section 2.6.

The table in Section 3.4 lists the proposed analytes and cutoff concentrations for hair. Most of the analytes and cutoffs are the same as those proposed in 2004. The Department has added the same prescription opioids (i.e., hydrocodone, hydromorphone, oxycodone, and oxymorphone) as the UrMG, with the same hair cutoffs as codeine and morphine. The codeine and morphine cutoffs are consistent with those recommended by the European Workplace Drug

Testing Society and the Society of Hair Testing.<sup>44, 45</sup> The Department is specifically requesting comments on the appropriateness of these analytes and cutoffs.

Due to issues of possible external contamination and possible concerns of hair color impact, SAMHSA is continuing to evaluate standards regarding these issues. The Department is soliciting comments, with supporting scientific information, on unique metabolites as defined in these Guidelines that show use, or ingestion, of a drug, thereby eliminating external contamination as a concern.

Other footnotes in the Section 3.4 table include the same calibration and immunoassay cross-reactivity requirements as the UrMG for the initial tests. This includes the requirement for a laboratory to use the confirmatory test cutoff as the cutoff for an alternate technology initial test that is specific for THCA. Immunoassays for cannabinoids react with multiple compounds that may be incorporated into hair as a result of marijuana use. Therefore, it is necessary to use an immunoassay cutoff higher than that of the confirmatory test in order to detect the target analyte (THCA) at or above the confirmatory test cutoff. An initial test using an alternate technology with specificity comparable to the confirmatory test requires use of the confirmatory test cutoff.

Section 3.5 has the same policy as the UrMG regarding additional tests to provide information that the MRO would use to report a verified drug test result. HHS-certified laboratories are authorized to perform additional tests upon MRO request on a case-by-case basis, but are not authorized to routinely perform such tests without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of D, L stereoisomers of amphetamine and methamphetamine. The Department is requesting comments including supporting data from the scientific literature on specimen validity tests and tests for

additional analytes (e.g., metabolites) that may be performed on a case-by-case basis or routinely upon MRO request.

Section 3.6 includes criteria for reporting a hair specimen as adulterated. While there are no known hair adulterants at this time, the Department is proposing to establish criteria similar to that for urine specimens, to ensure procedures that are forensically acceptable and scientifically sound, while allowing laboratories the flexibility necessary to develop specific testing requirements for an adulterant.

Section 3.7 includes criteria applicable for reporting a hair specimen as substituted (i.e., the laboratory has identified physical or chemical characteristics inconsistent with human hair).

Section 3.8 incorporates criteria from the UrMG that are applicable for reporting an invalid result for a hair specimen and includes additional criteria specific for hair specimens. As noted previously, the Department is proposing that laboratories subject each confirmatory drug test specimen to a validated and effective decontamination procedure prior to testing for the confirmatory test analyte(s) listed in Section 3.4. If a laboratory has used its validated decontamination procedure for a specimen with a positive confirmatory drug test and was unable to distinguish external contamination from drug ingestion based on its test results, the laboratory would report the specimen as invalid. Additionally, a hair specimen may be damaged to the extent that the drug test is invalid (i.e., the damaged hair is susceptible to incorporation of drug from external contamination or to loss of incorporated drug). Therefore, the Department is also proposing that each laboratory use a validated specimen validity test to identify damaged specimens and report specimens as invalid when the damage may affect the drug test result. The Department is requesting comments on whether testing for hair damage should be routinely performed on all specimens or only on certain specimens (e.g., based on initial test results).

## **Subpart D - Collectors**

Sections 4.1 through 4.5 contain the same policies as described in the UrMG regarding who may or may not collect a specimen, the requirements to be a collector, the requirements to be a trainer for collectors, and what a federal agency must do before a collector is permitted to collect a specimen.

## **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. These are the same requirements as in the UrMG.

## **Subpart F - Federal Drug Testing Custody and Control Form**

Sections 6.1 and 6.2 are the same as in the UrMG, requiring the 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 – Hair Specimen Collection Materials**

Section 7.1 describes the collection materials that must be used to collect a hair specimen. The Department is proposing that either single-use or reusable scissors may be used to cut the hair. If reusable scissors are used, the collector must use an individually packaged isopropyl alcohol wipe to clean the scissors in the presence of the donor. Materials also must include two

specimen guides, as defined in Section 1.5, and two sealable collection containers for the A and B specimens.

Section 7.2 describes specific requirements for the hair collection materials, to maintain the integrity of the specimen. All collection materials that come into contact with the hair must not substantially affect the composition of drug and/or drug metabolites in the specimen. The specimen guides and containers must be sufficiently transparent to enable an objective assessment of specimen appearance and identification of abnormal physical characteristics without opening the container. This is the same requirement as in the UrMG for urine collection bottles.

Section 7.3 details the minimum performance requirements for hair collection materials. Specimen guides must be capable of holding the hair specimen as positioned by the collector, and have an indication of the orientation (i.e., root or distal end) of the hair specimen collected. The specimen guides or the containers must have graduated markings or guides for collectors to verify the minimum width (i.e., 0.5 inches wide) and length (i.e., 1.0 inch, approximately 2.5 cm, long) of hair that would equate to 100 mg of hair or 50 mg of hair in each container labeled A and B.

### **Subpart H – Hair Specimen Collection Procedure**

This subpart addresses the same topics, in the same order, as the UrMG procedures for urine specimen collection, but excludes UrMG requirements that are specific for observed or monitored urine collection.

Section 8.1 includes the procedures required to provide privacy for the hair donor during the collection procedure.

Sections 8.2 through 8.5 describe the responsibilities and procedures the collector must follow before, during, and after a hair collection. Sections 8.3 and 8.5 specify how hair is to be selected, collected, and packaged. Section 8.3 requires the collector to stop the collection if lice or a similar infestation is present in the donor's hair and Section 8.4 requires the collector to stop the collection if the donor has false hair and the collector cannot collect a sufficient amount of the donor's own hair. In these cases, the collector proceeds with collection of another specimen type authorized by the federal agency. Section 8.5 specifies that only head hair should be collected.

Section 8.6 describes the procedures the collector must follow when a donor is unable to provide a hair specimen (i.e., as described in Sections 2.1, 8.3, and 8.4). In these cases, the collector proceeds with collection of another specimen type authorized by the federal agency.

Section 8.7 requires collection of an alternate specimen when a donor is unable to provide a sufficient amount of hair for faith-based or medical reasons, or due to an insufficient amount or length of hair. As noted earlier, if a federal agency authorizes the collection of hair specimens in its workplace drug testing program, it must also authorize the collection of one or more alternate specimen types in the event that hair cannot be collected, in accordance with the Mandatory Guidelines for the alternate specimen type. Enabling collection of another specimen without delay should facilitate the pre-employment process and may help reduce attempts to subvert the drug test.

Section 8.8 describes how the collector prepares the hair specimens, including the description of the hair split specimen collection.

Section 8.9 specifies how a collector is to report a refusal to test. The procedures are the same as in the UrMG.

Section 8.10 is the same as that in the UrMG in regard to federal agency responsibilities for ensuring that each collection site complies with all provisions of the Mandatory Guidelines. An example of appropriate action that may be taken in response to a reported collection site deficiency is self-assessment using the Collection Site Checklist for the Collection of Hair Specimens for Federal Agency Workplace Drug Testing Programs. This document will be available on the SAMHSA website <http://www.samhsa.gov/workplace/drug-testing>.

### **Subpart I – HHS-Certification of Laboratories**

This subpart addresses the same topics for HHS certification of laboratories to test hair specimens, as are included in the UrMG for HHS certification of laboratories to test urine specimens.

Sections 9.1 through 9.4 contain the same policies as in the UrMG for laboratories to become HHS-certified and to maintain HHS certification to conduct hair testing for a federal agency, as well as what a laboratory must do when certification is not maintained.

Section 9.5 contains specifications for NLCP PT samples, Section 9.6 contains PT requirements for an applicant laboratory, and Section 9.7 contains PT requirements for an HHS-certified laboratory. These sections incorporate the applicable requirements from the current UrMG, but exclude UrMG requirements that are specific for urine testing. In Sections 9.6 and 9.7, the Department also added a requirement for laboratories to correctly identify a sample that has been contaminated with one or more drugs.

As noted earlier, the Department plans to use multiple types of head hair (e.g., drug user hair, hair contaminated with drug analytes, hair subjected to cosmetic treatments, bleached hair) in the NLCP PT Program. These samples will be used to challenge the laboratories' abilities to

identify and quantify drug analytes, to remove external contamination, and to identify damaged hair. The Department will use additional PT materials (e.g., spiked reference materials) as part of a multi-pronged approach to assess accuracy and precision of HHS certified hair testing laboratories. The Department is specifically requesting comments on the types of samples and multi-pronged approach to be included in the hair PT program.

The remaining Sections 9.8 through 9.17 contain the same policies as the UrMG. These sections address inspection requirements for applicant and HHS-certified laboratories, inspectors, consequences of an applicant or HHS-certified laboratory failing to meet PT or inspection performance requirements, factors considered by the Secretary in determining the revocation or suspension of HHS-certification, the procedure for notifying a laboratory that adverse action (e.g., suspension or revocation) is being taken by HHS, and the process for re-application once a laboratory's certification has been revoked by the Department.

Section 9.17 states that a list of laboratories certified by HHS to conduct forensic drug testing for federal agencies will be published monthly in the Federal Register. The list will indicate the type of specimens (e.g., hair, oral fluid, and/or urine) that each laboratory is certified to test.

#### **Subpart J - Blind Samples Submitted by an Agency**

This subpart (Sections 10.1 through 10.4) describes the same policies for federal agency blind samples as the UrMG, with two exceptions. Hair blind samples that challenge specimen validity tests are not required, and the concentration of drug positive blind samples must be at least 1.5 times the initial drug test cutoff concentration (i.e., no upper limit as in the UrMG).

## **Subpart K - Laboratory**

This subpart addresses the same topics, in the same order, as the UrMG procedures for laboratories testing urine specimens. As appropriate, the section includes requirements that are specific for hair testing.

Sections 11.1 through 11.8 include the same requirements that are contained in the UrMG for the laboratory standard operating procedure (SOP) manual; responsibilities and scientific qualifications of the responsible person (RP); procedures in the event of the RP's extended absence from the laboratory; qualifications of the certifying scientists, certifying technicians, and other HHS-certified laboratory staff; security; and chain of custody requirements for specimens and aliquots.

A new Section 11.9 has been added to describe how an HHS-certified laboratory processes the alternate authorized specimen that was collected at the same time as a hair specimen in accordance with Section 8.5(e).

A new Section 11.10 has been added to describe the amount of hair tested. This section specifies that 1.0 inch of the hair specimen from the root end is tested, when the collector has identified the root end.

Sections 11.11 through 11.16 include the same requirements as in the UrMG in regard to initial and confirmatory drug test requirements, validation, and batch quality control as described in each section below.

Section 11.11 describes the requirements for the initial drug test which permit the use of an immunoassay or alternate technology (e.g., spectrometry or spectroscopy).

Sections 11.12 and 11.13 cover validation and quality control requirements for the initial tests.

Section 11.14 describes the same requirements for a confirmatory drug test as the UrMG with one exception. This section requires laboratories to perform a decontamination procedure prior to confirmatory drug testing.

Sections 11.15 and 11.16 cover validation and quality control requirements for the confirmatory tests. Section 11.15 includes the requirement to demonstrate and document the effectiveness of decontamination procedures and Section 11.16 requires at least one control in each batch to monitor the effectiveness of the decontamination procedure.

Sections 11.17 and 11.18 address specimen validity tests that a laboratory performs for hair specimens. The Department is proposing that each laboratory have a validated specimen validity test that identifies hair that has been damaged to the extent that a drug test may be affected. The HMG allow, but do not require, other specimen validity testing for hair. The HMG collection procedures greatly minimize the risks of donor attempts to tamper with the specimen. To avoid prohibiting use of scientifically supportable hair biomarker or adulterant tests that may become available, the Department is authorizing specimen validity testing upon request of the Medical Review Officer as described in Sections 3.1 and 3.5. All tests must be properly validated and include appropriate quality control samples in accordance with these Guidelines. Specimen validity testing methods must be approved by SAMHSA prior to use with federally regulated specimens. As noted earlier, the Department is requesting information on procedures to identify damaged hair and other specimen validity tests for hair. The Department is also requesting comments on whether testing for hair damage should be routinely performed on all specimens or only on certain specimens (e.g., based on initial test results).

Section 11.19 describes in detail, requirements for how a certified laboratory reports test results to the MRO for hair specimens. This section has requirements specific to hair.

Sections 11.20 and 11.21 contain the same requirements as the UrMG for length of time of specimen and record retention and specifies that hair specimens must be stored at room temperature and out of direct light. As noted in Section 11.9, the collector forwards the alternate authorized specimen collected at the same time as the hair specimen to a laboratory that is certified by HHS for that specimen type. Section 11.20 also requires that alternate authorized specimens (e.g., urine, oral fluid) be retained under appropriate storage conditions as specified by the Mandatory Guidelines for that specimen type, for the same period of time that the associated hair specimen is retained.

Section 11.22 describes the statistical summary report that a laboratory must provide to a federal agency for hair testing. This section is comparable to the same section in the UrMG, differing only in that the statistical report elements are specific for hair testing.

Section 11.23 addresses the laboratory information to be made available to a federal agency and describes the contents of a standard laboratory documentation package. This is the same policy as in the UrMG.

Section 11.24 addresses the laboratory information to be made available to an applicant or employee upon written request through the MRO, and clarifies that specimens are not a part of the information package that donors can receive from HHS-certified laboratories. This is the same policy as in the UrMG.

The remaining section, Section 11.25, describes the relationships that are prohibited between an HHS-certified laboratory and an MRO. These are the same as in the UrMG.

### **Subpart L – Instrumented Initial Test Facility (IITF)**

This subpart emphasizes that federal agencies may choose to use IITFs for urine testing

but not for hair testing. Section 12.1 clearly states that only HHS-certified laboratories are authorized to test hair specimens for federal agency workplace drug testing programs.

Instrumented Initial Test Facilities will not be allowed, primarily because of the limited amount of hair collected from the donor.

### **Subpart M - Medical Review Officer (MRO)**

MROs play a key role in the federal safety program and maintain the balance between the safety and privacy objectives of the program. This subpart addresses the same topics, in the same order, as the UrMG procedures for MROs.

The proposed requirements in Section 13.1 through 13.3 are the same as in the UrMG, including training requirements in Section 13.3 for a physician to receive training on the Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types prior to serving as an MRO, and for a certified MRO to complete training on any revisions to the Guidelines prior to their effective date, to continue serving as an MRO for federal agency specimens. Section 13.4 includes the same requirements as the UrMG except the HMG do not permit an MRO to conduct a medical evaluation or review the examining physician's findings to determine clinical evidence of opioid abuse when codeine or morphine is positive below a specified concentration in hair. Because of the longer detection time for hair, the medical evaluation would not be useful after limited drug use (e.g., injection site healing). Furthermore, this requirement would have significant effects on the costs of the program and the turnaround time of the result. The Department would like to clarify that the Mandatory Guidelines, including the HMG, authorize testing that detects illicit drug use, not drug "abuse."

Therefore, an MRO's inquiry in this context is limited to whether a legitimate medical explanation exists for the positive result, not whether the donor has "abused" opioids.

Section 13.5 describes an MRO's actions when reviewing a hair specimen's test results. This section includes procedures that are specific to hair specimen results. The review and verification procedures for negative, adulterated, and substituted results are the same as those for urine. The review and verification procedures for invalid results and rejected specimens are the same as those for urine, except that the HMG specifically requires testing of an alternate specimen type in these cases. MRO actions required for a positive hair test are described below.

When an HHS-certified laboratory reports a positive result for the primary (A) hair specimen, the MRO must contact the donor to determine if there is an explanation for the positive test. If the donor provides a legitimate medical explanation (e.g., a valid prescription), the MRO reports the hair test result as negative to the federal agency. If the donor admits illicit use of the drug(s) that caused the positive test, the MRO reports the hair test result as positive to the federal agency. If the donor is unable to provide a legitimate medical explanation and does not admit illicit drug use, the MRO cancels the test and directs testing of an alternate authorized specimen from the donor.

If an alternate authorized specimen was collected at the same time as the hair specimen, the MRO directs (in writing) the laboratory who has custody of the specimen to proceed with testing. If an alternate specimen was not collected, the MRO directs the agency to collect an alternate authorized specimen from the donor. The collector, laboratory, and MRO must follow the applicable Mandatory Guidelines for Federal Workplace Drug Testing Programs for that specimen type.

The MRO would also direct testing of the alternate authorized specimen for invalid and

rejected for testing hair results.

The Department had considered specifying a morphine or codeine confirmatory concentration that could be used as a decision point to rule out consumption of food products as a legitimate explanation for the donor having morphine or codeine at or above the specified concentration in his or her hair. There is limited information in the scientific literature on the codeine and/or morphine concentrations seen in hair after consumption of poppy seed food products. One study found morphine concentrations ranging from 0.05 -0.48 ng/10 mg (5.0-48.0 pg/mg) in the hair of 10 poppy seed consumers.<sup>46</sup> The Department had chosen a conservative concentration of 2000 pg/mg (i.e., 10 times the confirmatory test cutoff) as the decision point. Because the HMG require testing of an alternate specimen when a hair test is positive (i.e., unless the donor has a legitimate medical explanation or admits illicit drug use), the additional decision point for codeine and morphine results is not needed. However, in the event that this is needed in the final HMG, the Department specifically requests public comment on the appropriateness of this concentration.

Section 13.6 describes what an MRO must do when the collector reports that a donor did not provide a sufficient amount of hair for a drug test. In the event a donor was unable to provide a sufficient amount of hair, the collector should direct the donor to submit another authorized specimen type consistent with the respective federal agency's policies and procedures.

Sections 13.7 and 13.8 are similar to the UrMG, addressing who may request a test of the split (B) specimen and how an MRO reports a primary (A) specimen result. However, because the MRO does not report positive hair test results to the federal agency without corroborating evidence (i.e., donor admission of illicit drug use); the split specimen is not tested to reconfirm a

positive hair test result. Split hair specimens are only retested to reconfirm adulterated or substituted results at the donor's request.

Section 13.9 is the same as in the UrMG, addressing the types of relationships that are prohibited between an MRO and an HHS- certified laboratory.

### **Subpart N - Split Specimen Tests**

Section 14.1 includes the same policies as the UrMG in regard to when a split (B) specimen may be tested. As noted previously in this preamble, because the MRO does not report positive hair test results to the federal agency without corroborating evidence (i.e., donor admission of illicit drug use), split specimens are not tested to reconfirm positive hair test results. A split hair specimen may be tested only to reconfirm an adulterated or substituted result reported for the primary hair specimen.

Section 14.2 specifies how the split testing laboratory tests a split (B) hair specimen when the primary (A) specimen was reported as adulterated. As noted previously in this Preamble, the Department is not aware of any adulterants being used for hair specimens, but has included policies in these Guidelines to allow for the testing and reporting of adulterants in hair.

Section 14.3 specifies how the split testing laboratory tests a split (B) hair specimen when the primary (A) specimen was reported as substituted. As noted previously in this Preamble, the Department is requesting information from the public on specimen validity tests for hair, and has included policies in these Guidelines to allow for the testing and reporting of hair as substituted.

Section 14.4 includes the same policy as the UrMG, requiring the laboratory to report the split (B) specimen result to the MRO.

In Section 14.5, the Department is proposing the actions an MRO must take after receiving the split (B) specimen result. This section is analogous to the corresponding section in the UrMG with differences, where applicable, for hair specimen reports.

Section 14.6 is the same as the UrMG in regard to how an MRO reports a split (B) specimen result to an agency.

Section 14.7 is the same as the UrMG, requiring the HHS-certified laboratory to retain a split hair specimen for the same length of time that the primary specimen is retained.

### **Subpart O – Criteria for Rejecting a Specimen for Testing**

Section 15.1 specifies the same fatal flaws as the UrMG that require the laboratory to reject the specimen, with one addition specific to hair specimens. Section 15.1, item (i) requires the laboratory to reject the specimen when the physical characteristics of the primary (A) and split (B) specimen are clearly different (i.e., could not be from the same individual). An example of a hair specimen that would be rejected is a short straight hair sample labeled as A and a long curly hair labeled as B. However, this requirement does not apply to A and B specimens that only have different hair color, because an individual may have different colored hair. Sections 3.8(c) and 11.19(e) address reporting as invalid when A and B specimens have clearly different colors, and the A specimen has been tested.

Section 15.3 lists those discrepancies that would not affect either testing or reporting of a hair specimen result. These are similar to the corresponding section in the UrMG, with differences where applicable for hair specimens.

The other sections in this Subpart (i.e., Sections 15.2 and 15.4) contain the same policies as the UrMG concerning correctable discrepancies and fatal flaws that may require the MRO to cancel the test.

### **Subpart P - Laboratory Suspension/Revocation Procedures**

In this subpart, the Department proposes the same procedures that are described in the UrMG to revoke or suspend the HHS certification of laboratories.

### **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 HMG into each of 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.

The continuing questions and concerns on the impact of hair color on drug test results are discussed in this preamble. The Department is requesting information including, at a minimum, support from the scientific literature to address the impact of hair color on hair drug test results.

To address the potential issues of both disparate impact and external contamination, Section 2.1 includes the requirement to collect a second biological specimen (i.e., urine or other authorized specimen type) at the same time as the hair specimen or as directed by the MRO after

verification of a hair specimen as positive, invalid, or when the laboratory rejected the hair specimen. Under these procedures, MROs would only be authorized to report the results of a positive hair test to an agency when the donor admits to the MRO the illicit use of the drug(s) that caused the positive test. The Department is specifically requesting comments including support from the recent scientific literature on advances in the science of hair testing that adequately address these issues and elucidate the extent to which hair color, external contamination as well as other factors (e.g., hair treatments, hygiene) will affect hair tests and the interpretation of hair drug test results. The Department is also requesting comment with scientific support on whether THCA positive hair tests should be excluded from the requirement to test an alternate authorized specimen (i.e., MROs would report verified positive THCA hair results to the federal agency) and information on other unique metabolites that can be analyzed on a stand-alone basis for the other proposed drugs listed in Section 3.4.

Section 2.2 describes the circumstances under which a hair specimen may be collected. The Department proposes to limit the reasons for testing to pre-employment and random. Because drug analytes do not appear in hair for 5-7 days after use, hair is not an appropriate specimen to detect recent use. However, the longer window of detection makes hair an appropriate choice for pre-employment and random. The Department is requesting comments on whether hair may be used for other reasons (e.g., return to duty, follow-up).

In Sections 3.1 and 3.5, the Department allows laboratories to perform specimen validity testing for hair specimens. The Department is seeking comments on whether validity testing is necessary for hair and, if so, what tests could be used.

Section 3.4 lists the proposed test analytes and cutoff concentrations. The Department is specifically requesting comments on the appropriateness of these analytes and cutoffs.

Section 3.5 allows laboratories to perform additional tests to provide information that the MRO would use to report a verified drug test result. The Department is specifically requesting comments including supporting data from the scientific literature on additional analytes (e.g., metabolites) that may be tested on a case-by-case basis or routinely upon MRO request.

Section 9.5 contains the specifications for PT samples. The Department is specifically requesting comments on the types of samples and the multi-pronged approach that should be included in a hair PT program.

In Section 11.14, the Department is proposing that laboratories implement procedures to distinguish external contamination from drug use using a validated and effective decontamination procedure prior to confirmatory testing. The Department is requesting comment on 1) decontamination procedures that remove drug present as a result of external contamination, 2) procedures used to prepare decontamination controls, and 3) drug metabolites that are uniquely found in hair after drug use.

In Section 11.17, the Department is proposing that laboratories implement procedures to identify damaged hair specimens. The Department is requesting information including, at a minimum, support from the scientific literature, on procedures to identify damaged hair. The Department is also requesting comments on whether testing for hair damage should be routinely performed on all specimens or only on certain specimens (e.g., based on initial test results).

In Section 13.5, the Department had considered a concentration equal to or greater than 2000 pg/mg morphine or codeine be used by the MRO to report a positive hair test result for these drugs in the absence of a legitimate medical explanation (i.e., prescription), to rule out the possibility of a positive result due to consumption of food products. The proposal for testing an alternate specimen type for all positive hair tests negates the need for this procedure. However,

the Department is requesting specific comments on this proposed concentration if it is included in the final HMG.

### **Regulatory Impact and Notices**

The Department welcomes public comment on all figures and assumptions 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. While this is a significant regulatory action as defined by Executive Order 12866, the Secretary finds that it does not confer significant costs to regulated entities warranting a regulatory flexibility analysis. Therefore, the Department does not find these proposed mandatory guidelines to be a significant burden for federal agencies or incur a significant cost. In addition, a federal agency is not required to adopt hair testing in their Drug-free Workplace 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 HMG will not require additional expenditures. Therefore, an initial regulatory flexibility analysis is not required for this notice.

#### *Need for regulation*

#### ***Enhances Flexibility***

The proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Hair (HMG) will provide flexibility to address workplace drug testing needs of federal

agencies and federally regulated entities while continuing to promulgate established standards to ensure the full reliability and accuracy of drug test results.

### ***Enhances Versatility***

Medical conditions exist that may prevent a federal employee or applicant from providing sufficient urine or oral fluid for a drug test. When the HMG are implemented, in the event that an individual is unable to provide a urine or oral fluid specimen, the federal agency may authorize the collection of a hair specimen. In the event a federal agency adopts hair testing and the donor is unable to provide a hair specimen for faith-based or medical reasons, or due to an insufficient amount or length of hair, the federal agency would be required to collect an alternate specimen. Thus, the inclusion of hair in federal workplace drug testing programs will reduce both the need to reschedule collections and the need for the Medical Review Officer (MRO) to arrange a medical evaluation of a donor's inability to provide a urine or oral fluid specimen.

Urine collection requires use of a specialized collection facility, secured restrooms, observers of the same gender as the donor for observed collections, and other special requirements. Hair may be collected in various settings and may not necessarily require a specialized collection facility, but if a second authorized specimen is collected at the same time then the collection facility must meet the requirements for a collection facility for the alternate specimen. An acceptable hair collection site must allow the collector to observe the donor, maintain control of the collection materials during the process, maintain record storage, and protect donor privacy.

### ***Decreases Invalid Tests***

Hair collections will occur under direct observation, which should substantially lessen the risks of invalid results due to specimen substitution and adulteration. The Department is also proposing that each laboratory have a method to identify damaged hair as invalid specimens, which would further decrease the risk of invalid results.

### ***Saves Time***

The requirement to collect a urine or oral fluid specimen in the event that the donor cannot provide a hair specimen (and vice versa) will reduce both the need to reschedule a collection and the need for the MRO to arrange a medical evaluation of a donor's inability to provide a urine or oral fluid specimen.

### ***Versatility in Detection***

The time course of drugs and metabolites differs between hair, urine, and oral fluid, resulting in some differences in analytes and detection times. A federal agency may wish to pursue hair testing if they want to use a longer detection window and retain the ability to use other specimen types for circumstances necessitating more recent use, such as post-accident situations.

### ***Current Testing in the Drug-free Workplace Program***

Urine was the original specimen of choice for forensic workplace drug testing, and urine testing is expected to remain an established and reliable component of federal workplace drug testing programs. Urine testing provides scientifically accurate and legally defensible results and has proven to be an effective deterrent to drug use in the workplace. However, urine testing is

not observed in all cases. Hair testing, like oral fluid testing, is observed, and therefore, less susceptible to substitution or adulteration.

### ***Time Horizon of this Analysis***

The transition to the testing of hair will be gradual over the course of four years, when it should plateau. By that time, it is expected that hair tests will account for 25-30% of all regulated drug testing. This estimate is based on the current percentage of regulated pre-employment and random tests using urine and the non-regulated sector's time course of the testing of hair, oral fluid, and urine in the past four years.

### ***Cost and Benefit***

Using data obtained from the Federal Workplace Drug Testing Programs and HHS certified laboratories, the Department estimates that 275,000 specimens are will be tested annually by federal agencies. HHS projects that approximately 1% (or 2,750) of the 275,000 specimens tested per year will be hair specimens and 92% (or 253,000) will be urine specimens, with the remainder being oral fluid specimens (19,250). The approximate annual number of regulated specimens for the Department of Transportation (DOT) and Nuclear Regulatory Commission (NRC) is 6.1 million and 150,000, respectively. Should DOT and NRC allow hair testing in their regulated workplace programs, the estimated annual numbers of specimens for DOT would be 25% (1.53 million) hair specimens for pre-employment, 7% (427,000) oral fluid specimens and 68% (4.15 million) urine, and numbers of specimens for NRC would be 10% (15,000) hair, 7% (10,500) oral fluid and 83% (124,500) urine. These projected numbers are

based on existing annual pre-employment testing that currently occurs in the regulated industries and current hair testing being conducted.

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. 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 hair testing and testing for oxycodone, oxymorphone, hydrocodone and hydromorphone will be minimal based on information from some HHS-certified laboratories currently testing non-regulated hair specimens. Likewise, there will be minimal costs associated with changing initial testing to include MDA and MDMA since current immunoassays can be adapted to test for these analytes. Prior to being allowed to test regulated hair specimens, laboratories must be certified by the Department through the NLCP. Estimated laboratory costs to complete and submit the application are \$3,000, and estimated costs for the Department to process the application are \$10,200. These estimates are based on the NLCP fee schedule and historical costs. The initial certification process includes the requirement to demonstrate that their performance meets Guidelines requirements by testing three (3) groups of PT samples. The Department will provide the three groups of PT samples through the NLCP at no cost to laboratories participating in the NLCP Hair Pilot PT Program. Based on costs charged for urine specimen testing, laboratory costs to conduct the PT testing would range from \$900 to \$1,800 for each applicant laboratory.

Agencies choosing to use hair in their drug testing programs may also incur some costs for training of federal employees such as drug program coordinators. Based on current training modules offered to drug program coordinators, and other associated costs including travel for 90% of drug program coordinators, the estimated total training cost for a one-day training session would be between \$108,000 and \$138,000 (i.e., assuming 8 hours of time multiplied by a GS 12/13 wage including benefits and overhead adjustments). This training cost is included in the costs of the proposed HMG. The Department will offer the choice of online or in-person training. This will eliminate travel costs for those federal agencies who choose to use online training.

*Summary of One-Time Costs*

	<b>Lower</b>	<b>Upper</b>	
	<b>Bound</b>	<b>Bound</b>	<b>Primary</b>
Cost of Application*	-	-	\$12,000.00
<hr/>			
Application			
Processing*	-	-	\$40,800.00
<hr/>			
Performance			
Testing*	\$3600.00	\$7200.00	
<hr/>			
Training*	\$54,000.00	\$69,000.00	
<hr/>			
<b>Total</b>	<b>\$110,400.00</b>	<b>\$129,000.00</b>	

\*Estimated using costs presented above multiplied by the number of laboratories (4).

### *Costs and Benefits*

Thus, the Department estimates one-time, upfront costs of between \$110,400 and \$129,000 for hair testing laboratories. While the Department has only monetized a small portion of the benefits to a small subset of the workplace drug testing programs that could be affected by the HMG (i.e., federal employee testing programs and not drug testing programs conducted under NRC and DOT regulations), the Department is confident that the benefits would outweigh the one-time upfront costs. Even if NRC and DOT do not implement hair testing, the benefits to federal workplace testing programs could be a cost savings, which would recur on annual basis.

### *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 HMG will not require additional expenditures. Therefore, an initial regulatory flexibility analysis is not required for this notice.

As mentioned in the section on Executive Orders 13563 and 12866, the Secretary anticipates that there will be no reduction in costs if drug testing is expanded under the HMG. The costs to implement this change to regulations are negligible. The added flexibility will permit federal agencies to select the specimen type best suited for their needs and to authorize collection of an alternate specimen type when an applicant or employee is unable to provide the originally authorized specimen type. The added flexibility will also benefit federal applicants

and employees, who should be able to provide one of the specimen types, thereby facilitating the drug test required for their employment.

### *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 HMG. 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.

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 Hair is not a system of records as noted in the information collection/recordkeeping requirements below.

Note the collection of information on the Federal Chain of Custody Form as required by the Mandatory Guidelines are discussed below under information collection and record keeping and are a separate submission and approval by the Office of Management and Budget.

*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 (82 FR 7920 for urine, 84 FR 57554 for oral fluid), which establish the scientific and technical guidelines for federal workplace drug testing programs and establish standards for certification of laboratories engaged in urine and oral fluid 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 and oral fluid 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 be revised for the use of hair specimens when the final Guidelines using hair 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 Hair

*Description:* The Guidelines establish the scientific and technical guidelines for federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for federal agencies under authority of Public Law 100-71, 5 U.S.C. section 7301 note, and Executive Order No. 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions. The program has depended on urine specimen testing since 1988; the reporting, recordkeeping and disclosure requirements associated with urine specimen testing are approved under OMB control number 0930-0158. Since 1988, several products have appeared on the market making it easier for individuals to adulterate or substitute the urine specimen. Scientific advances in the use of hair in detecting drugs have made it possible for this alternative

specimen to be pursued in federal programs. The proposed Guidelines establish when hair specimens may be collected, the procedures that must be used in collecting a hair specimen, and the certification process for approving a laboratory to test hair specimens.

*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, 10 hair specimen testing laboratories, and 100 MROs.

### **Estimate of Annual Reporting Burden**

Section	Purpose	No. of Respondents	Responses/ Respondent	Hours/ Response	Total Hours
9.2(a)(1)	Laboratory required to submit application for certification	10	1	3	30
9.10(a)(3)	Materials to submit to become an HHS inspector	10	1	2	20
11.3	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

Section	Purpose	No. of Respondents	Responses/ Respondent	Hours/ Response	Total Hours
11.21	Specifications for laboratory semi-annual statistical report of test results to each federal agency	10	5	0.5	25
14.7	Specifies that MRO must report all verified split specimen test results to the federal agency	100	5	0.05 (3 min)	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	1	1	0.5	0.5

Section	Purpose	No. of Respondents	Responses/ Respondent	Hours/ Response	Total Hours
	resolution status at end of abeyance period				
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

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(d)); Section 13.5 describes the actions an MRO takes to report a primary specimen result; and Section 14.6 describes the actions an MRO takes to report a split specimen result. SAMHSA has

not calculated a separate reporting burden for these requirements because they are included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to federal agencies.

### **Estimate of Annual Disclosure Burden**

Section	Purpose	No. of Respondents	Responses / Respondent	Hours/ Response	Total Hours
8.3(a) & 8.6	Collector must contact federal agency point of contact	100	1	0.05 (3 min)	5
11.23 & 11.24	Information on drug test that laboratory must provide to federal agency upon request or to donor through MRO	10	10	3	300
13.7(b)	MRO must inform donor of right to request split specimen test when an adulterated or substituted result is reported	100	5	3	1,500
<b>TOTAL</b>		<b>210</b>			<b>1,805</b>

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(h), and must review the procedures for the hair specimen collection materials used with the donor (Section 8.4(c)). 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	No. of Respondents	Responses / Response	Hours/ Response	Total Hours
8.3, 8.4, & 8.8	Collector completes Federal CCF for specimen collected	100	380	0.07 (4 min)	2,534
8.8(c) & (e)	Donor initials specimen labels/seals and signs statement on the Federal CCF	38,000	1	0.08 (5 min)	3,167
11.8(a) & 11.18	Laboratory completes Federal CCF upon receipt of specimen and before reporting result	10	3,800	0.05 (3 min)	1,900
13.4(d) (4), 13.8	MRO completes Federal CCF before reporting the result	100	380	0.05 (3 min)	1,900

Section	Purpose	No. of Responses	Responses / Respondent	Hours/ Response	Total Hours
(c), & 14.7(c)					
14.1(b)	MRO documents donor's request to have split hair specimen tested	300	1	0.05 (3 min)	15
TOTAL		38,510			9,516

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 8.3 (f), and 8.4 (d), (f)] requires collectors to enter any information on the Federal CCF of any unusual findings during the hair specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to

documenting the chain of custody for the specimens collected. The burden for these entries is included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. 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; 11.12(a); 11.15(a); 11.18; 11.19(a), (b), and (c); 11.22; 11.23, 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 hair specimens by the laboratories 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 17<sup>th</sup> 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).

## **References**

1. DuPont RL, Baumgartner WA. 1995. Drug testing by urine and hair analysis: complementary features and scientific issues. *Forensic Sci Int.* 70:63-76.
2. Barroso M, Gallardo E, Vieira DN, Lopez-Rivadulla M, Queiroz JA. 2011. Hair: a complementary source of bioanalytical information in forensic toxicology. *Bioanalysis.* 3:67-79.
3. LeBeau MA, Montgomery MA, Brewer JD. 2011. The role of variations in growth rate and sample collection on interpreting results of segmental analyses of hair. *Forensic Sci Int.* 210:110-6.
4. Boumba VA, Ziavrou KS, Vougiouklakis T. 2006. Hair as a biological indicator of drug use, drug abuse or chronic exposure to environmental toxicants. *Int J Toxicol.* 25:143-63.

5. de Berker D, Higgins CA, Johoda C, Christiano AM. 2012. Biology of hair and nails. In: Bologna, JL, Jorizzo, JL, Schaffer, JV, editors. *Dermatology*. 3<sup>rd</sup> ed. China: Elsevier Saunders.
6. Pötsch L, Skopp G, Moeller MR. 1997. Biochemical approach on the conservation of drug molecules during hair fiber formation. *Forensic Sci Int*. 84:25-35.
7. Caplan YH, Goldberger BA. 2001. Alternative specimens for workplace drug testing. *J Anal Toxicol*, 25:396-399.
8. Henderson GL. 1993. Mechanisms of drug incorporation into hair. *For Sci Int*. 63:19-29.
9. Mak WC, Patzelt A, Richter H, Renneberg R, Lai KK, Ruhl E, Sterry W, Lademann J. 2012. Triggering of drug release of particles in hair follicles. *J.Control Release*. 160:509-514.
10. Auwarter V, Wohlfarth A, Traber, J, Thieme D, Weinmann W. 2010. Hair analysis for delta-9-tetrahydrocannabinolic acid A—new insights into the mechanism of drug incorporation of cannabinoids into hair. *Forensic Sci Int*. 196:10-13.
11. Mantinieks D, Gerostamoulos D, Wright P, Drummer, O. 2018. The effectiveness of decontamination procedures used in forensic hair analysis. *Forensic Sci Med Pathol*. 14:349-357.
12. Morris-Kukoski C, Montgomery MA, Hammer RI. 2014. Analysis of extensively washed hair from cocaine users and drug chemists to establish new reporting criteria. *J Anal Toxicol*. 38:628-36.
13. Cuypers E, Flinders B, Boone CM, Bosman IJ, Lusthof KL, Van Asten AC, Tygat J Heeren RMA. 2016. Consequences of Decontamination Procedures in Forensic Hair

- Analysis Using Metal-Assisted Secondary Ion Mass Spectrometry Analysis. *Anal Chem.* 88:3091-3097.
- 14 Wright J, Kenneally M, Edwards J, Walker S. 2017. Adverse Health Effects Associated with Living in a Former Methamphetamine Drug Laboratory-Victoria, Australia, 2015. *MMWR.* 65 (52): 1470-1473.
  - 15 Tsanaclis L, Wicks J. 2008. Differentiation between Drug Use and Environmental Contamination when Testing for Drugs in Hair. *Forensic Sci Int.* 176:19-22.
  16. de La Torre R, Civit E, Svaizer F, Lotti A, Gottardi M, Miozzo M. 2010. High throughput analysis of drugs of abuse in hair by combining purposely designed sample extraction compatible with immunometric methods used for drug testing in urine. *Forensic Sci Int.* 196:18-21.
  17. Kamata T, Shima N, Sasaki K, Matsuta S, Takei S, Katagi M, Miki A, Zaitso K, Nakanishi T, Sato T, Suzuki K, Tsuchihashi H. 2015. Time-course mass spectrometry imaging for depicting drug incorporation into hair. *Anal Chem.* 87:5476-81.
  18. Grabenauer M, Bynum N, Moore K, White R, Mitchell J, Hayes E, Flegel R. 2018. Detection and quantification of codeine-6-glucuronide, hydromorphone-3-glucuronide, oxycodone-3-glucuronide, morphine 3-glucuronide and morphine-6-glucuronide in human hair from opioid users by LC-MS-MS. *J Anal Toxicol.* 42(2):115-125.
  19. Musshoff F, Thieme D, Schwarz G, Sachs H, Skopp G, Franz T. 2018. Determination of hydroxy metabolites of cocaine in hair samples for proof of consumption. *Drug Test Anal.* 10(4):681-688.

20. Scholz C, Quednow B, Herdener M, Kraemer T, Baumgartner M. 2019. Cocaine Hydroxy Metabolites in Hair: Indicators for Cocaine Use Versus External Contamination. *J Anal Toxicol.* 43(7):543-552.
21. Franz T, Scheufler F, Stein K, Uhl M, Dame T, Schwarz G, Sachs H, Skopp G, Musshoff F. 2018. Determination of hydroxy metabolites of cocaine from hair samples and comparison with street cocaine samples. *Forensic Sci Int.* 288:223-226.
22. Schaffer M, Cheng C, Chao O, Hill V, Matsui P. 2016. Analysis of cocaine and metabolites in hair: validation and application of measurement of hydroxycocaine metabolites as evidence of cocaine ingestion. *Anal Bioanal Chem.* 408(8):2043-54.
23. Castanet J, Ortonne JP. 1997. Hair melanin and hair color. In: Jolles P, Zahn H, Hoecker H, editors. *Formation and structure of human hair.* Basel, Switzerland: Birkhauser Verlag. Pp. 209-225.
24. Rollins DE, Wilkins DG, Gygi SP, Slawson MH, Nagasawa PR. 1997. Testing for drugs of abuse in hair – experimental observations and indications for future research. *Forensic Sci Rev.* 9:24-35.
25. Borges CR, Martin SD, Meyer LJ, Wilkins DG, Rollins DE. 2002. Influx and efflux of amphetamine and N-acetylamphetamine in keratinocytes, pigmented melanocytes, and nonpigmented melanocytes. *J. Pharm. Sci.* 91:1523-1535.
26. Joseph RE Jr, Su TP, Cone EJ. 1996. In vitro binding studies of drugs to hair: influence of melanin and lipids on cocaine binding to Caucasoid and Africoid hair. *J Anal Toxicol.* 20:338-344.

27. Borges CR, Roberts JC, Wilkins DG, Rollins DE. 2003. Cocaine, benzoylecgonine, amphetamine, and N-acetylamphetamine binding to melanin subtypes. *J Anal Toxicol.* 27:125-134.
28. Borges R, Wilkins DG, Rollins DE. 2001. Amphetamine and N-acetylamphetamine incorporation into hair: an investigation of the potential role of drug basicity in hair color bias. *J Anal Toxicol.* 25:221-227.
29. Stout PR, Claffey DJ, Ruth JA. 2000. Incorporation and retention of radiolabeled S-(+)- and R(-)-methamphetamine and S(+)- and R(-)-N-(n-butyl)-amphetamine in mouse hair after systemic administration. *Drug Metab Dispos.* 28:286-291.
30. Green SJ, Wilson JF. 1996. The effect of hair color on the incorporation of methadone into hair in the rat. *J Anal Toxicol.* 20:121-123.
31. Slawson MH, Wilkins DG, Rollins DE. 1998. The incorporation of drugs into hair: relationship of hair color and melanin concentration to phencyclidine incorporation. *J Anal Toxicol.* 22:406-413.
32. Henderson GL, Harkey MR, Zhou C, Jones RT, Jacob P III. 1998. Incorporation of isotopically labeled cocaine into human hair: race as a factor. *J Anal Toxicol.* 22:156-165.
33. Rollins DE, Wilkins DG, Krueger GG, Augsburg MP, Mizuno A, O'Neal C, Borges CR, Slawson MH. 2003. The effect of hair color on the incorporation of codeine into human hair. *J Anal Toxicol.* 27, 545-551.
34. Kronstrand R, Forstberg-Peterson S, Kagedal B, Ahlner J, Larson G. 1999. Codeine concentration in hair after oral administration is dependent on melanin content. *Clin Chem.* 45:1485-1494.

35. Mieczkowski T. 2003. Assessing the potential of a “color effect” for hair analysis of 11-nor-9-carboxy-delta(9)-tetrahydrocannabinol: analysis of a large sample of hair specimens. *Life Sci.* 74:463-469.
36. Mieczkowski T, Newel R. 2000. Statistical examination of hair color as a potential biasing factor in hair analysis. *Forensic Sci. Int.* 107:13-38.
37. Mieczkowski T, Newel R. 1993. An evaluation of patterns of racial bias in hair assays for cocaine: black and white arrestees compared. *Forensic Sci. Int.* 63:85-98.
38. Cuypers E, Flinders B., Bosman IJ, Lusthof KJ, Van Asten AC, Tytgat J, Heeren RMA. 2014. Hydrogen peroxide reactions on cocaine in hair using imaging mass spectrometry. *Forens Sci Int.* 242:103-110.
39. Tanaka S, Iio R, Takayama N., Hayakawa K. 2001. Identification of reaction products of methamphetamine and hydrogen peroxide in hair dye and decolorant treatments by high performance liquid chromatography/mass spectrometry. *Biomed Chromatogr.* 15:45-49.
40. Pritchett JS, Phinney KW. 2015. Influence of chemical straightening on the stability of drugs of abuse in hair. *J Anal Toxicol.* 39:13-16.
41. Baeck S, Han E, Chung H, Pyo M. 2011. Effects of repeated hair washing and a single hair dyeing on concentrations of methamphetamine and amphetamine in human hairs. *Forens Sci Int.* 206:77-80.
42. Kidwell DA, Smith FP, Shepherd AR. 2015. Ethnic hair care products may increase false positives in hair drug testing. *Forens Sci Int.* 257:160-164.
43. Hill V, Loni E, Cairns T, Sommer J, Schaffer M. 2014. Identification and analysis of damaged or porous hair. *Drug Test Anal.* 6:42-54.

44. European Workplace Drug Testing Society. 2015. European guidelines for workplace drug and alcohol testing in hair. 2015-11-01 Version 2.0. Retrieved from <http://www.ewdts.org/>.
45. Cooper GAA, Kronstrand R, Kintz P. 2012. Society of hair testing guidelines for drug testing in hair. *Forens Sci Int.* 218:20-24.
46. Hill V, Cairns T, Cheng CC, Schaffer M. 2005. Multiple aspects of hair analysis for opiates: methodology, clinical and workplace populations, codeine, and poppy seed ingestion. *J Anal Toxicol.* 29:696-703.

## **Summary**

The Department believes that the benefits of pursuing the proposed Mandatory Guidelines using Hair outweigh the costs to include this additional specimen type in federal workplace drug testing programs. There is no requirement for federal agencies to use hair as part of their drug testing program. A federal agency may choose to use urine, oral fluid, hair or any combination of specimen types in accordance with the Mandatory Guidelines for each matrix in their program based on the agency's mission, its employees' duties, and the danger to the public health and safety or to national security that could result from an employee's failure to carry out the duties of his or her position.

Dated: July 20, 2020.

**Elinore F. McCance-Katz,**

*Assistant Secretary for Mental Health and Substance Use,*

*Substance Abuse and Mental Health Services Administration.*

Approved: July 23, 2020.

**Alex M. Azar II,**

*Secretary,*

*Department of Health and Human Services.*

The Mandatory Guidelines using Hair are hereby proposed to be adopted in accordance with section 503 of Public Law 100–71 and Executive Order 12564.

## **MANDATORY GUIDELINES FOR FEDERAL WORKPLACE DRUG TESTING PROGRAMS USING HAIR**

### **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 – Hair Specimens**

- 2.1 What type of specimen may be collected?
- 2.2 Under what circumstances may a hair specimen be collected?

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

### **Subpart C – Hair Specimen Tests**

- 3.1 Which tests are conducted on a hair specimen?
- 3.2 May a hair 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 hair?
- 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 hair specimen as adulterated?
- 3.7 What criteria are used to report a hair specimen as substituted?
- 3.8 What criteria are used to report an invalid result for a hair 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 a trainer for collectors?
- 4.5 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 hair 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 – Hair Specimen Collection Materials**

- 7.1 What is used to collect a hair specimen?
- 7.2 What are the requirements for hair collection materials?
- 7.3 What are the minimum performance requirements for hair collection materials?

### **Subpart H – Hair Specimen Collection Procedure**

- 8.1 What privacy must the donor be given when providing a hair specimen?
- 8.2 What must the collector ensure at the collection site before starting a hair specimen collection?
- 8.3 What are the preliminary steps in the hair specimen collection procedure?

- 8.4 What steps does the collector take in the collection procedure before the donor provides a hair specimen?
- 8.5 What steps does the collector take during and after the hair specimen collection procedure?
- 8.6 What procedure is used when the donor is unable to provide a hair specimen?
- 8.7 If the donor is unable to provide a hair specimen, may another specimen type be collected for testing?
- 8.8 How does the collector prepare the hair specimens?
- 8.9 How does the collector report a donor's refusal to test?
- 8.10 What are a federal agency's responsibilities for a collection site?

### **Subpart I – HHS Certification of Laboratories**

- 9.1 Who has the authority to certify laboratories to test hair specimens for federal agencies?
- 9.2 What is the process for a laboratory to become HHS-certified?
- 9.3 What is the process for a laboratory to maintain HHS certification?
- 9.4 What is the process when a laboratory 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 that seeks to perform hair testing?
- 9.7 What are the PT requirements for an HHS-certified hair laboratory?
- 9.8 What are the inspection requirements for an applicant laboratory?
- 9.9 What are the maintenance inspection requirements for an HHS-certified laboratory?

- 9.10 Who can inspect an HHS-certified laboratory and when may the inspection be conducted?
- 9.11 What happens if an applicant laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?
- 9.12 What happens if an HHS-certified laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?
- 9.13 What factors are considered in determining whether revocation of a laboratory's HHS certification is necessary?
- 9.14 What factors are considered in determining whether to suspend a laboratory's HHS certification?
- 9.15 How does the Secretary notify an HHS-certified laboratory that action is being taken against the laboratory?
- 9.16 May a laboratory that had its HHS certification revoked be recertified to test federal agency specimens?
- 9.17 Where is the list of HHS-certified laboratories published?

#### **Subpart J – Blind Samples Submitted by an Agency**

- 10.1 What are the requirements for federal agencies to submit blind samples to HHS-certified laboratories?
- 10.2 What are the requirements for blind samples?
- 10.3 How is a blind sample submitted to an HHS-certified laboratory?
- 10.4 What happens if an inconsistent result is reported for a blind sample?

## **Subpart K – Laboratory**

- 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?
- 11.2 What are the responsibilities of the responsible person (RP)?
- 11.3 What scientific qualifications must the RP have?
- 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?
- 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?
- 11.6 What qualifications and training must other personnel of an HHS-certified laboratory have?
- 11.7 What security measures must an HHS-certified laboratory maintain?
- 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?
- 11.9 How must an HHS-certified laboratory process an alternate specimen that was collected at the same time as a hair specimen?
- 11.10 What amount of hair is tested?
- 11.11 What are the requirements for an initial drug test?
- 11.12 What must an HHS-certified laboratory do to validate an initial drug test?
- 11.13 What are the batch quality control requirements when conducting an initial drug test?
- 11.14 What are the requirements for a confirmatory drug test?
- 11.15 What must an HHS-certified laboratory do to validate a confirmatory drug test?
- 11.16 What are the batch quality control requirements when conducting a confirmatory drug test?
- 11.17 What are the analytical and quality control requirements for conducting specimen validity

tests?

- 11.18 What must an HHS-certified laboratory do to validate a specimen validity test?
- 11.19 What are the requirements for an HHS-certified laboratory to report a test result?
- 11.20 How long must an HHS-certified laboratory retain specimens?
- 11.21 How long must an HHS-certified laboratory retain records?
- 11.22 What statistical summary reports must an HHS-certified laboratory provide for hair testing?
- 11.23 What HHS-certified laboratory information is available to a federal agency?
- 11.24 What HHS-certified laboratory information is available to a federal employee?
- 11.25 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

#### **Subpart L – Instrumented Initial Test Facility (IITF)**

- 12.1 May an IITF test hair specimens for a federal agency’s workplace drug testing program?

#### **Subpart M – Medical Review Officer (MRO)**

- 13.1 Who may serve as an MRO?
- 13.2 How are nationally recognized entities or subspecialty boards that certify MROs approved?
- 13.3 What training is required before a physician may serve as an MRO?
- 13.4 What are the responsibilities of an MRO?
- 13.5 What must an MRO do when reviewing a hair specimen’s test results?
- 13.6 What action does the MRO take when the collector reports that the donor did not provide

a sufficient amount of hair for a drug test?

- 13.7 Who may request a test of a split (B) hair specimen?
- 13.8 How does an MRO report a primary (A) specimen test result to an agency?
- 13.9 What types of relationships are prohibited between an MRO and an HHS-certified laboratory?

### **Subpart N – Split Specimen Tests**

- 14.1 When may a split (B) hair specimen be tested?
- 14.2 How does an HHS-certified laboratory test a split (B) hair specimen when the primary (A) specimen was reported adulterated?
- 14.3 How does an HHS-certified laboratory test a split (B) hair specimen when the primary (A) specimen was reported substituted?
- 14.4 Who receives the split (B) specimen result?
- 14.5 What action(s) does an MRO take after receiving the split (B) hair specimen result from the second HHS-certified laboratory?
- 14.6 How does an MRO report a split (B) specimen test result to an agency?
- 14.7 How long must an HHS-certified laboratory retain a split (B) specimen?

### **Subpart O - Criteria for Rejecting a Specimen for Testing**

- 15.1 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing?
- 15.2 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing unless the discrepancy is corrected?

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

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

### **Subpart P - Laboratory Suspension/Revocation Procedures**

16.1 When may the HHS certification of a laboratory be suspended?

16.2 What definitions are used for this subpart?

16.3 Are there any limitations on issues subject to review?

16.4 Who represents the parties?

16.5 When must a request for informal review be submitted?

16.6 What is an abeyance agreement?

16.7 What procedures are used to prepare the review file and written argument?

16.8 When is there an opportunity for oral presentation?

16.9 Are there expedited procedures for review of immediate suspension?

16.10 Are any types of communications prohibited?

16.11 How are communications transmitted by the reviewing official?

16.12 What are the authority and responsibilities of the reviewing official?

16.13 What administrative records are maintained?

16.14 What are the requirements for a written decision?

16.15 Is there a review of the final administrative action?

## **Subpart A - Applicability**

### Section 1.1 To whom do these Guidelines apply?

(a) These Guidelines apply to:

(1) Executive Agencies as defined in 5 U.S.C. 105;

(2) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));

(3) Any other employing unit or authority of the federal government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and

(4) The Intelligence Community, as defined by Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;

(5) Laboratories that provide drug testing services to the federal agencies;

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

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

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

### 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 a normal constituent (e.g., nitrite in urine).

Aliquot. A portion of a specimen used for testing.

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

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

Artificial hair. A weave or other synthetic forms of hair, as well as animal substitutes.

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), the specimen has been rejected for testing, when a hair specimen has been reported as positive and the MRO directs testing of the alternate specimen for the donor, 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 donor's drug test 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 an initial 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 substituted) or the need for further testing.

Decontamination. The removal of external contamination (i.e., environmentally-deposited drug) in or on a hair specimen.

Donor. The individual from whom a specimen is collected.

External Service Provider. An independent entity that performs services related to federal workplace drug testing on behalf of a federal agency, a collector/collection site, an HHS-certified laboratory, a Medical Review Officer (MRO), or, for urine, an HHS-certified Instrumented Initial Test Facility (IITF).

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

False Hair. Hair that is not the donor's hair. False hair may be artificial or human in origin.

Federal Drug Testing Custody and Control Form (Federal CCF). The Office of Management and Budget (OMB) approved form that is used to document the collection and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (i.e., HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic, or combination electronic and paper format (hybrid). The form may also be used to report the test result to the Medical Review Officer.

HHS. The Department of Health and Human Services.

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

Initial Specimen Validity Test. The first analysis used to determine if a specimen is

invalid, adulterated, or substituted.

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

Invalid Result. The result reported by an HHS-certified laboratory in accordance with the criteria established in Section 3.8 when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test.

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

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

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

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

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

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

Performance Testing (PT) Sample. A program-generated sample sent to a laboratory or

(for urine) to an IITF to evaluate performance.

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

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

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

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

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

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

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

Specimen guide. An item that holds the hair specimen as positioned by the collector, and has an indication of the orientation (i.e., root or distal end) of the hair specimen collected.

Split Specimen Collection (for Hair). 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 with physical or chemical characteristics that are not consistent with those observed in human hair.

Wash procedures. A rinse with organic solvents to remove oils and residue on the hair prior to initial testing.

Unique metabolite. A drug metabolite present in a hair specimen only as a result of biotransformation following drug use, and whose detection by a confirmatory drug test distinguishes drug use from external contamination. A unique metabolite does not occur as a contaminant in licit and illicit drug products and is not produced from the drug as an artifact and only results from biotransformation following drug use.

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

Consistent with 5 U.S.C. 552a and 48 CFR 24.101-24.104, all agency contracts with laboratories, collectors, and MROs must require that they comply with the Privacy Act, 5 U.S.C. 552a. In addition, the contracts must require compliance with employee access and confidentiality provisions of Section 503 of Public Law 100-71. Each federal agency must establish a Privacy Act System of Records or modify an existing system or use any applicable Government-wide system of records to cover the records of employee drug test results. All contracts and the Privacy Act System of Records must specifically require that employee records be maintained and used with the highest regard for employee privacy.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule (Rule), 45 CFR Parts 160 and 164, Subparts A and E, may be applicable to certain health care providers with whom a federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it

maintains in accordance with the requirements of the Rule, which includes not using or disclosing the information except as permitted by the Rule and ensuring there are reasonable safeguards in place to protect the privacy of the information. For more information regarding the HIPAA Privacy Rule, please visit <http://www.hhs.gov/ocr/hipaa>.

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

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

(1) Fail to appear for any test (except a pre-employment test) within a reasonable time, as determined by the federal agency, consistent with applicable agency regulations, after being directed to do so by the federal agency;

(2) Fail to remain at the collection site until the collection process is complete with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test as described in Section 8.5(d);

(3) Fail to provide a hair specimen for any drug test required by these Guidelines or federal agency regulations with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test as described in Section 8.5(d); or a donor who is unable to provide a sufficient amount of hair for faith-based or medical reasons, or due to an insufficient amount or length of hair; or when the collector identifies lice or a similar infestation in the hair.

(4) Fail or decline to participate in an alternate specimen collection (e.g., urine, oral fluid) as directed by the federal agency or collector (i.e., as described in Section 8.5);

(5) Fail to cooperate with any part of the testing process (e.g., disrupt the collection process; refuse to allow the collector to collect a sufficient amount of hair; fail to provide a split specimen);

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

(7) Attempt to adulterate or substitute the specimen; or

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

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

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

(b) When a donor has refused to participate in a part of the collection process, the collector must terminate 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 facsimile [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 and 13.5, 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 - Hair Specimens**

### Section 2.1 What type of specimen may be collected?

a. Only specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs may be collected.

b. A federal agency may collect hair and/or an alternate specimen type for its workplace drug testing program, but may not implement hair testing as the exclusive means of drug testing. A federal agency using hair testing must follow these Guidelines.

c. A federal agency that collects hair specimens for its workplace drug testing program must also authorize an alternate specimen type to be collected either:

(1) at the time that a donor's hair specimen is collected, or

(2) at the direction of the MRO, following verification of a hair test as positive or invalid, or when the laboratory rejected the hair specimen.

Alternate specimens collected under Section 2.1(c)(1) and (2) can be tested only if an MRO directs, in writing, that such specimens be tested and following the MRO's receipt and verification of a positive, invalid, or rejected hair test result from a laboratory (see Section 13.5).

d. A federal agency that collects hair specimens for its workplace drug testing program must also authorize the collection of one or more alternative specimen types when a donor is unable to provide a sufficient amount of hair for faith-based or medical reasons, or due to an insufficient amount or length of hair.

### Section 2.2 Under what circumstances may a hair specimen be collected?

A federal agency may only collect a hair specimen for federal agency pre-employment and random testing purposes, and may not use hair specimens for reasonable suspicion/cause, post accident, return to duty, or follow-up testing purposes (i.e., for purposes other than pre-employment or random testing).

Section 2.3 How is each hair specimen collected?

Each hair specimen is collected as a split specimen as described in Sections 2.5 and 8.8.

Section 2.4 What amount of hair is collected?

At least 100 mg of hair is collected, as described in Section 8.5.

Section 2.5 How does the collector split the hair specimen collected?

The collector subdivides the collected hair into 2 specimens designated as “A” (primary) and “B” (split) as described in Section 8.5.

Section 2.6 When may an entity or individual release a hair 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 13.9.

## **Subpart C – Hair Drug and Specimen Validity Tests**

### Section 3.1 Which tests are conducted on a hair specimen?

A federal agency:

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

Section 3.4;

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

(c) Is authorized to test hair specimens for damage that may affect drug test results;

(d) Is authorized upon a Medical Review Officer's request to test a hair specimen to determine specimen validity, using, for example, a test for a biomarker or a test for a specific adulterant; and

(e) May perform additional testing if a specimen exhibits abnormal 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.

### Section 3.2 May a hair specimen be tested for additional drugs?

For approval to routinely test for any drugs listed in Schedule I or II of the Controlled Substances Act that are not listed in Section 3.1, a federal agency must petition the Secretary in writing. Such approval must be limited to the use of the appropriate science and technology. If an initial test procedure is not available upon request for a Schedule I or Schedule II drug, the HHS-certified laboratory must test for the drug using the confirmatory analytical method. For

any specimen with a positive result, the laboratory must test a separate aliquot of the specimen in a separate testing batch using the same confirmatory analytical method. Additionally, the split (B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

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 hair?

<b>Initial Test Analyte</b>	<b>Initial Test Cutoff<sup>1</sup></b>	<b>Confirmatory Test Analyte</b>	<b>Confirmatory Test Cutoff Concentration</b>
Marijuana Metabolites (THCA) <sup>2</sup>	1 pg/mg <sup>3</sup>	THCA	0.05 pg/mg
Cocaine/	500 pg/mg <sup>3</sup>	Cocaine	500 pg/mg

Benzoyllecgonine		Benzoyllecgonine	50 pg/mg
Codeine/ Morphine/ 6-Acetylmorphine	200 pg/mg	Codeine Morphine 6-Acetylmorphine	200 pg/mg 200 pg/mg 200 pg/mg
Hydrocodone/ Hydromorphone	200 pg/mg	Hydrocodone Hydromorphone	200 pg/mg 200 pg/mg
Oxycodone/ Oxymorphone	200 pg/mg	Oxycodone Oxymorphone	200 pg/mg 200 pg/mg
Phencyclidine	300 pg/mg	Phencyclidine	300 pg/mg
Amphetamine/ Methamphetamine <sup>4</sup>	500 pg/mg <sup>3</sup>	Amphetamine Methamphetamine	300 pg/mg 300 pg/mg
MDMA <sup>5</sup> /MDA <sup>6</sup>	500 pg/mg <sup>3</sup>	MDMA MDA	300 pg/mg 300 pg/mg

<sup>1</sup>For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):

**Immunoassay:** The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.

<p><b>Alternate technology:</b> Either one analyte or analytes as grouped in the table above 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.</p>
<p><sup>2</sup>An immunoassay must be calibrated with the target analyte, L-Δ-9-tetrahydrocannabinol-9-carboxylic acid (THCA).</p>
<p><sup>3</sup><b>Alternate technology (THCA):</b> The confirmatory test cutoff (i.e., 0.05 pg/mg) must be used for an alternate technology initial test that is specific for THCA).</p>
<p><sup>4</sup>An immunoassay must be calibrated with the target analyte, D-amphetamine or D-methamphetamine.</p>
<p><sup>5</sup>Methylenedioxymethamphetamine (MDMA)</p>
<p><sup>6</sup>Methylenedioxyamphetamine (MDA)</p>

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

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

control requirements in accordance with these Guidelines.

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

An HHS-certified laboratory reports a hair specimen as adulterated when the presence of an adulterant is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

Section 3.7 What criteria are used to report a hair specimen as substituted?

An HHS-certified laboratory documents and reports a hair specimen as substituted if it has physical or chemical characteristics inconsistent with those observed in human hair. Such documentation should briefly describe the physical or chemical characteristics that are inconsistent with human hair.

Section 3.8 What criteria are used to report an invalid result for a hair specimen?

An HHS-certified laboratory reports a primary (A) hair specimen as an invalid result when:

- (a) Interference occurs on the initial drug tests on two separate aliquots (i.e., valid initial drug test results cannot be obtained);
- (b) Interference with the confirmatory drug assay occurs on two separate aliquots of the specimen and the laboratory is unable to identify the interfering substance;
- (c) The specimen has been tested and the color of the primary (A) and the split (B) specimens are clearly different;
- (d) The laboratory determines the hair is damaged (i.e., using a validated method) to the

extent that the drug test result may be affected; or

(e) The laboratory obtains a positive confirmatory drug test result and is unable to definitively remove external contamination from the specimen (i.e., using a validated decontamination procedure).

## **Subpart D - Collectors**

### Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect hair 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 must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.

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

#### Section 4.3 What are the requirements to be a collector?

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

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

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

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

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

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

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

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

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

(i) The five mock collections must include two uneventful collection scenarios, one

insufficient specimen quantity scenario, one scenario in which the donor refuses to sign the Federal CCF, and one scenario in which the donor refuses to initial the specimen container 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 a trainer for collectors?

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

(1) Qualified as a trained collector and regularly conducted hair 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 4.5 What must a federal agency do before a collector is permitted to collect a specimen?

A federal agency must ensure the following:

- (a) The collector has satisfied the requirements described in Section 4.3;
- (b) The collector, who may be self-employed, or an organization (e.g., third party administrator that provides a collection service, collector training company, federal agency that employs its own collectors) maintains a copy of the training record(s); and
- (c) The collector has been provided the name and telephone number of the federal agency representative.

**Subpart E - Collection Sites**

Section 5.1 Where can a collection for a drug test take place?

- (a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.
- (b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect a hair specimen, another site may be used for the collection, providing the collection is performed by a trained hair specimen collector.

Section 5.2 What are the requirements for a collection site?

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

- (a) Provisions to ensure donor privacy during the collection (as described in Section 8.1);
- (b) A suitable and clean surface area that is not accessible to the donor for handling the specimens and completing the required paperwork;
- (c) A secure temporary storage area to maintain specimens until the specimen is transferred to an HHS-certified laboratory;
- (d) A restricted access area where only authorized personnel may be present during the collection;
- (e) A restricted access area for the storage of collection supplies; and
- (f) A restricted access area for the secure storage of records.

### Section 5.3 Where must collection site records be stored?

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

### Section 5.4 How long must collection site records be stored?

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

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

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

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

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

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

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

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

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

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

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

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

The collector collects hair from the donor (as described in Section 8.5). The donor must be allowed privacy while the collector obtains the hair specimen. Collections must be performed at a site that provides reasonable privacy (as described in Section 8.1).

### **Subpart F - Federal Drug Testing Custody and Control Form**

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

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

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

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

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

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

**Subpart G – Hair Specimen Collection Materials**

### Section 7.1 What is used to collect a hair specimen?

Collection materials include a means (i.e., single-use or reusable scissors) to cut the hair, individually packaged isopropyl alcohol wipe (i.e., to clean reusable scissors), two specimen guides (items that hold the hair specimen as positioned by the collector), and two sealable collection containers (e.g., envelopes) labelled A for the primary (A) and B for the split (B) specimens.

### Section 7.2 What are the requirements for hair collection materials?

(a) The specimen guides and the collection containers must not substantially affect the composition of drugs and/or drug metabolites in the hair specimen.

(b) All collection items (e.g., scissors, clip) that come into contact with the hair must be single-use items or must be cleaned before each use, as described in section 8.4.

(c) The specimen guides and containers 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 for the presence of drugs and/or their metabolites.

(d) The specimen guides and containers must be sufficiently transparent to enable an assessment of specimen appearance and identification of abnormal physical characteristics without opening the container.

### Section 7.3 What are the minimum performance requirements for hair collection materials?

(a) The specimen guides must be capable of holding the hair specimen as positioned by the collector, and have an indication of the orientation (i.e., root or distal end) of the hair specimen collected.

(b) The specimen guides or containers must have graduated markings or guides for collectors to verify the minimum width and length of hair that would equate to 100 mg of hair or 50 mg of hair in each container labeled A and B.

## **Subpart H – Hair Specimen Collection Procedure**

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

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

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

(b) The collector is not required to be the same gender as the donor.

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

The collector must take all reasonable steps to prevent the adulteration or substitution of a hair specimen at the collection site.

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

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

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

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

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

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

(e) If, at any point in the collection, the collector sees any item that appears to have been brought by the donor to the collection site with the intent to adulterate or substitute the specimen, this is considered a refusal to test. The collector must stop the collection and report the refusal to test as described in Section 8.9.

(f) If, at any point in the collection, the collector sees any evidence that the donor has lice or similar infestation in his or her hair, the collector immediately stops the collection procedure. The collector records the reason for not collecting a hair specimen on the Federal CCF, contacts the federal agency's designated representative for authorization to collect an alternate specimen, and assuming proper authorization is provided, begins 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 alternate specimen. The collector sends the appropriate copies of the Federal CCF used for the hair specimen to the MRO and to the federal agency's

designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to contact the agency's designated representative for authorization in each case.

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

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

(i) The collector informs the donor that the instructions for completing the Federal Custody and Control Form are located on the Federal CCF (e.g., on the back of Copy 5 or on a separate page) or are available upon request.

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

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

(a) At the beginning of the collection, the collector must put on single-use gloves that are clean and unused. The collector must remove the gloves from the package in the presence of the donor.

(b) The collector will provide or the donor may select specimen collection materials that are clean, unused, and wrapped/sealed in original packaging. The specimen collection materials will be opened in view of the donor. Specimen collection materials must be single-use, with the exception of scissors and/or clips which may be either single-use or reusable (as described in item 2 below).

(1) Both the donor and the collector must keep the unwrapped collection materials in view at all times until the container containing the donor's hair specimen has been sealed and labeled.

(2) Scissors and/or clips may be reused provided that the collector cleans such items in the presence of the donor with an isopropyl alcohol wipe prior to use in the hair collection. If single-use items are used, the collector is not required to clean the item before use assuming such use is the first use of the item.

(c) The collector reviews with the donor the procedures required for hair specimen collection as stated in the instructions for the specimen collection kit.

(d) The collector asks the donor whether they have false hair (i.e., artificial or natural hair that is not their own such as a wig, weave, or extensions). If the donor admits the presence of false hair or the collector identifies false hair after the donor denies having false hair, this does not constitute a refusal to test. If the collector can collect a sufficient amount of the donor's own hair, the collector proceeds with the collection.

(e) If the collector is unable to collect the donor's hair, the collector immediately stops the collection procedure. The collector records the reason for not collecting a hair specimen on the Federal CCF, contacts the federal agency's designated representative for authorization to collect the alternate specimen, and assuming proper authorization is provided, begins 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 alternate specimen. The collector sends the appropriate copies of the Federal CCF used for the hair specimen to the MRO and to the federal agency's designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring

the collector to contact the agency's designated representative for authorization in each case.

(f) 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, the collector must report a refusal to test in accordance with Section 8.9.

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

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

(a) The collector shall be present and maintain visual contact with the donor during the procedures outlined in this section.

(b) The collector cuts a portion of the donor's hair that is approximately one-half (0.5) inches wide and at least one (1.0) inch long on the crown (i.e., posterior vertex) of the head and as close to the scalp as possible.

(1) The collector must ensure that at least 100 mg of hair is collected for testing.

(2) If the donor's hair is sparse or is short (i.e., between one-half and one inch long), the collector may collect hair from multiple sites on the posterior vertex and back of the head, avoiding the front and side regions.

(3) If the donor's hair is less than one-half inch long or if the collector cannot collect at least 100 mg from the posterior vertex or back of the head, the collector stops the collection and takes actions described in Section 8.6.

(c) The collector subdivides the hair specimen into two approximately equal specimens (A and B), and places specimen A in the first specimen guide and specimen B in the second

specimen guide. If possible, the collector aligns the hairs with the root end identified as indicated on the specimen guide. For short hair (between one-half and one inch long), the collector is not required to identify the root end. The collector secures the hair in each specimen guide (e.g., folds the guide).

(d) If the donor fails to remain present through the completion of the collection, fails to follow the instructions for the collection, refuses to allow the collector to collect sufficient hair as required in step (b) above for reasons other than those described in Section 2.1, or refuses to provide an alternate specimen when directed to do so, the collector stops the collection and reports the refusal to test in accordance with Section 8.9.

(e) If the federal agency requires collection of an alternate specimen at the same time as the hair collection, the collector should collect the hair specimen first, and then collect the other authorized specimen (e.g., urine or oral fluid) using the applicable collection procedures described in the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen.

(i) The collector must record a comment on the Federal CCF for each specimen with sufficient information to link the two specimens (including the unique specimen identification number of the associated specimen).

(ii) The collector must also record a comment on the Federal CCF for the alternate specimen noting that the laboratory is to hold the specimen for testing pending the MRO's request for testing.

(iii) The collector must forward the hair specimen to an HHS-certified hair testing laboratory. The collector forwards the alternate specimen, if one is authorized to be collected at the same time as the hair specimen, to a laboratory that is certified by HHS for that specimen

type. The laboratory will accession and store the alternate specimen under appropriate storage conditions in the event that the MRO requests testing as described in Section 13.5.

Section 8.6 What procedure is used when the donor is unable to provide a hair specimen?

If the donor is unable to provide a hair specimen (i.e., as described in sections 2.1, 8.3, and 8.4), the collector records the reason for not collecting a hair specimen on the Federal CCF, contacts the federal agency's designated representative for authorization to collect an alternate specimen, and assuming proper authorization is provided, begins the collection procedure for the alternate specimen authorized by the federal agency (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen. The collector sends the appropriate copies of the Federal CCF used for the hair specimen to the MRO and to the federal agency's designated representative. The federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to contact the agency's designated representative for authorization to collect an alternate specimen in each case.

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

Yes. A federal agency that elects to implement hair testing is required to authorize collections of one or more alternate specimen types authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Section 8.8 How does the collector prepare the hair specimens?

(a) All federal agency collections are to be split specimen collections.

(b) After placing the A and B hair specimens (i.e., in the specimen guides) into separate envelopes, in the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF on each envelope. The collector records the date of the collection on the tamper-evident labels/seals.

(c) The collector instructs the donor to initial the tamper-evident labels/seals on each specimen envelope. If the donor refuses to initial the labels/seals, the collector notes the refusal on the Federal CCF and continues with the collection process.

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

(e) 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.

(f) 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.

(g) The collector seals the specimens (A and B) in a package and, within 24 hours or during the next business day, sends them to the HHS-certified laboratory that will be testing the primary (A) hair specimen.

(h) If the specimen and Federal CCF are not immediately transported to an HHS-certified laboratory, they must remain under direct control of the collector or be appropriately secured under proper specimen storage conditions until transported.

Section 8.9 How does the collector report a donor's refusal to test?

If there is a refusal to test as defined in Section 1.7, the collector stops the collection, discards any hair specimen collected and reports the refusal to test by:

(a) Notifying the federal agency by means (e.g., telephone, e-mail, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test including the reason on the Federal CCF. In the event that a donor is unable to provide a sufficient amount of hair for faith-based or medical reasons, or due to an insufficient amount or length of hair, the collector must specify the circumstances, and

(c) Sending all copies of the Federal CCF to the federal agency's designated representative.

Section 8.10 What are a federal agency's responsibilities for a collection site?

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

(b) A federal agency (or only one federal agency when several agencies are using the same collection site) must inspect 5 percent or up to a maximum of 50 collection sites each year, selected randomly from those sites used to collect agency specimens (e.g., virtual, onsite, or self-evaluation).

(c) A federal agency must investigate reported collection site deficiencies (e.g., specimens reported "rejected for testing" by an HHS-certified laboratory) and take appropriate action which may include a collection site self-assessment (i.e., using the Collection Site Checklist for the Collection of Hair Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection

sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

## **Subpart I - HHS Certification of Laboratories**

### Section 9.1 Who has the authority to certify laboratories to test hair specimens for federal agencies?

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

(b) A laboratory is prohibited from stating or implying that it is certified by HHS under these Guidelines to test hair specimens for federal agencies unless it holds such certification.

### Section 9.2 What is the process for a laboratory to become HHS-certified?

(a) A laboratory seeking HHS certification must:

(1) Submit a completed OMB-approved application form (i.e., the applicant laboratory provides detailed information on both the administrative and analytical procedures to be used for federally regulated specimens);

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

(3) Successfully complete the PT challenges in 3 consecutive sets of initial PT samples;

(4) Satisfy all the requirements for an initial inspection; and

(5) Receive notification of certification from the Secretary before testing specimens for federal agencies.

### Section 9.3 What is the process for a laboratory to maintain HHS certification?

(a) To maintain HHS certification, a laboratory must:

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

(2) Respond in an appropriate, timely, and complete manner to required corrective action requests if deficiencies are identified in the maintenance PT performance, during the inspections, operations, or reporting; and

(3) Satisfactorily complete corrective remedial actions, and undergo special inspection and special PT sets to maintain or restore certification when material deficiencies occur in either the PT program, inspection program, or in operations and reporting.

Section 9.4 What is the process when a laboratory does not maintain its HHS certification?

(a) A laboratory that does not maintain its HHS certification must:

(1) Stop testing federally regulated specimens;

(2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.20, 11.21, and 14.7;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.23 and 11.24 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. The PT samples must satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff concentration for the drug or drug metabolite;

(ii) The concentration of a drug or metabolite may be as low as 40 percent of the confirmatory test cutoff concentration when the PT sample is designated as a retest sample; or

(iii) The concentration of drug or metabolite may differ from 9.5(a)(1)(i) and 9.5(a)(1)(ii) for a special purpose.

(2) A PT sample may contain an interfering substance or other substances for special purposes.

(3) A PT sample may be prepared in various ways (e.g., using drug user hair, hair externally contaminated with drug analytes, hair subjected to cosmetic treatments) to challenge the laboratory's decontamination and test procedures.

(4) A negative PT sample will not contain a measurable amount of a target analyte.

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

Section 9.6 What are the PT requirements for an applicant laboratory that seeks to perform hair testing?

(a) An applicant laboratory that seeks certification under these Guidelines to perform hair testing 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  $\pm 20$  percent or  $\pm 2$  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  $\pm 50$  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  $\pm 20$  percent or  $\pm 2$  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) For each confirmatory drug test, correctly identify a sample that has been contaminated with one or more drugs;

(b) Failure to satisfy these requirements will result in the denial of the laboratory's application for HHS certification to perform hair testing.

#### Section 9.7 What are the PT requirements for an HHS-certified hair laboratory?

(a) A laboratory certified under these Guidelines to perform hair testing 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  $\pm 20$  percent or  $\pm 2$  standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(5) For the confirmatory drug tests, must not obtain any drug concentration that differs by

more than  $\pm 50$  percent from the appropriate reference or peer group means;

(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  $\pm 20$  percent or  $\pm 2$  standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(7) For each confirmatory drug test, correctly identify a sample contaminated with one or more drugs;

(b) Failure to participate in all PT cycles or to satisfy these requirements may result in suspension or revocation of an HHS-certified laboratory's certification.

Section 9.8 What are the inspection requirements for an applicant laboratory?

(a) An applicant laboratory is inspected by a team of two inspectors.

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

Section 9.9 What are the maintenance inspection requirements for an HHS-certified laboratory?

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

(b) An HHS-certified laboratory is inspected by two or more inspectors. The number of inspectors is determined according to the number of specimens to be reviewed. Additional information regarding inspections is available from SAMHSA.

(c) Inspectors conduct an independent evaluation and review of the HHS-certified

laboratory's procedures, records, and facilities using guidance provided by the Secretary.

(d) To remain certified, an HHS-certified laboratory must continue to satisfy the minimum requirements as stated in these Guidelines.

Section 9.10 Who can inspect an HHS-certified laboratory and when may the inspection be conducted?

(a) An individual may be selected as an inspector for the Secretary if they satisfy the following criteria:

(1) Has experience and an educational background similar to that required for either a responsible person or a certifying scientist for an HHS-certified laboratory as described in Subpart K;

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

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

(4) Attends approved training; and

(5) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory.

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

Section 9.11 What happens if an applicant laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

If an applicant laboratory fails to satisfy the requirements established for the initial certification process, the laboratory must start the certification process from the beginning.

Section 9.12 What happens if an HHS-certified laboratory does not satisfy the minimum requirements for either the PT program or the inspection program?

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

(b) A laboratory's HHS certification may be revoked, suspended, or no further action taken depending on the seriousness of the deficiencies and whether there is evidence that the deficiencies have been corrected and that current performance meets the requirements for certification.

(c) An HHS-certified laboratory may be required to undergo a special inspection or to test additional PT samples to address deficiencies.

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

Section 9.13 What factors are considered in determining whether revocation of a laboratory's HHS certification is necessary?

(a) The Secretary shall revoke certification of an HHS-certified laboratory in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure fully reliable and accurate drug test results and reports.

(b) The Secretary shall consider the following factors in determining whether revocation

is necessary:

(1) Unsatisfactory performance in analyzing and reporting the results of drug tests (e.g., an HHS-certified laboratory reporting a false positive result for an employee's drug test);

(2) Unsatisfactory participation in performance testing or inspections;

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

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

(5) Any other cause that materially affects the ability of the HHS-certified laboratory to ensure fully reliable and accurate drug test results and reports.

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

Section 9.14 What factors are considered in determining whether to suspend a laboratory's HHS certification?

(a) The Secretary may immediately suspend (either partially or fully) a laboratory's HHS certification to conduct drug testing for federal agencies if the Secretary has reason to believe that revocation may be required and that immediate action is necessary to protect the interests of the United States and its employees.

(b) The Secretary shall determine the period and terms of suspension based upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug testing.

Section 9.15 How does the Secretary notify an HHS-certified laboratory that action is being taken against the laboratory?

(a) When a laboratory's HHS certification is suspended or the Secretary seeks to revoke HHS certification, the Secretary shall immediately serve the HHS-certified laboratory with written notice of the suspension or proposed revocation by fax, mail, personal service, or registered or certified mail, return receipt requested. This notice shall state the following:

- (1) The reasons for the suspension or proposed revocation;
- (2) The terms of the suspension or proposed revocation; and
- (3) The period of suspension or proposed revocation.

(b) The written notice shall state that the laboratory will be afforded an opportunity for an informal review of the suspension or proposed revocation if it so requests in writing within 30 days of the date the laboratory received the notice, or if expedited review is requested, within 3 days of the date the laboratory received the notice. Subpart P contains detailed procedures to be followed for an informal review of the suspension or proposed revocation.

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

(d) The Secretary will publish in the **Federal Register** the name, address, and telephone number of any HHS-certified laboratory that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any HHS-certified laboratory that has its suspension lifted. The Secretary shall provide to any member of the public upon request the

written notice provided to a laboratory that has its HHS certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of Subpart P.

Section 9.16 May a laboratory that had its HHS certification revoked be recertified to test federal agency specimens?

Following revocation, a laboratory may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under Section 9.15 or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory which has had its certification revoked may reapply for HHS certification as an applicant laboratory.

Section 9.17 Where is the list of HHS-certified laboratories published?

(a) The list of HHS-certified laboratories is published monthly in the **Federal Register**.

This notice is also available on the Internet at <http://www.samhsa.gov/workplace>.

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

**Subpart J - Blind Samples Submitted by an Agency**

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

(a) Each federal agency is required to submit blind samples for its workplace drug testing program. The collector must send the blind samples to the HHS-certified laboratory that the collector sends employee specimens.

(b) Each federal agency must submit at least 3 percent blind samples along with its donor specimens based on the projected total number of donor specimens collected per year (up to a maximum of 400 blind samples). Every effort should be made to ensure that blind samples are submitted quarterly.

(c) Approximately 75 percent of the blind samples submitted each year by an agency must be negative and 25 percent must be positive for one or more drugs.

#### Section 10.2 What are the requirements for blind samples?

(a) Drug positive blind samples must be validated by the supplier using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must contain one or more of the drugs or metabolites listed in Section 3.4.

(2) Drug positive blind samples must contain concentrations of drugs at least 1.5 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) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory, and must provide the information upon request to the MRO, the federal agency for which the blind sample was submitted, or the Secretary.

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

(a) A blind sample must be submitted as a split specimen (specimens A and B) with the

current Federal CCF that the HHS-certified laboratory uses for donor specimens. The collector provides the required information to ensure that the Federal CCF has been properly completed and provides fictitious initials on the specimen label/seal. The collector must indicate that the specimen is a blind sample on the MRO copy where a donor would normally provide a signature.

(b) A collector should attempt to distribute the required number of blind samples randomly with donor specimens rather than submitting the full complement of blind samples as a single group.

#### Section 10.4 What happens if an inconsistent result is reported for a blind sample?

If an HHS-certified laboratory reports a result for a blind sample that is inconsistent with the expected result (e.g., a laboratory reports a negative result for a blind sample that was supposed to be positive, a laboratory reports a positive result for a blind sample that was supposed to be negative):

(a) The MRO must contact the laboratory and attempt to determine if the laboratory made an error during the testing or reporting of the sample;

(b) The MRO must contact the blind sample supplier and attempt to determine if the supplier made an error during the preparation or transfer of the sample;

(c) The MRO must contact the collector and determine if the collector made an error when preparing the blind sample for transfer to the HHS-certified laboratory;

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

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must

be sent to the federal agency. The Secretary shall ensure notification of the finding as appropriate to other federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

## **Subpart K - Laboratory**

### Section 11.1 What must be included in the HHS-certified laboratory's standard operating procedure manual?

(a) An HHS-certified laboratory must have a standard operating procedure (SOP) manual that describes, in detail, all HHS-certified laboratory operations. When followed, the SOP manual ensures that all specimens are tested using the same procedures.

(b) The SOP manual must include at a minimum, but is not limited to, a detailed description of the following:

- (1) Chain of custody procedures;
  - (2) Accessioning;
  - (3) Security;
  - (4) Quality control/quality assurance programs;
  - (5) Analytical methods and procedures;
  - (6) Equipment and maintenance programs;
  - (7) Personnel training;
  - (8) Reporting procedures; and
  - (9) Computers, software, and laboratory information management systems.
- (c) All procedures in the SOP manual must be compliant with these Guidelines and all

guidance provided by the Secretary.

(d) A copy of all procedures that have been replaced or revised and the dates on which the procedures were in effect must be maintained for at least 2 years.

#### Section 11.2 What are the responsibilities of the responsible person (RP)?

(a) Manage the day-to-day operations of the HHS-certified laboratory even if another individual has overall responsibility for alternate areas of a multi-specialty laboratory.

(b) Ensure that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the HHS-certified laboratory. The RP must ensure the continued competency of laboratory staff by documenting their in-service training, reviewing their work performance, and verifying their skills.

(c) Maintain a complete and current SOP manual that is available to all personnel of the HHS-certified laboratory and ensure that it is followed. The SOP manual must be reviewed, signed, and dated by the RP(s) when procedures are first placed into use and when changed or when a new individual assumes responsibility for the management of the HHS-certified laboratory. The SOP must be reviewed and documented by the RP annually.

(d) Maintain a quality assurance program that ensures the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and calibrators; monitor quality control testing; and document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: quality control systems not within performance specifications; errors in result reporting or in analysis of

performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

### Section 11.3 What scientific qualifications must the RP have?

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

(a) Certification or licensure as a laboratory director by the state in forensic or clinical laboratory toxicology, a Ph.D. in one of the natural sciences, or training and experience comparable to a Ph.D. in one of the natural sciences with training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology;

(b) Experience in forensic toxicology with emphasis on the collection and analysis of biological specimens for drugs of abuse;

(c) Experience in forensic applications of analytical toxicology (e.g., publications, court testimony, conducting research on the pharmacology and toxicology of drugs of abuse) or qualify as an expert witness in forensic toxicology;

(d) Fulfillment of the RP responsibilities and qualifications, as demonstrated by the HHS-certified laboratory's performance and verified upon interview by HHS-trained inspectors during each on-site inspection; and

(e) Qualify as a certifying scientist.

### Section 11.4 What happens when the RP is absent or leaves an HHS-certified laboratory?

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If

the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

(1) If an HHS-certified laboratory is without the RP and alternate RP for 14 calendar days or less (e.g., temporary absence due to vacation, illness, or business trip), the HHS-certified laboratory may continue operations and testing of federal agency specimens under the direction of a certifying scientist.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all specimens if the laboratory does not have an RP or alternate RP for a period of more than 14 calendar days. The suspension will be lifted upon the Secretary's approval of a new permanent RP or alternate RP.

(b) If the RP leaves an HHS-certified laboratory:

(1) The HHS-certified laboratory may maintain certification and continue testing federally regulated specimens under the direction of an alternate RP for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the RP's replacement.

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's HHS certification for all federally regulated specimens if the laboratory does not have a permanent RP within 180 days. The suspension will be lifted upon the Secretary's approval of the new permanent RP.

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: the candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official

academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

(d) The HHS-certified laboratory must fulfill additional inspection and PT criteria as required prior to conducting federally regulated testing under a new RP.

Section 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?

(a) A certifying scientist must have:

(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

(2) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

(b) A certifying technician must have:

(1) Training and experience in the analytical methods and forensic procedures used by the HHS-certified laboratory relevant to the results that the individual certifies; and

(2) Training and experience in reviewing and reporting forensic test results and maintaining chain of custody, and an understanding of appropriate remedial actions in response to problems that may arise.

Section 11.6 What qualifications and training must other personnel of an HHS-certified

laboratory have?

(a) All HHS-certified laboratory staff (e.g., technicians, administrative staff) must have the appropriate training and skills for the tasks they perform.

(b) Each individual working in an HHS-certified laboratory must be properly trained (i.e., receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before they are permitted to work independently with federally regulated specimens. All training must be documented.

Section 11.7 What security measures must an HHS-certified laboratory maintain?

(a) An HHS-certified laboratory must control access to the drug testing facility, specimens, aliquots, and records.

(b) Authorized visitors must be escorted at all times, except for individuals conducting inspections (i.e., for the Department, a federal agency, a state, or other accrediting agency) or emergency personnel (e.g., firefighters and medical rescue teams).

(c) An HHS-certified laboratory must maintain records documenting the identity of the visitor and escort, date, time of entry and exit, and purpose for access to the secured area.

Section 11.8 What are the laboratory chain of custody requirements for specimens and aliquots?

(a) HHS-certified laboratories must use chain of custody procedures (internal and external) to maintain control and accountability of specimens from the time of receipt at the laboratory through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.

(b) HHS-certified laboratories must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process until final disposal.

(c) The chain of custody must be documented using either paper copy or electronic procedures.

(d) Each individual who handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody form when the specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(e) The date and purpose must be recorded on an appropriate chain of custody form each time a specimen or aliquot is handled or transferred.

Section 11.9 How must an HHS-certified laboratory process an alternate specimen that was collected at the same time as a hair specimen?

When an alternate specimen is collected at the same time as a hair specimen, the collector must forward the hair specimen to an HHS-certified hair testing laboratory and forward the alternate specimen to a laboratory that is certified by HHS for that specimen type. Section 8.5(e) requires the collector to record a comment on each Federal CCF with sufficient information (including the associated specimen's unique specimen identification number) to enable the laboratory to identify that there is an associated hair specimen.

(a) When a laboratory receives a specimen that it is not certified by HHS to test, the laboratory must contact the federal agency representative to select a laboratory with the appropriate HHS certification to test the specimen, and must forward the specimen to the selected laboratory.

(b) The laboratory certified to test the alternate specimen must accession and hold the

specimen under the storage conditions specified by the Mandatory Guidelines for Federal Workplace Drug Testing Programs for that specimen type. The laboratory does not test the alternate specimen unless an MRO submits a signed request for testing.

(c) Upon receipt of a written MRO request for testing of the alternate specimen, the laboratory tests and reports the specimen in accordance with its standard operating procedures for that specimen type.

#### Section 11.10 What amount of hair is tested?

The laboratory prepares an aliquot of the hair specimen of the specified weight needed for the test. If the root end is identified, the laboratory uses the first one inch of the hair from the root end.

#### Section 11.11 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 11.12 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 11.13 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 11.14 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 hair specimen when identifying and quantifying drugs or their metabolites.

(d) The laboratory must subject each confirmatory drug test specimen to a validated and effective decontamination procedure prior to testing.

Section 11.15 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;

(8) The effectiveness of the decontamination procedure; and

(9) 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 11.16 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;

(4) At least one control targeted at or less than 40 percent of the cutoff; and

(5) At least one control contaminated with drug analyte to monitor the effectiveness of the decontamination procedure.

(b) Calibrators and controls must total at least 10 percent of the aliquots analyzed in each batch.

Section 11.17 What are the analytical and quality control requirements for conducting specimen

### validity tests?

An HHS-certified laboratory must perform specimen validity testing to identify hair that has been damaged to the extent that the drug test may be affected, and may perform other specimen validity tests in accordance with Sections 3.1 and 3.5.

(a) Each invalid, adulterated, or substituted specimen validity result must be based on an initial specimen validity test on one aliquot and a confirmatory specimen validity test on a second aliquot;

(b) The HHS-certified laboratory must establish acceptance criteria and analyze calibrators and controls as appropriate to verify and document the validity of the test results; and

(c) Controls must be analyzed concurrently with specimens.

### Section 11.18 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 11.19 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, as described in items (l) and (m) below. Before any test result can be reported, it must be certified by a certifying scientist or a certifying technician (as appropriate).

(b) A primary (A) specimen is reported negative when each initial drug test is negative or

if the specimen is negative upon confirmatory drug testing, and the specimen does not meet invalid criteria as described in items (e)(1) through (e)(5) below.

(c) A primary (A) specimen is reported positive for a specific drug or drug metabolite when both the initial drug test is positive and the confirmatory drug test is positive in accordance with Section 3.4.

(d) For a specimen that has an invalid result for one of the reasons stated in items (e)(1) or (e)(2) 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, adulterated, or substituted result. If no further testing is necessary, the HHS-certified laboratory then reports the invalid result to the MRO.

(e) A primary (A) hair specimen is reported as an invalid result when:

(1) The color of the A and B specimens are clearly different (note: A is tested);

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

(3) 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;

(4) The hair is damaged to the extent that the drug test result may be affected (i.e., based on at least two separate aliquots of the specimen tested using a validated method to assess damage); or

(5) The laboratory obtains a positive confirmatory drug test result and is unable to definitively remove external contamination from the specimen using a validated decontamination procedure.

(f) An HHS-certified laboratory shall reject a primary (A) specimen for testing when a

fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The HHS-certified laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

(g) An HHS-certified laboratory must report all positive, adulterated, substituted, and invalid test results for a hair specimen, with the exceptions noted below. For example, a specimen can be positive for a drug and invalid because of interference on the confirmatory test for a different drug analyte. The following exceptions apply:

(1) When a specimen is positive and invalid because the hair is damaged as described in item (e)(4) above, the laboratory does not report the positive result.

(2) When a specimen is invalid because the laboratory cannot definitively remove a drug present from external contamination as described in item (e)(5) above, the laboratory does not report the positive result for that drug. If the specimen is also positive for another drug and the laboratory was able to remove external contamination for that drug, the laboratory reports that positive result in addition to the invalid result.

(h) An HHS-certified laboratory must report the confirmatory concentration of each drug or drug metabolite reported for a positive result.

(i) An HHS-certified laboratory must report numerical values of the specimen validity test results that support an adulterated, substituted, or invalid result (as appropriate).

(j) When the concentration of a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than “*insert the actual value for the upper limit of the linear range,*” or laboratories may report a

quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method's linear range and multiplying the result by the appropriate dilution factor.

(k) HHS-certified laboratories may transmit test results to the MRO by various electronic means (e.g., teleprinter, fax, or computer). Transmissions of the reports must ensure confidentiality and the results may not be reported verbally by telephone. Laboratories and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(l) HHS-certified laboratories must fax, 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. HHS-certified laboratories must use the drug/metabolite names in Section 3.4 and/or the drug/metabolite abbreviations on the Federal CCF on computer-generated electronic reports.

(m) For positive, adulterated, substituted, invalid, and rejected specimens, laboratories must fax, 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, or as an invalid result for a minimum of 1 year.

(b) Retained hair specimens must be kept in secured storage at room temperature and out

of direct light, to ensure their availability for retesting during an administrative or judicial proceeding.

(c) Alternate specimens (i.e., urine or oral fluid) must be kept in appropriate long-term storage conditions, as specified by the Mandatory Guidelines for Federal Workplace Drug Testing Programs for that specimen type.

(d) The laboratory must retain the alternate specimen for the same period of time that the associated hair specimen is retained.

(e) Federal agencies may request that the HHS-certified laboratory retain a specimen for an additional specified period of time and must make that request within the 1-year period following the laboratory's receipt of the specimen.

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

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years. The laboratory may convert hardcopy records to electronic records for storage and then discard the hardcopy records after 6 months.

(b) A federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.23) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

(c) An HHS-certified laboratory may retain records other than those included in the documentation package beyond the normal 2-year period of time.

Section 11.22 What statistical summary reports must an HHS-certified laboratory provide for hair 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, fax, or e-mail within 14 working days after the end of the semiannual period. The summary report must not include any personally identifiable information. A copy of the semiannual statistical summary report will also be sent to the Secretary or designated HHS representative. The semiannual statistical report contains the following information:

- (1) Reporting period (inclusive dates);
  - (2) HHS-certified laboratory name and address;
  - (3) Federal agency name;
  - (4) Number of specimen results reported;
  - (5) Number of specimens collected by reason for test;
  - (6) Number of specimens reported negative;
  - (7) Number of specimens rejected for testing because of a fatal flaw;
  - (8) Number of specimens rejected for testing because of an uncorrected flaw;
  - (9) Number of specimens tested positive by each initial drug test;
  - (10) Number of specimens reported positive;
  - (11) Number of specimens reported positive for each drug and drug metabolite;
  - (12) Number of specimens reported adulterated;
  - (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, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(5) Copies of the initial test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the initial tests;

(6) A brief description of the HHS-certified laboratory's confirmatory drug (and specimen validity, if applicable) testing procedures, instrumentation, and batch quality control requirements;

(7) Copies of the confirmatory test data for the donor's specimen with all calibrators and controls and copies of all internal chain of custody documents related to the confirmatory tests; and

(8) Copies of the résumé or curriculum vitae for the RP(s) and the certifying technician or certifying scientist of record.

Section 11.24 What HHS-certified laboratory information is available to a federal applicant or employee?

Federal applicants or employees who are 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 their 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 applicants or 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.

#### **Subpart L – Instrumented Initial Test Facility (IITF)**

Section 12.1 May an IITF test hair specimens for a federal agency’s workplace drug testing program?

No, only HHS-certified laboratories are authorized to test hair specimens for federal agency workplace drug testing programs in accordance with these Guidelines.

#### **Subpart M - Medical Review Officer (MRO)**

Section 13.1 Who may serve as an MRO?

- (a) A currently licensed physician who has:
  - (1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;
  - (2) Knowledge regarding the pharmacology and toxicology of illicit drugs;
  - (3) The training necessary to serve as an MRO as set out in Section 13.3;

(4) Satisfactorily passed an initial examination administered by a nationally recognized entity or subspecialty board that has been approved by the Secretary to certify MROs; and

(5) At least every five years from initial certification, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

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

All nationally recognized entities or subspecialty boards which seek approval by the Secretary to certify physicians as MROs for federal workplace drug testing programs must submit their qualifications, a sample examination, and other necessary supporting examination materials (e.g., answers, previous examination statistics or other background examination information, if requested). Approval will be based on an objective review of qualifications that include a copy of the MRO applicant application form, documentation that the continuing education courses are accredited by a professional organization, and the delivery method and content of the examination. Each approved MRO certification entity must resubmit their qualifications for approval every two years. The Secretary shall publish at least every two years a notice in the **Federal Register** listing those entities and subspecialty boards that have been approved. This notice is also available on the Internet at <http://www.samhsa.gov/workplace/drug-testing>.

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

(a) A physician must receive training that includes a thorough review of the following:

- (1) The collection procedures used to collect federal agency specimens;
- (2) How to interpret test results reported by HHS-certified IITFs and laboratories (e.g., negative, negative/dilute, positive, adulterated, substituted, rejected for testing, and invalid);
- (3) Chain of custody, reporting, and recordkeeping requirements for federal agency specimens;

- (4) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs for all authorized specimen types; and

- (5) Procedures for interpretation, review (e.g., donor interview for legitimate medical explanations, review of documentation provided by the donor to support a legitimate medical explanation), and reporting of results specified by any federal agency for which the individual may serve as an MRO.

(b) Certified MROs must complete training on any revisions to these Guidelines prior to their effective date, to continue serving as an MRO for federal agency specimens.

#### Section 13.4 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, rejected for testing, invalid, and 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(d) to determine whether testing at another HHS-certified laboratory may be warranted.

(d) After receiving a report from an HHS-certified laboratory or (for urine) HHS-certified IITF, the MRO must:

(1) Review the information on the MRO copy of the Federal CCF that was received from the collector and the report received from the HHS-certified laboratory or HHS-certified IITF;

(2) Interview the donor when required;

(3) Make a determination regarding the test result; and

(4) Report the verified result to the federal agency.

(e) The MRO must maintain records for a minimum of 2 years while maintaining the confidentiality of the information. The MRO may convert hardcopy records to electronic records for storage and discard the hardcopy records after 6 months.

### Section 13.5 What must an MRO do when reviewing a hair specimen's test results?

(a) When the HHS-certified laboratory reports a negative result for the primary (A) hair specimen, the MRO reports a negative result to the agency.

(b) When the HHS-certified laboratory reports multiple results for the primary (A) hair specimen, the MRO must follow the verification procedures described in 13.5(c) through (g) and:

(1) The MRO reports all verified refusal to test results to the federal agency.

(2) If an invalid result was reported in conjunction with a positive, adulterated, or substituted result, the MRO does not report the verified invalid result to the federal agency at this

time. The MRO takes action for the verified invalid result(s) for the primary (A) specimen as described in 13.5(f) only when:

(i) The MRO verifies the positive or adulterated result as negative based on a legitimate medical explanation as described in 13.5(c)(2) and 13.5(d)(1); or

(ii) The split (B) specimen is tested and reported as a failure to reconfirm the adulterated or substituted result reported for the primary (A) specimen as described in Section 14.5(b) and 14.5(c).

(c) When the HHS-certified laboratory reports a positive result for the primary (A) specimen, the MRO must contact the donor to determine if there is an explanation for the positive result.

(1) If the donor admits illicit use of the drug(s) that caused the positive result, the MRO reports the test result as positive to the agency.

(2) If the donor provides documentation (e.g., a valid prescription) to support a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency.

(i) Passive exposure to a drug (e.g., exposure to marijuana smoke) is not a legitimate medical explanation for a positive drug test result.

(ii) Ingestion of food products containing marijuana is not a legitimate medical explanation for a positive marijuana test result.

(3) If the donor is unable to provide a legitimate medical explanation and there is no admission of illicit use supporting the positive hair test result, the MRO reports a test cancelled result to the agency and takes actions as follows:

(i) If an alternate specimen was collected at the same time as the hair specimen, the MRO directs (in writing) the laboratory who has custody of the donor's alternate specimen to test the specimen. The laboratory and MRO follow the procedures in the Mandatory Guidelines for Federal Workplace Drug Testing Programs for that specimen type.

(ii) If an alternate specimen was not collected at the same time as the hair specimen, the MRO directs the agency to immediately collect an alternate specimen from the donor. The collector, laboratory and MRO follow the procedures in the Mandatory Guidelines for Federal Workplace Drug Testing Programs for the alternate specimen type.

(d) When the HHS-certified laboratory reports an adulterated result for the primary (A) hair specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated result.

(1) If the donor provides a legitimate medical explanation, the MRO reports a negative result to the federal agency.

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a refusal to test to the federal agency because the hair specimen was adulterated.

(e) When the HHS-certified laboratory reports a substituted result for the primary (A) hair specimen, the MRO reports a refusal to test to the federal agency because the hair specimen was substituted.

(f) When the HHS-certified laboratory reports an invalid result for the primary (A) hair specimen, the MRO reports a test cancelled result to the agency and takes action as follows:

(1) If an alternate specimen was collected at the same time as the hair specimen, the MRO directs (in writing) the laboratory who has custody of the donor's alternate specimen to

test the specimen. The laboratory and MRO follow the procedures in the Mandatory Guidelines for Federal Workplace Drug Testing Programs for the alternate specimen type.

(2) If an alternate specimen was not collected at the same time as the hair specimen, the MRO directs the agency to immediately collect an alternate specimen from the donor. The collector, laboratory and MRO follow the procedures in the Mandatory Guidelines for Federal Workplace Drug Testing Programs for the alternate specimen type.

(g) When the HHS-certified laboratory reports a rejected for testing result for the primary (A) specimen, the MRO reports a test cancelled result to the agency and takes action as follows:

(1) If an alternate specimen was collected at the same time as the hair specimen, the MRO directs (in writing) the laboratory who has custody of the donor's alternate specimen to test the specimen. The laboratory and MRO follow the procedures in the Mandatory Guidelines for Federal Workplace Drug Testing Programs for the alternate specimen type.

(2) If an alternate specimen was not collected at the same time as the hair specimen, the MRO directs the agency to immediately collect an alternate specimen from the donor. The collector, laboratory and MRO follow the procedures in the Mandatory Guidelines for Federal Workplace Drug Testing Programs for the alternate specimen type.

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

(a) When another specimen type (e.g., urine, oral fluid) was collected in accordance with section 8.6, the MRO reviews and reports the alternate specimen's test result in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen.

(b) If the donor is unable to provide a sufficient amount of the alternate specimen authorized by the federal agency, the MRO consults with the federal agency. The federal agency follows the required procedures in the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen. This includes immediately directing 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.

#### Section 13.7 Who may request a test of a split (B) hair specimen?

(a) For an adulterated or substituted result reported on a primary (A) hair 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 adulterated or substituted to request a test of the split (B) specimen. The MRO must inform the donor that the donor has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that an adulterated or substituted result is being reported to the federal agency on the primary (A) specimen.

#### Section 13.8 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, fax, 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 adulterated and substituted results.

(d) The MRO must not disclose numerical values of drug test results to the agency.

Section 13.9 What types of relationships are prohibited between an MRO and an HHS-certified laboratory?

An MRO must not be an employee, agent of, or have any financial interest in an HHS-certified laboratory for which the MRO is reviewing drug test results.

This means an MRO must not derive any financial benefit by having an agency use a specific HHS-certified laboratory or have any agreement with the HHS-certified laboratory that may be construed as a potential conflict of interest.

**Subpart N - Split Specimen Tests**

Section 14.1 When may a split (B) hair specimen be tested?

(a) The donor may request, verbally or in writing, through the MRO that the split (B) hair specimen be tested at a different (i.e., second) HHS-certified laboratory when the primary (A) specimen was determined by the MRO to be adulterated or substituted.

(b) A donor has 72 hours to initiate the request after being informed of the result by the

MRO. The MRO must document in the MRO's records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) hair 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 to perform the test), the MRO reports a cancelled test to the federal agency and takes action as follows:

(i) If an alternate specimen was collected at the same time as the hair specimen, the MRO directs (in writing) the laboratory who has custody of the donor's alternate specimen to test the specimen. The laboratory and MRO follow the procedures in the Mandatory Guidelines for Federal Workplace Drug Testing Programs for the alternate specimen type.

(ii) If an alternate specimen was not collected at the same time as the hair specimen, the MRO directs the agency to collect an alternate specimen from the donor. The collector, laboratory and MRO follow the procedures in the Mandatory Guidelines for Federal Workplace Drug Testing Programs for the alternate specimen type.

(d) If a donor chooses not to have the split (B) specimen tested by a second HHS-certified hair laboratory, a federal agency may have a split (B) specimen retested as part of a legal or administrative proceeding to defend an original adulterated or substituted result.

Section 14.2 How does an HHS-certified laboratory test a split (B) hair specimen when the primary (A) specimen was reported adulterated?

(a) The HHS-certified laboratory must use its confirmatory specimen validity test at an established limit of quantification (LOQ) to reconfirm the presence of the adulterant.

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen

validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

Section 14.3 How does an HHS-certified laboratory test a split (B) hair specimen when the primary (A) specimen was reported substituted?

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 14.4 Who receives the split (B) specimen result?

The second HHS-certified laboratory must report the result to the MRO.

Section 14.5 What action(s) does an MRO take after receiving the split (B) hair 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) hair specimen as:

(a) Reconfirmed adulteration and/or substitution result. The MRO reports reconfirmed to the agency.

(b) Failed to reconfirm adulteration or substitution. 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.

(c) 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]. The MRO shall notify the HHS office responsible for coordination of the Drug Free Workplace Program regarding the test results for the specimen.

(d) 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.

(e) 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 14.6 How does an MRO report a split (B) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (e.g., teleprinter, fax, or computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all split specimen results.

(d) The MRO must not disclose the numerical values of the drug test results to the agency.

Section 14.7 How long must an HHS-certified laboratory retain a split (B) specimen?

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions, in accordance with Section 11.20. This applies even for those cases when the split (B) specimen is tested by a second HHS-certified laboratory and the second HHS-certified laboratory does not confirm the original result reported by the first HHS-certified laboratory for the primary (A) specimen.

**Subpart O - Criteria for Rejecting a Specimen for Testing**

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

The following discrepancies are considered to be fatal flaws. The HHS-certified laboratory must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

- (a) The specimen ID number on the primary (A) or split (B) specimen label/seal does not match the ID number on the Federal CCF, or the ID number is missing either on the Federal CCF or on either specimen label/seal;
- (b) The primary (A) specimen label/seal is misapplied, broken or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;
- (c) The collector's printed name and signature are omitted on the Federal CCF;

(d) There is an insufficient amount of specimen for analysis in the primary (A) specimen unless the split (B) specimen can be re-designated as the primary (A) specimen; 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.

(f) The specimen was received at the HHS-certified laboratory without a CCF;

(g) The CCF was received at the HHS-certified laboratory without a specimen;

(h) The collector performed two separate collections using one CCF;

(i) The physical appearances (other than color) of the primary (A) and split (B) specimen are clearly different;

(j) The laboratory identifies lice or a similar infestation in the hair; or

(k) The HHS-certified laboratory identifies a flaw (other than those specified above) that prevents testing or affects the forensic defensibility of the drug test and cannot be corrected.

Section 15.2 What discrepancies require an HHS-certified laboratory to report a specimen as rejected for testing unless the discrepancy is corrected?

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified laboratory must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the HHS-certified laboratory may report the test result for the specimen. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot recover the collector's signature, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the

Federal CCF.

(b) If a specimen is submitted using a non-federal form or an expired Federal CCF, the HHS-certified laboratory must test the specimen and also attempt to obtain a memorandum for record explaining why a non-federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If, after holding the specimen for at least 5 business days, the HHS-certified laboratory cannot obtain a memorandum for record from the collector, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

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

(a) The following omissions and discrepancies on the Federal CCF that are received by the HHS-certified laboratory should not cause an HHS-certified laboratory to reject a hair specimen or cause an MRO to cancel a test:

- (1) An incorrect laboratory name and address appearing at the top of the form;
- (2) Incomplete/incorrect/unreadable employer name or address;
- (3) MRO name is missing;
- (4) Incomplete/incorrect MRO address;
- (5) A transposition of numbers in the donor's Social Security Number or employee identification number;
- (6) A telephone number is missing/incorrect;
- (7) A fax number is missing/incorrect;
- (8) A "drug tests to be performed" box is not marked;

(9) A “specimen collection” box is not marked;

(10) The collection site address is missing;

(11) The collector’s printed name is missing but the collector’s signature is properly recorded;

(13) The time of collection is not indicated;

(14) The date of collection is not indicated;

(15) Incorrect name of delivery service;

(16) 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

(17) The donor’s name inadvertently appears on the HHS-certified laboratory copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory should not cause an MRO to cancel a test:

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

(2) The accessioner fails to print 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 should occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When

an error occurs more than once a month, the MRO must direct the collector or HHS-certified laboratory (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

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

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the Federal CCF for a specimen being reported adulterated, invalid, or substituted; or

(3) The electronic report provided by the HHS-certified laboratory does not contain all the data elements required for the HHS standard laboratory electronic report for a specimen being reported adulterated, invalid result, or substituted.

(b) If error (a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If, after at least 5 business days, the collector cannot provide such a statement, the MRO must cancel the test.

(c) If error (a)(2) occurs, the MRO must obtain a statement from the certifying scientist that they forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If, after at least 5 business days, the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory. If, after at least 5 business days, the laboratory does not retransmit a corrected electronic report, the MRO must cancel the test.

## **Subpart P - Laboratory Suspension/Revocation Procedures**

### Section 16.1 When may the HHS certification of a laboratory be suspended?

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory in writing that its certification to perform drug testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

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

### Section 16.2 What definitions are used for this subpart?

Appellant. Means the HHS-certified laboratory which has been notified of its suspension or proposed revocation of its certification to perform testing and has requested an informal review thereof.

Respondent. Means the person or persons designated by the Secretary in implementing these Guidelines.

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

reasons for the suspension and proposed revocation.

Section 16.3 Are there any limitations on issues subject to review?

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

Section 16.4 Who represents the parties?

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

Section 16.5 When must a request for informal review be submitted?

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

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also

send a copy of the acknowledgment to the respondent.

#### Section 16.6 What is an abeyance agreement?

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

#### Section 16.7 What procedures are used to prepare the review file and written argument?

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

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

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

essential documents should be submitted to the reviewing official.

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

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

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

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

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

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

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

Section 16.8 When is there an opportunity for oral presentation?

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

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

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

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

(e) Conduct of the Oral Presentation.

(1) General. The presiding official is responsible for conducting the oral presentation.

The presiding official may be assisted by one or more of the official's employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

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

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

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

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

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

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

#### Section 16.9 Are there expedited procedures for review of immediate suspension?

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

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

(c) Review File and Briefs. Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing

official the following:

(1) A review file containing essential documents relevant to the review, which is tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) Oral Presentation. If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7-10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with Section 16.8(c) and will conduct the oral presentation in accordance with the procedures of Sections 16.8(e), (f), and (g).

(e) Written Decision. The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7-10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

(f) Transmission of Written Communications. Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between both party and the reviewing official shall be by fax, 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 fax, secured electronic transmissions, or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and federal holidays. However, if a due date falls on a Saturday, Sunday, or federal holiday, then the due date is the next federal working day.

Section 16.12 What are the authority and responsibilities of the reviewing official?

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

### Section 16.13 What administrative records are maintained?

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

### Section 16.14 What are the requirements for a written decision?

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

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

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

Section 16.15 Is there a review of the final administrative action?

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal Law. The reviewing official's decision, under Section 16.9(e) or 16.14(a) constitutes final agency action and is ripe for judicial review as of the date of the decision.

[FR Doc. 2020-16432 Filed: 9/4/2020 4:15 pm; Publication Date: 9/10/2020]