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), Department of Health and Human Services (HHS).

ACTION: Issuance of mandatory guidelines.

SUMMARY: The Department of Health and Human Services (''HHS'' or ''Department'') has revised the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) which published in the **Federal Register** of October 25, 2019.

DATES: The mandatory guidelines are effective October 10, 2023.

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SUPPLEMENTARY INFORMATION:

Executive Summary

These revised Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) establish a process whereby the Department annually publishes the authorized drug testing panel (*i.e.,* drugs, analytes, or cutoffs) to be used for Federal workplace drug testing programs; revise the definition of a substituted specimen to include specimens with a biomarker concentration inconsistent with that established for a human specimen, establish a process whereby the Department publishes an authorized biomarker testing panel (*i.e.,* biomarker analytes and cutoffs) for Federal workplace drug testing programs; update and clarify the oral fluid collection procedures; revise the Medical Review Officer (MRO) verification process for positive codeine and morphine specimens; and require MROs to submit semiannual reports to the Secretary or designated HHS representative on Federal agency specimens that were reported as positive for a drug or drug metabolite by a laboratory and verified as negative by the MRO. In addition, some wording changes have been made for clarity and for consistency with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) or to apply to any authorized specimen type.

The Department is publishing a separate Federal Register Notification (FRN) elsewhere in this issue of the **Federal Register** with the revised UrMG, which include the same or similar revisions as the OFMG, where appropriate.

Background

Pursuant to its authority under section 503 of Public Law 100–71, 5 U.S.C. 7301, and Executive Order 12564, HHS 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.

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. No Federal agencies are testing hair or oral fluid specimens at this time.

HHS originally published the Mandatory Guidelines for Federal Workplace Drug Testing Programs (hereinafter referred to as Guidelines or Mandatory 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 current Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG) on January 23, 2017 (82 FR 7920) and published the current Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (OFMG) on October 25, 2019 (84 FR 57554). SAMHSA published proposed Mandatory Guidelines for Federal Workplace Drug Testing Programs using Hair (HMG) on September 10, 2020 (85 FR 56108) and proposed revisions to the UrMG (87 FR 20560) and OFMG (87 FR 20522) on April 7, 2022.

There was a 60-day public comment period following publication of the proposed OFMG, during which 53 commenters submitted 204 comments on the OFMG. These commenters were comprised of individuals, organizations, and private sector companies. The comments are available for public view at *https://www.regulations.gov/.* All comments were reviewed and taken into consideration in the preparation of the Guidelines. The issues and concerns raised in the public comments for the OFMG are set forth below. Similar comments are considered together in the discussion.

Summary of Public Comments and HHS's Response

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

Some submitted comments were specific to transportation industry drug testing which is regulated by the Department of Transportation (DOT). The Department has noted these comments below, but responded only to comments that are relevant to these Guidelines. DOT issued a notice of proposed rulemaking (NPRM) on February 28, 2022 (87 FR 11156). Subsequently, DOT extended the comment period to April 29, 2022 (87 FR 16160), and published the final rule on May 2, 2023 (88 FR 27596).

Authorized Drug Testing Panel

The Department requested comments on its proposal to publish the drug testing panel separately from the OFMG in a Federal Register\[[[[p Notification (FRN) each year. Fifteen commenters submitted a total of 40 comments on this topic for the OFMG.

Nine commenters disagreed with publishing a revised drug testing panel without a public comment period, expressing concerns that stakeholders including individuals subject to federally regulated drug testing would not be given the opportunity to provide comment and that the Department would miss valuable input including information on costs and burden. Some of these commenters suggested alternate ways to permit public comment while enabling a quicker response to testing panel changes (*e.g.,* setting a shorter comment period, publishing the Guidelines as an interim final rule or issuing an advance notice of proposed rulemaking). The Department has reviewed these comments and suggestions and determined that no changes to the proposed Guidelines are needed. The Department has developed procedures which will allow review and comment before testing panel changes are published, as described below.

Consistent with current procedures, prior to making a change to the drug or biomarker testing panel, the Department will conduct a thorough review of the scientific and medical literature, and will solicit review and input from subject matter experts such as Responsible Persons (RPs) of HHS-certified laboratories, Medical Review Officers (MROs), research scientists,

manufacturers of collection devices and/or immunoassay kits, as well as Federal partners such as DOT, the Food and Drug Administration (FDA), and the Drug Enforcement Administration (DEA). Further, the Department plans to provide notice and opportunity for public comment regarding any proposed changes to the drug and biomarker testing panels as part of Drug Testing Advisory Board (DTAB) meetings and procedures.

Information regarding any proposed changes to the drug and biomarker testing panels and a request for public comment will be included in an advance notice of the DTAB meeting published in the **Federal Register**, along with the timeframe and method(s) for comment submission. During the meeting, the Department will present the basis for adding or removing analytes (*i.e.,* including technical and scientific support for the proposed changes), as well as a discussion of related costs and benefits. This information will be provided in advance to DTAB members. The Department will review all submitted public comments and will share information during a DTAB session prior to DTAB's review of SAMHSA's recommendation to the Secretary regarding each proposed change.

The Department will make the final decision on any panel changes and include the effective date(s) in the annual Notice, to allow time for drug testing service providers (*e.g.,* immunoassay kit manufacturers, oral fluid collection device manufacturers) to develop or revise their products, and for HHS-certified laboratories to develop or revise assays, complete validation studies, and revise procedures.

Three commenters specifically agreed with the need to streamline and improve processes for making changes to the testing panels, but expressed concern over the process for testing panel review and who would be involved. These commenters suggested involving other stakeholders (*e.g.,* HHS-certified laboratories, DTAB, FDA). As noted above, the Department will use multiple methods and involve subject matter experts from various stakeholder groups to determine testing panel changes, and will provide opportunity for public review and comment before changes are made. FDA, DOT, and other Federal partners will have opportunities to review and provide input.

Four commenters disagreed that HHS is exempt from the Administrative Procedure Act (APA) requirements. Two of these specifically stated that the Guidelines are subject to APA requirements because DOT is required to use the Guidelines for their transportation industry drug testing programs. The Department has reviewed these comments and determined that no change is needed to the proposed Guidelines. The Department explained why the APA does not apply under the *Regulatory Impact and Notices* section of the current OFMG (84 FR 57554) and has repeated the same information in that section below.

Two commenters suggested that the Department limit changes to every few years (*e.g.,* four to five years). The Department will not set such time limits for panel changes. The need for more timely testing panel changes was clearly explained in the preamble to the proposed Guidelines.

Eight commenters were concerned that the Department will not allow sufficient time for stakeholders to implement changes (*e.g.,* time for FDA clearance for new or revised products, information technology [IT] changes, process development and/or changes, contractual changes, and training). Some of these commenters suggested that the Department set a standard time for implementation of all changes (*e.g.,* 90 days, six months) or based on the complexity of the change (*e.g.,* between 90 and 365 days). The Department will establish a reasonable time for implementation based on the change, rather than setting a standard time period for all changes. As noted above, the Department will solicit information from multiple sources to assist in decision making.

In regard to the use of FDA-cleared collection devices and immunoassay initial tests, four commenters suggested that federally regulated drug testing could fall under what they referred to as the FDA's Employment and Insurance exemption. The Department notes that, while some drugs of abuse test systems intended for employment and insurance testing are, under certain circumstances, exempt from the premarket notification procedures in 21 CFR part 807, subpart E, such exemptions do not apply to test systems intended for Federal drug testing programs. See 21 CFR part 862, subpart D. Because the Department does not address FDA clearance requirements for test systems in the Mandatory Guidelines, the reference to FDA clearance for oral fluid collection devices has been removed from Section 7.1. Applicant and HHS-certified laboratories must verify that oral fluid collection devices and test systems subject to FDA regulations are approved or otherwise cleared by FDA and, in addition, must validate the oral fluid collection devices and test systems prior to use in accordance with requirements specified in the National Laboratory Certification Program (NLCP) Manual for Oral Fluid Laboratories.

Two commenters appeared to misinterpret the Department's testing panel proposal, objecting to the Department making changes to the testing panels each year. The Department plans to issue an annual Notice with the current testing panels and required nomenclature, but will make changes only when needed to ensure the continued effectiveness of Federal workplace drug testing programs, which may not be every year.

See additional comments under Section 3.4 below.

Authorized Biomarker Testing Panel

The Department requested comments on its proposal to publish the biomarker testing panel separately from the OFMG in a **Federal Register** Notification each year. Seven commenters submitted a total of 14 comments on this topic for the OFMG.

One commenter disagreed with specimen validity or biomarker testing for oral fluid specimens, because all collections are observed and collection devices are required to have volume indicators. The commenter stated these tests would be unnecessary and increase costs. The commenter also noted that the observed collections and required inspection of the oral fluid reduced the risk of adulteration or substitution. Four commenters suggested that the Department require all HHS-certified laboratories to perform standardized specimen validity and biomarker tests on all federally regulated specimens, and allow laboratories to choose whether to offer additional specialized tests upon MRO request on a case-by-case basis. The Department agrees that there are no known effective subversion products for oral fluid specimens at this time; however, such products may be available in the future. The Department has also included examples in the HHS Oral Fluid Specimen Handbook (posted on SAMHSA's website, *https://www.samhsa.gov/workplace*) to assist trained collectors in identifying donor attempts to tamper with the collection of their oral fluid specimen. The Department is not requiring all certified laboratories to conduct oral fluid specimen validity testing or biomarker testing at this time. However, if the drug testing industry identifies a need for such tests and an HHS-certified laboratory chooses to offer them to their regulated clients, the Department will ensure that the tests provide scientifically valid and forensically defensible results and will revisit the

need for requiring the tests on all specimens.

Two commenters disagreed with publishing a biomarker testing panel without a public comment period, expressing concerns that stakeholders would not be given the opportunity to provide comment and that the Department would miss valuable input including information on costs and burden. The Department has reviewed these comments and determined that no changes to the proposed Guidelines are needed. The Department has developed procedures which will allow review and comment before testing panel changes are published, as described under *Authorized drug testing panel* above.

Three commenters specifically agreed with the need to streamline and improve processes for making changes to the testing panels. One of these commenters noted that since there are no currently agreed-upon analytes to assess OF validity and there may be differences in buffered collection devices, determining a biomarker panel may be complex. The other two commenters suggested involving other stakeholders (*e.g.,* HHS-certified laboratories, DTAB). A different commenter recommended that the Department consult with immunoassay manufacturers and OF testing laboratories to understand the scope of making proposed changes, availability of materials/reagents, etc. As noted under *Authorized drug testing panel* above, the Department will use multiple methods and involve subject matter experts from various stakeholder groups to determine testing panel changes, and will provide opportunity for public review and comment before changes are made. Federal partners will also have opportunities to review and provide input.

One commenter disagreed that HHS is exempt from the APA requirements. The Department has reviewed the comment and determined that no change is needed to the proposed Guidelines. The Department explained why the APA does not apply under the *Regulatory Impact and Notices* section of the current OFMG (84 FR 57554) and has repeated the same information in that section below.

Medical Review Officer (MRO) Verification of Codeine and Morphine Test Results

In Section 13.5, the Department removed the requirement for the MRO to report specimens with morphine and/or codeine between the cutoff and 150 ng/mL as positive based on clinical evidence of illicit drug use and, instead, directed the MRO to verify such specimens as negative unless the donor admits to illegal opioid use that could have caused the positive result. Four commenters agreed with this change.

Medical Review Officer (MRO) Semiannual Reports

In Section 13.11, the Department added requirements for each MRO performing medical review services for Federal agencies to submit semiannual reports, in January and July of each year, of Federal agency specimens that were reported as positive for a drug or drug metabolite by the laboratory and verified as negative by the MRO, along with the reason for the negative verification (*e.g.,* a valid prescription for a drug). Six commenters submitted eight comments on this topic for the OFMG.

Three commenters disagreed, stating that HHS had not clearly described the reason and the process for such reports. One commenter noted that the Department had not presented data documenting that MROs were incorrectly reporting specimens, and it was unclear how the reports could be matched to laboratory report information submitted to the National Laboratory Certification Program (NLCP). Another commenter stated that it was unclear what actions would be taken if the Department disagreed with the MRO report. The third commenter was concerned that donors would be identifiable, and that ''a database of legal drug use'' would violate donor privacy. One of the commenters expressed concern over ''unintended consequences'' for DOT and state workplace drug testing programs, without further explanation.

Two commenters disagreed on the basis of added costs and burden to MROs. One claimed that this would result in MROs tracking and reporting all results sent by the laboratory, as they are already required to report positive results to the Federal Motor Carrier Safety Administration (FMCSA) Clearinghouse. The other claimed that this would require documentation and report generation for each non-negative result, and expressed concern that smaller MRO practices could find the process too time-consuming and costly to continue in the program.

One commenter agreed that such reports could be beneficial, but suggested that MROs provide the same information as provided by laboratories to the NLCP. The commenter incorrectly stated that laboratories do not provide specimen identification numbers to the NLCP.

The Department has reviewed the comments and determined that no change is needed to the proposed Guidelines. To clarify, this reporting policy is only for Federal agency specimens, not DOT-regulated specimens. Further, the reports are not for all positive specimens, only for those specimens that were reported as positive by the laboratory and verified as negative by the MRO. The requested MRO information is sufficient to enable matching to HHS-certified laboratory information provided to the NLCP without identifying the donor. At this time, there is no system-wide mechanism for identifying MRO verification practices for Federal agency specimens that are inconsistent with the Guidelines, so data on incorrect reporting is not available. The Department is not planning to share MRO-specific information, but may share statistical information and deidentified examples by various means (*e.g.,* DTAB meeting presentations, revisions to the MRO Guidance Manual and/or Case Studies). The Department will also provide this information to HHS-approved MRO certification organizations to share with their certified MROs and to update training materials and examinations as needed.

Marijuana Testing

The Department did not propose any changes to the OFMG in regard to marijuana testing, but received comments from 21 commenters: 20 disagreed and one agreed with the current requirements. Seventeen commenters supported medical use of marijuana. Some of these noted that many doctors and medical professionals support the use of medical marijuana and that many States have legalized marijuana for medical use. Commenters expressed concern that Federal employees using marijuana for health reasons could lose their jobs or benefits or that Federal employees without access to medical marijuana may use other drugs such as opioids. Three commenters supported legalization of marijuana in general. One commenter stated that marijuana testing should be removed from the Guidelines until research can establish reliable levels to distinguish marijuana use from use of a legal hemp product (*i.e.,* as defined by the 2018 Farm Bill).

One commenter agreed with continuing to recognize marijuana as a Schedule I drug, with zero tolerance for safety-sensitive positions. The commenter stated that the liability and risk are not worth allowing employees in safety-sensitive positions to use medical marijuana.

Current Federal law requires Federal agencies to test for marijuana under E.O. 12564 in their workplace drug testing

programs. The Department also edited Section 13.5(c) to clarify that only prescription medications can be offered as a legitimate medical explanation for a positive drug test (as described under Section 13.5 below). No further edits are required at this time.

General Comments

Five commenters submitted general comments concerning the OFMG. Three agreed with the use of oral fluid testing, citing benefits of oral fluid as a testing matrix compared to urine (*e.g.,* less invasive collection is preferable for body/gender issues and the need to respect donor privacy; reduces specimen tampering; eliminates need for same gender observers; saves time). Two commenters disagreed with making any changes to the previous OFMG (published October 25, 2019).

Discussion of Sections

The Department has not included a discussion in the preamble of any sections for which public comments were not submitted or for minor wording changes (*e.g.,* edits for clarity, typographical or grammatical corrections).

Subpart A—Applicability

Section 1.5 What do the terms used in these Guidelines mean?

Two commenters agreed and two disagreed with the Department's proposed revision to the Substituted Specimen definition in Section 1.5 to include specimens tested for a biomarker.

Of the two commenters who disagreed, one stated that there are situations in which a legitimate specimen may be reported as outside the standards for human specimens, and these should be reported as invalid. The other commenter stated that there should be clear notice and the opportunity to comment on specific biomarkers and criteria for substitution and that HHS should continue to require laboratories to report specimens as invalid based on normally occurring endogenous substances that appear unusual but do not violate standards for identified validity tests. The Department has reviewed the comments and determined that no change is needed to the proposed Guidelines. The Department will follow the procedures summarized under *Authorized drug testing panel* above to enable public comment and review, and will ensure that a biomarker test is scientifically supported and forensically sound to identify specimens as substituted before allowing its use with federally regulated drug testing. Specimens that do not meet established criteria for the biomarker test will not be reported as substituted.

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

In Section 1.7(a), the Department proposed to remove two exceptions for reporting a refusal to test for a pre-employment test: a donor who fails to appear in a reasonable time and a donor who leaves the collection site before the collection process begins. Nine commenters submitted a total of 16 comments on this proposal. Many of the commenters referenced DOT drug testing requirements and/or transportation industry issues that are not relevant to these Guidelines.

Eight commenters disagreed with the changes, noting that an applicant may fail to appear because they have taken a different job offer. The commenters noted that a refusal to test in the individual's record could prevent individuals from taking other job offers and/or require them to undergo unnecessary return-to-duty testing. The Department has reviewed the comments and determined that no change is needed. As stated in this section, the Federal agency determines a reasonable time for the donor to take the test, specifies the time consistent with agency regulations, and directs the individual accordingly. At the time an applicant is scheduled for a pre-employment drug test, or before, Federal agencies should provide the applicant with instructions on how to notify the agency in the event that they decide to withdraw their application or to not accept a job offer. Such instructions will allow the agency to cancel the drug test and help applicants avoid a refusal to test result.

Three commenters noted that the Guidelines should state that the designated employer representative (DER) makes the determination of a refusal to test. A fourth commenter noted that the employer, not the collector, should determine whether a failure to appear for a pre-employment test should be considered a refusal, as the collection site may not know that a donor is coming or how much time the employer allows the donor to complete a test. The Department has reviewed the comments and determined that no change is needed. As stated in this section, the Federal agency takes action consistent with applicable agency regulations. Corresponding wording in Section 8.3 specifies that the collector follows the Federal agency policy or contacts the Federal agency representative to obtain guidance on action to be taken before reporting a refusal to test because a donor does not arrive at an assigned time.

One commenter suggested that the Department add procedures to follow when the collection site cannot collect a specimen (*e.g.,* collection site closed early, collection site ran out of supplies). The Department disagrees with this suggestion. The applicant and/or the collector should contact the Federal agency representative when a situation beyond the applicant's control prevents completing a drug test within the specified time.

Subpart B—Oral Fluid Specimens

Section 2.2 Under what circumstances may an oral fluid specimen be collected?

In Section 2.2, the Department allows oral fluid to be used for any type of testing conducted in Federal agency drug testing programs, and had not proposed any changes. Six commenters submitted comments in response to DOT's February 28, 2022 NPRM, regarding whether oral fluid should be allowed for all or only some testing reasons.

Section 2.5 How is the split oral fluid specimen collected?

The Department did not propose any changes to the requirements for split oral fluid collections in Sections 2.5 and 8.8 (*How does the collector prepare the oral fluid specimens?*). In its February 28, 2022 NPRM, DOT prohibits serial or simultaneous collections of A and B oral fluid specimens using two separate devices, which are allowed under the OFMG. Four commenters requested that HHS and DOT harmonize their requirements.

Three of the commenters requested a clear definition of ''single device'' and the fourth commenter recommended that both HHS and DOT specifically allow a device that collects a specimen that is then split or divided into the primary (A) and split (B) specimens. HHS and DOT have discussed oral fluid collection requirements. The Department will retain the split specimen collection requirements in the current OFMG which are based on current devices used in non-regulated drug testing and also allow for development of additional device types validated to meet program requirements. HHS-certified laboratories must ensure compliance with DOT regulations for specimens collected and tested under their regulations.

Subpart C—Oral Fluid Specimen Tests

Section 3.4 What are the drug and biomarker test analytes and cutoffs for undiluted (neat) oral fluid?

The Department revised Section 3.4 to describe the annual publication of the drug testing and biomarker testing panels and the nomenclature required for laboratory and MRO reports. Seven commenters submitted 10 comments on the required nomenclature required for laboratory and MRO reports, which are addressed below. Comments on the testing panels are addressed under *Authorized drug testing panel* and *Authorized biomarker testing panel* above.

In regard to the required nomenclature specified in the annual **Federal Register** Notice, four commenters noted it is difficult and requires substantial effort for stakeholders to make such changes to their information technology (IT) systems. Three of these commenters suggested that HHS convene a working group for review and input on nomenclature changes, to include employers, third party administrators, providers of electronic Federal Custody and Control Forms (ECCF providers), laboratories, and MROs. The other commenter stated that ''industry consensus'' should determine how analytes are identified. This commenter also stated that standardizing nomenclature for urine and oral fluid testing is not practical. One commenter agreed with publishing the required nomenclature for each change to the testing panel, but suggested that nomenclature not be changed after publication to avoid increased costs and confusion. Two commenters recommended a minimum of one-year implementation period after nomenclature changes are published. Another commenter agreed with specifying nomenclature, but noted that clear instructions will be needed for training and updating databases. The Department will establish required terminology based on correct scientific nomenclature for added analytes. As described under *Authorized drug testing panel* above, the Department has developed procedures to allow public notice and comment on proposed drug analyte changes through DTAB meetings and procedures. The Department will publish separate nomenclature lists for urine and oral fluid analytes.

One commenter disagreed with requiring both cocaine and benzoylecgonine as confirmatory test analytes, and recommended testing oral fluid specimens for benzoylecgonine only. The commentor cited their experience in testing for cocaine and metabolites in oral fluid; however, the commentor did not provide a scientific literature citation for their recommendation. SAMHSA has reviewed the literature and disagrees that testing for benzoylecgonine alone yields the same results as testing for both analytes. A 2010 dosing study showed that testing for both cocaine and benzoylecgonine increases detection rates in the periods 0.08–0.25 hours and 24–48 hours post-dosing as compared to testing for cocaine or benzoylecgonine alone.[1]

The annual **Federal Register** Notification will be posted on the SAMHSA website, *https://www.samhsa.gov/workplace.* The table in Section 3.4 of these final Guidelines will remain in effect until the effective date of the new panels published in the separate FRN.

Section 4.1 Who may collect a specimen?

One commenter submitted suggested rewording Section 4.1(a) to require the collector to be trained on ''each manufacturer's procedures for the collection device.'' The Department disagrees with the suggested edit, which may be misconstrued as requiring a collector to be trained on all devices. The current OFMG wording (*i.e.,* ''the manufacturer's procedures for the collection device'') is clear and consistent with the Oral Fluid Specimen Collection Handbook.

Five commenters submitted comments in response to DOT's February 28, 2022 NPRM, regarding who may collect an oral fluid specimen.

Subpart F—Federal Drug Testing Custody and Control Form

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

The Department did not propose any changes to this section. One commenter submitted a comment in response to DOT's February 28, 2022 NPRM, regarding maintaining a fax number on the Federal Custody and Control Form (CCF).

Section 6.2 What happens if the correct Office of Management and Budget (OMB)-approved Federal CCF is not available or is not used?

One commenter stated that the Department should specify what constitutes an incorrect form, how a collector's signed memorandum must be submitted to correct submission of an incorrect CCF, and what actions an HHS-certified laboratory must take in response to an incorrect CCF. The Department has determined that no changes to the Guidelines are needed. The Department issues Guidance for Using the Federal CCF as part of the OMB-approved package and provides information and guidance specific to the current and expired versions of the Federal CCF, rather than including them in these Guidelines.

Subpart G—Oral Fluid Specimen Collection Devices

Section 7.2 What are the requirements for an oral fluid collection device?

In Section 7.2(b)(2), the Department added a requirement for oral fluid specimen tubes to be sufficiently transparent to enable a visual assessment of the contents without opening the tube. See also Section 8.5(a)(3). Two commenters disagreed with the term ''sufficiently transparent,'' noting that opaque tubes would enable visual assessment. The Department did not intend that all tubes must be entirely clear (thus, the term ''sufficiently transparent''). An opaque tube would not allow visual assessment of the contents. For clarity, the Department has added ''(*e.g.,* translucent)''.

In Section 7.2(b)(3), the Department added a requirement for the collection device manufacturer to include the device lot expiration date on each specimen tube, to enable the collector to verify that each tube is within its expiration date prior to use. This is consistent with the current Federal CCF and associated documents (*i.e.,* Instructions for Completing the Federal CCF for Oral Fluid Specimen Collection, Guidance for Using the Federal CCF) which require the collector to verify the expiration date and mark the checkbox in Step 2 of the Federal CCF. The collector may, but is not required to, document the expiration date on each tube in Step 4 of the CCF. Four commenters disagreed with current requirements, stating that it is sufficient for the collector and not the laboratory to document the expiration date of each device on the Federal CCF. These commenters suggested that failure of the collector to record the date could be recovered with a signed memorandum for the record (MFR). Three of the four commenters also stated that the expiration date would likely be covered by the label/seal applied by the collector and noted changing to a transparent label would incur additional costs, while the fourth noted that even a partially transparent label would take time to develop and would not eliminate concerns about label/seal placement. The Department has

reviewed the comments and determined that no change is needed to the proposed OFMG. The expiration date is critical information supporting the scientific and forensic defensibility of the test result, and the laboratory must not test the specimen if it is unable to verify that the device was within its expiration date at the time of collection. A trained collector should avoid covering this information when placing the label on the tube. If the collector records an incorrect expiration date on the CCF, the laboratory corrects the information and is not required to obtain an MFR from the collector to recover the error.

One commenter agreed that the manufacturer should include the lot number and expiration date on each collection tube. The Department has provided additional guidance to laboratories noting that if the expiration date is not visible on the tube upon receipt and the device lot number is visible, the laboratory may use that information to recover the expiration date.

One of the commenters noted that the expiration date could be a required field on an ECCF, preventing the collector from continuing the collection without entering an expiration date. The Department agrees that ECCF system providers could implement this safeguard, but this does not obviate the need for the laboratory to verify the expiration date on each tube, just as the laboratory must verify the specimen identification number on each tube and the CCF.

Subpart H—Oral Fluid Specimen Collection Procedure

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

The Department proposed revisions to Section 8.3 consistent with removal of refusal to test exceptions for pre-employment collections (see Section 1.7), reordered collection steps (*e.g.,* item d, item h.4), and reworded items for clarity (*e.g.,* items g and h). The Department also added steps similar to those for urine collections to deter donor attempts to adulterate or substitute the specimen. Eight commenters submitted comments concerning this section.

In regard to determining a refusal to test, one commenter suggested that the Department establish the beginning of the collection by specifying that the collection begins when the collector has checked the donor's identification. Another commenter who suggested the Department retain exceptions for pre-employment drug test collections (see Section 1.7) also suggested that this step be specified as the beginning of a pre-employment collection. The Department has determined that no revision is needed. The Guidelines clearly describe the preliminary collection steps and specify that the collector reports a refusal to test when a donor leaves the collection site before the collection is complete.

To deter donor attempts to adulterate or substitute the specimen, the Department proposed that the collector inspect the contents of the donor's pockets only when the collector does not keep the donor under direct observation until the end of the collection, including the 10-minute wait period described in Section 8.3(h). If the donor refuses to display the contents of their pockets, the collector will continue with the oral fluid collection, but will keep the donor under their direct observation and will not report this as a refusal to test. Five commenters disagreed, stating that a donor's refusal to empty their pockets should be reported as a refusal to test, for consistency with requirements for a urine collection. The Department has considered these comments and decided that no change is needed. The proposed procedures facilitate the collection process and prevent specimen tampering while maintaining donor privacy. There were no comments on this topic; however, the Department added a sentence in item e stating that a donor is not required to remove any items worn for faith-based reasons. This requirement will be specified for all authorized specimen types.

One commenter expressed concern over the requirement in Section 8.3(h)(4) for the collector to direct the donor to remain at the collection site until the end of the collection, stating that the refusal to test could be cancelled if the donor claimed that the collector did not mention this. The Department has determined that no revision is needed. It is incumbent upon the collector to instruct the donor throughout the collection process, including the instruction to remain through the end of the collection, and to inform the donor of the consequences for leaving early.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

The Department added steps in Section 8.4 to deter donor attempts to tamper with the specimen. Added item a requires the donor to wash their hands under the collector's observation and to keep their hands within view and avoid touching items or surfaces after handwashing. Added Section 8.4(b)(1) specifies that the collector opens the package containing the collection device in the presence of the donor. Five commenters submitted comments on this section.

Two commenters stated that requiring the donor to wash their hands was unnecessary and could cause a problem when the oral fluid collection site has no sink or water. The commenters suggested allowing the donor to wear gloves or use hand wipes as an alternative. The Department has reviewed these comments and determined that no changes are needed to the Guidelines. The instruction does not preclude the use of other means of handwashing. The Department has included examples of alternate means (*e.g.,* alcohol-free hand wipes, moist towelette, or hand sanitizer) in the Oral Fluid Specimen Collection Handbook.

The same two commenters suggested that the donor be instructed not to touch the collection pad. The Department does not agree that this added instruction is needed. The OFMG require the collector to be present and maintain visual contact with the donor throughout the collection, and specifically require the collector to go over the manufacturer's instructions for use of the device with the donor, observe the donor washing their hands before handling the device, and observe the donor positioning the device in their mouth. If the collector detects any conduct that clearly indicates an attempt to tamper with the specimen, the collector reports a refusal to test.

One commenter stated that requiring the donor to avoid touching items or surfaces was unnecessary and unreasonable. Two others agreed that the donor should not touch items that they brought with them after washing their hands, but stated that it may be difficult for the donor to avoid touching surfaces at the collection site. The Department has reviewed the comments and determined that no changes are needed to the Guidelines. The instruction to not touch items or surfaces at the collection site is a reasonable precaution, and compliance should not be difficult for the donor.

Another commenter specifically agreed with added Section 8.4(a)(1), noting this would eliminate errors and attempts to subvert the test.

In regard to added Section 8.4(b)(1), three commenters disagreed with the collector opening the package containing the collection device. Two recommended that the donor open the package, because some devices that are

inserted into the donor's mouth may not be separately wrapped. A third commenter disagreed, stating that a donor could argue that the collector contaminated the device when opening the package. This commenter also noted that remote collections would not be possible if the collector was required to open the package. The Department has reviewed the comments and determined that no change is needed to the Guidelines. Collectors must be trained to maintain the integrity of the specimen (per Section 4.4), and remotely viewed collections are not allowed (*i.e.,* the collector must be present).

Another commenter suggested adding the instruction for the collector to verify and record the device expiration date in Section 8.4(b)(1). The Department agrees with the commenter in part, and has edited Section 8.4(b) to state that each device used must be within the manufacturer's expiration date and inserted a new Section 8.4(c) requiring the collector to verify that each device is within its expiration date prior to use and to document the action on the Federal CCF. As discussed under Section 7.2 above, the Department disagrees with requiring the collector and not the laboratory to record the expiration date.

Section 8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?

One commenter suggested that the Department clarify how many collection attempts should be allowed when a donor is unable to provide a sufficient specimen and recommended that only one additional attempt be allowed to limit costs. The Department reviewed the comment and determined that no change is needed to the proposed Guidelines. As noted in the preamble to the current OFMG, the Department set the time limit but did not set a limit for the number of attempts because there may be different reasons for failing to collect the specimen from the donor.

Section 8.8 How does the collector prepare the oral fluid specimens?

Comments relating to Section 8.8 are addressed under Section 2.5 above.

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

One commenter disagreed with the requirement for the collector to send all copies of the Federal CCF to the Federal agency's designated representative, and stated that the collector should keep the Collector Copy and give the Donor Copy to the donor. The Department has reviewed the comment and determined that no change is needed. The current wording reflects HHS requirements.

Subpart M—Medical Review Officer (MRO)

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

Two commenters submitted comments on this section. One commenter stated that the requirements for additional MRO training in the section are unclear and should be revised to clarify requirements (*e.g.,* what must training consist of, must the MRO take another certification exam, would training be required for annual panel changes). This commenter also suggested that MROs register with SAMHSA to get updates/announcements and acknowledge review of that information. A second commenter indicated that new and existing MROs should receive additional training for oral fluid testing (*e.g.,* collection procedures and documentation; differences in drug detection times for oral fluid and urine; urine and oral fluid cutoffs; criteria for substituted, adulterated, and refusal to test results; dry mouth scenarios; and effect of pre-existing conditions on ability to provide oral fluid).

The Department has reviewed these comments and edited item b of this section to clarify that MROs must be trained on any revisions to the drug and biomarker testing panels. In regard to training, SAMHSA relies on the approved MRO certification entities to ensure that MROs certified by their organizations meet Guidelines requirements. Current documents on the SAMHSA website *https://www.samhsa.gov/workplace* include the HHS Medical Review Officer Guidance Manual, MRO Cases Studies for Urine, and MRO Case Studies for Oral Fluid which address most of the suggested topics. The Department does not maintain an email list, but sends a notice through the NLCP to HHS-approved MRO certification organizations for dissemination to their certified MROs. The Department also sends additional guidance to HHS-certified laboratories to share with MROs, clients, and collectors as applicable.

Section 13.5 What must an MRO do when reviewing an oral fluid specimen's test results?

The Department received three comments on its proposed revisions to Section 13.5.

One commenter agreed with the Department's proposed revision to item 13.5(b)(2) clarifying that the MRO acts on an invalid result only when the MRO has verified the other results for the specimen as negative or when the split specimen was reported as a failure to reconfirm.

The Department revised Section 13.5(c)(2) to clarify that passive exposure to any drug (not just marijuana smoke) and ingestion of food products containing a drug (not just those containing marijuana) are not acceptable medical explanations for a positive drug test. The Department clarified existing item ii regarding ingestion of food products containing a drug and added a new item iii. Although an increased number of States have authorized marijuana use for medical purposes, marijuana remains a Schedule 1 controlled substance and cannot be prescribed under Federal law. For purposes of the Federal drug free workplace program, Federal law pertaining to marijuana control supersedes State marijuana laws, so a physician's recommendation for marijuana use is not a legitimate medical explanation for a positive marijuana test. Also see comments under *Marijuana testing* above.

In addition to the changes described above, the Department reordered OFMG Sections 13.8 and 13.9 to reflect the procedural order (*i.e.,* requirements for an MRO to report a primary specimen test result are now in Section 13.8, and requests for a test of the split specimen are addressed in Section 13.9).

Subpart O—Criteria for Rejecting a Specimen for Testing

15.1 What discrepancies require an HHS-certified laboratory to report an oral fluid specimen as rejected for testing?

As noted in Section 7.2(b), an oral fluid collection device must have an indicator that demonstrates the adequacy of the volume of oral fluid specimen collected. Because the oral fluid specimen volume is critical for determining the specimen concentration, the collector must document that they observed the volume indicator(s) at the time of collection. The Department has revised Section 15.1 (*i.e.,* new paragraph (e)) specifying that the laboratory must reject the specimen when the collector failed to document observation of the volume indicator at the time of collection. This is consistent with current program documents (*e.g.,* Oral Fluid Specimen Collection Handbook for Federal Agency Workplace Drug

Testing Programs, Collection Site Manual, and Medical Review Officer Guidance Manual) posted on the SAMSHSA website, as well as the NLCP Manual for Oral Fluid Laboratories.

Regulatory Impact and Notices

The potential impact that these Guidelines have on the Department of Transportation (DOT) and/or Nuclear Regulatory Commission (NRC) regulated industries depend on the extent to which these agencies incorporate the OFMG revisions into their regulatory programs. Therefore, analysis of the potential impact of these Guidelines on such programs falls under the regulatory purview of DOT and NRC.

Executive Order 14094, 13563 and 12866

Executive Order 14094 of April 6, 2023 (Modernizing Regulatory Review) reaffirms the statement set forth in 13563 of January 18, 2011 (Improving Regulation and Regulatory Review) that ''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.'' The regulatory approach in this document will reduce burdens to providers and to consumers while continuing to provide adequate protections for public health and welfare.

The Secretary has examined the impact of the Guidelines under Executive Order 12866, as amended by Executive Order 14094, 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, as amended by Executive Order 14094, a ''significant regulatory action'' is one that is likely to result in a rule that may meet any one of a number of specified conditions, including: (1) have an annual effect on the economy of $200 million or more in any one year (adjusted every 3 years by the Administrator of the Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product); or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in the Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case. The Administrative Procedure Act (APA) delineates an exception to its rulemaking procedures for ''a matter relating to agency management or personnel'' 5 U.S.C. 553(a)(2). Because the Guidelines issued by the Secretary govern Federal workplace drug testing programs, HHS has taken the position that the Guidelines are a ''matter relating to agency management or personnel'' and, thus, are not subject to the APA's requirements for notice and comment rulemaking. This position is consistent with Executive Order 12564 regarding Drug-Free Workplaces, which directs the Secretary to promulgate scientific and technical guidelines for executive agency drug testing programs.

Costs and Benefits

The Department included a Regulatory Impact and Notices section with cost and benefits analysis and burden estimates in the April 7, 2022 **Federal Register** Notification for the proposed OFMG (87 FR 20522), and requested public comment on all estimates and assumptions. Three commenters submitted comments concerning the Department's costs and benefits analysis.

One commenter noted that the Department did not consider the application of the Guidelines to DOT testing, and recommended reanalysis of the costs and burden of the proposed changes with consideration of the impact on testing by the transportation industry. Please see the first paragraph of the Regulatory Impact and Notices section above.

One commenter stated that the Department did not consider costs to MROs for training and education to bring MROs and MRO staff up to date on new drug panels and reporting methods. This commenter requested that the MRO community be allowed input to testing panel and nomenclature changes to enable adequate staffing and preparation. Another commenter disagreed with the Department's statement in the preamble to the proposed OFMG that ''implementation costs would be lower for laboratories that already offer the drug test'' compared to those laboratories that do not test for the added drug. The commenter indicated that the list of cost impacts for any change should include the laboratory's assay validation, materials management, and updates to IT systems (*e.g.,* laboratory information management system [LIMS], recipient systems, and electronic ordering systems). This commenter indicated that these additional costs should be considered, and that they will be dependent on the complexity and adaptability of these systems. The Department agrees that costs will depend on the change and noted that in the preamble to the proposed OFMG. The Department will continue to proactively solicit cost information from stakeholders when conducting a cost analysis. As described under *Authorized drug testing panel* above, the Department will include a discussion of related costs and benefits when presenting a proposed panel change during a DTAB meeting.

Information Collection/Record Keeping Requirements

The information collection requirements (*i.e.,* reporting and recordkeeping) in the current Guidelines, which establish the scientific and technical guidelines for Federal workplace drug testing programs and establish standards for certification of laboratories engaged in 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 (Federal CCF) 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 remain in effect.

In support of the Government Paperwork Reduction Act (PRA), the

Department revised the Federal CCF to enable its use as an electronic form (78 FR 42091, July 15, 2013) and developed requirements and oversight procedures to ensure that HHS-certified test facilities and other service providers (*e.g.,* collection sites, MROs) using an ECCF maintain the accuracy, security, and confidentiality of electronic drug test information. Before a Federal ECCF can be used for Federal agency specimens, HHS-certified test facilities must submit detailed information and proposed standard operating procedures (SOPs) to the NLCP for SAMHSA review and approval, and undergo an NLCP inspection focused on the proposed ECCF.

Since 2013, SAMHSA has encouraged the use of Federal ECCFs and other electronic processes in HHS-certified test facilities, when practicable, for federally regulated testing operations. In accordance with section 8108(a) of the SUPPORT for Patients and Communities Act, SAMHSA originally set a deadline of August 31, 2023 for all HHS-certified laboratories to submit a request for approval of a digital (paperless) electronic Federal CCF. The Department subsequently extended the deadline to August 31, 2026, to enable sufficient time for all HHS-certified laboratories to identify and contract with an ECCF supplier or to develop an ECCF.

The title and description of the information collected and respondent description are shown in the following paragraphs with an estimate of the annual reporting, disclosure, and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: The Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid

Description: The Mandatory Guidelines establish the scientific and technical guidelines for Federal drug testing programs and establish standards for certification of laboratories engaged in drug testing for Federal agencies under authority of Public Law 100–71, 5 U.S.C. 7301 note, and Executive Order 12564. Federal drug testing programs test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions.

Description of Respondents: Individuals or households, businesses, or other-for-profit and not-for-profit institutions.

The burden estimates in the tables below are based on the following number of respondents: 10,500 donors who apply for employment or are employed in testing designated positions, 100 collectors, 10 oral fluid specimen testing laboratories, and 100 MROs.

ESTIMATE OF ANNUAL REPORTING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
9.2(a)(1)	Laboratory or IITF 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 responsible person (RP) to HHS.	10	1	2	20
11.4(c)	Laboratory submits information to HHS on new RP or alternate RP.	10	1	2	20
11.20	Specifications for laboratory semiannual statistical report of test results to each Federal agency.	10	5	0.5	25
13.8 and 14.7	Specifies that MRO must report all verified primary and split specimen test results to the Federal agency.	100	14	0.05 (3 min)	70
13.11	Specifications for MRO semiannual report to the Secretary or designated representative for Federal agency specimen results that were laboratory-positive and MRO-verified negative.	100	2	0.5	100
16.1(b) & 16.5(a).	Specifies content of request for informal review of suspension/proposed revocation of certification.	1	1	3	3
16.4	Specifies information appellant provides in first written submission when laboratory suspension/revocation is proposed.	1	1	0.5	0.5
16.6	Requires appellant to notify reviewing official of resolution status at end of abeyance period.	1	1	0.5	0.5
16.7(a)	Specifies contents of appellant submission for review	1	1	50	50
16.9(a)	Specifies content of appellant request for expedited review of suspension or proposed revocation.	1	1	3	3
16.9(c)	Specifies contents of review file and briefs	1	1	50	50
Total	.....	256	.....	.....	392

The following reporting requirements are also in the Guidelines, but have not been addressed in the above reporting burden table: collector must report any unusual donor behavior or refusal to participate in the collection process on the Federal CCF (Sections 1.8, 8.9); collector annotates the Federal CCF when a sample is a blind sample (Section 10.3(a)); MRO notifies the Federal agency and HHS when an error occurs on a blind sample (Section 10.4(d)); and Sections 13.6 and 13.7 describe the actions an MRO takes for the medical evaluation of a donor who cannot provide an oral fluid specimen. SAMHSA has not calculated a separate reporting burden for these requirements because they are included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to Federal agencies.

ESTIMATE OF ANNUAL DISCLOSURE BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3(a), 8.6(b)(2)	Collector must contact Federal agency point of contact	100	1	0.05 (3 min)	5
11.21, 11.22	Information on drug test that laboratory must provide to Federal agency upon request or to donor through MRO.	25	10	3	750
13.9(b)	MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported.	100	14	3	4,200
Total		225			4,955

The following disclosure requirements are also included in the Guidelines, but have not been addressed in the above disclosure burden table: the collector must explain the basic collection procedure to the donor and answer any questions (Section 8.3(h)). SAMHSA believes having the collector explain the collection procedure to the donor and answer any questions is a standard business practice and not a disclosure burden.

ESTIMATE OF ANNUAL RECORDKEEPING BURDEN

Section	Purpose	Number of respondents	Responses/ respondent	Hours/ response	Total hours
8.3, 8.4, 8.5, 8.8	Collector completes Federal CCF for specimen collected	100	380	0.07 (4 min)	2,660
8.8(d) & (f)	Donor initials specimen labels/seals and signs statement on the Federal CCF.	38,000	1	0.08 (5 min)	3,040
11.8(a) & 11.17	Laboratory completes Federal CCF upon receipt of specimen and before reporting result.	25	1,520	0.05 (3 min)	1,900
13.4(d)(4), 13.8(c), 14.7(c).	MRO completes Federal CCF before reporting the primary or split specimen result.	100	380	0.05 (3 min)	1,900
14.1(b)	MRO documents donor's request to have split specimen tested	100	2	0.05 (3 min)	10
Total		38,325			9,510

The Guidelines contain several 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 (Section 8.4(e)) requires collectors to enter any information on the Federal CCF of any unusual findings during the oral fluid specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries is included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. 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; 11.10(a); 11.13(a); 11.16; 11.19(a), (b), and (c); 11.20; 11.21(a) and 11.22). These recordkeeping requirements are necessary for any laboratory to conduct forensic drug testing and to ensure the scientific supportability of the test results. These practices are integrated in the current processes and, therefore, SAMHSA does not consider these standard business practices to be an additional burden for disclosure.

Thus, the total annual response burden associated with the testing of oral fluid specimens by the laboratories is estimated to be 13,221 hours (that is, the sum of the total hours from the above tables). Because of the expected transition from urine to oral fluid testing, this number will replace some of the 1,788,809 hours currently approved by OMB under control number 0930–0158 for urine testing under the current Guidelines.

As required by section 3507(d) of the PRA, the Secretary submitted a copy of the proposed Guidelines to OMB for its review. Comments on the information collection requirements were specifically solicited in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of HHS's functions, including whether the information will have practical utility; (2) evaluate the accuracy of HHS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

References

1. Scheidweiler K.B., Spargo E.A., Kelly T.L., Cone E.J., Barnes A.J., Huestis M.A., 2010. Pharmacokinetics of cocaine and metabolites in human oral fluid and correlation with plasma concentrations after controlled administration. *Ther Drug Monit.,* 32(5), 628–37.

Dated: September 27, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Mandatory Guidelines for Federal Workplace Drug Testing Programs Using Oral Fluid Specimens

Subpart A—Applicability

1.1 To whom do these Guidelines apply?

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) Revisions to these Guidelines will be published in final as a notification 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.

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

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

Biomarker Testing Panel. The panel published in the **Federal Register** that includes the biomarkers authorized for testing, with analytes and cutoffs for initial and confirmatory biomarker tests, as described under Section 3.4.

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

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

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

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

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

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

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

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

Collection Device. A product that is used to collect an oral fluid specimen and may include a buffer or diluent.

Collection Site. The location where specimens are collected.

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

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

Confirmatory Specimen Validity Test. A second test performed on a separate aliquot of a specimen to further support 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, drug metabolite, or biomarker concentration) used as the decision point to determine a result (*e.g.,* negative, positive, adulterated, invalid, or substituted) or the need for further testing.

Donor. The individual from whom a specimen is collected.

Drug Testing Panel. The panel published in the **Federal Register** that includes the drugs authorized for testing, with analytes and cutoffs for initial and confirmatory drug tests, as described under Section 3.4.

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

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

Federal Drug Testing Custody and Control Form (Federal CCF). The Office of Management and Budget (OMB)

approved form that is used to document the collection and chain of custody of a specimen from the time the specimen is collected until it is received by the test facility (*i.e.,* HHS-certified laboratory or, for urine, HHS-certified IITF). It may be a paper (hardcopy), electronic(digital), 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 adulterated, invalid, substituted, or (for urine) dilute.

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

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

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

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

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

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

Oxidizing Adulterant. A substance that acts alone or in combination with other substances to oxidize drug or drug metabolites to prevent the detection of the drugs or drug metabolites, or affects the reagents in either the initial or confirmatory drug test.

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

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

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

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

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

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

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

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

Split Specimen Collection (for Oral Fluid). A collection in which two specimens (primary [A] and split [B]) are collected, concurrently or serially, and independently sealed in the presence of the donor; or a collection in which a single specimen is collected using a single collection device and is subdivided into a primary (A) specimen and a split (B) specimen, which are independently sealed in the presence of the donor.

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

Substituted Specimen. A specimen that has been submitted in place of the donor's specimen, as evidenced by the absence of a biomarker or a biomarker concentration inconsistent with that established for a human specimen, as indicated in the biomarker testing panel, or (for urine) creatinine and specific gravity values that are outside the physiologically producible ranges of human urine, in accordance with the criteria to report a urine specimen as substituted in the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (UrMG), Section 3.7.

Undiluted (neat) oral fluid. An oral fluid specimen to which no other solid or liquid has been added. For example, see Section 2.4: a collection device that uses a diluent (or other component, process, or method that modifies the volume of the testable specimen) must collect at least 1 mL of undiluted (neat) oral fluid.

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

Consistent with 5 U.S.C. 552a and 48 CFR 24.101 through 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 *https://www.hhs.gov/hipaa/index.html.*

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 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;

(3) Fail to provide a specimen (*e.g.,* oral fluid or another authorized specimen type) for any drug test required by these Guidelines or Federal agency regulations;

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

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

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

(7) Fail to cooperate with any part of the testing process (*e.g.,* disrupt the collection process, fail to rinse the mouth or wash hands after being directed to do so by the collector, refuse to provide a split specimen);

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

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

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

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

(a) A refusal to take a test may result in the initiation of disciplinary or adverse action for a Federal employee, up to and including removal from Federal employment. An applicant's refusal to take a pre-employment test may result in non-selection for Federal employment.

(b) When a donor has refused to participate in a part of the collection process, including failing to appear in a reasonable time for any test, the collector must terminate the collection process and take action as described in Section 8.9. Required action includes immediately notifying the Federal agency's designated representative by any means (*e.g.,* telephone, email, or secure facsimile [fax] machine) that ensures that the refusal notification is immediately received and, if a Federal CCF has been initiated, documenting the refusal on the Federal CCF, signing and dating the Federal CCF, and sending all copies of the Federal CCF to the Federal agency's designated representative.

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

(1) Checking the refusal to test box;

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

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

Subpart B—Oral Fluid Specimens

Section 2.1 What type of specimen may be collected?

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

Section 2.2 Under what circumstances may an oral fluid specimen be collected?

A Federal agency may collect an oral fluid specimen for the following reasons:

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

(b) Random test;

(c) Reasonable suspicion/cause test;

(d) Post accident test;

(e) Return to duty test; or

(f) Follow-up test.

Section 2.3 How is each oral fluid specimen collected?

Each oral fluid specimen is collected as a split specimen (*i.e.,* collected either simultaneously or serially) as described in Sections 2.5 and 8.8.

Section 2.4 What volume of oral fluid is collected?

A volume of at least 1 mL of undiluted (neat) oral fluid for each oral fluid specimen (designated ''Tube A'' and ''Tube B'') is collected using a collection device. If the device does not include a diluent (or other component, process, or method that modifies the volume of the testable specimen), the A and B tubes must have a volume marking clearly noting a level of 1 mL.

Section 2.5 How is the split oral fluid specimen collected?

The collector collects at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ''A'' (primary) and at least 1 mL of undiluted (neat) oral fluid in a collection device designated as ''B'' (split) either simultaneously or serially (*i.e.,* using two devices or using one device and subdividing the specimen), as described in Section 8.8.

Section 2.6 When may an entity or individual release an oral fluid specimen?

Entities and individuals subject to these Guidelines under Section 1.1 may not release specimens collected pursuant to Executive Order 12564, Public Law 100–71, and these Guidelines to donors or their designees. Specimens also may not be released to any other entity or individual unless expressly authorized by these Guidelines or by applicable Federal law. This section does not prohibit a donor's request to have a split (B) specimen tested in accordance with Section 13.9.

Subpart C—Oral Fluid Specimen Tests

Section 3.1 Which tests are conducted on an oral fluid specimen?

A Federal agency:

(a) Must ensure that each specimen is tested for marijuana and cocaine as provided in the drug testing panel described under Section 3.4;

(b) Is authorized to test each specimen for other Schedule I or II drugs as provided in the drug testing panel;

(c) Is authorized upon a Medical Review Officer's request to test an oral fluid specimen to determine specimen validity using, for example, a test for a specific adulterant;

(d) Is authorized to test each specimen for one or more biomarkers as provided in the biomarker testing panel; and

(e) May perform additional testing if a specimen exhibits abnormal characteristics (*e.g.,* unusual odor or color, semi-solid characteristics), causes reactions or responses characteristic of an adulterant during initial or confirmatory drug tests (*e.g.,* non-recovery of internal standard, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis.

Section 3.2 May a specimen be tested for drugs other than those in the drug testing panel?

(a) On a case-by-case basis, a specimen may be tested for additional

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

(b) A Federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in the drug testing panel described under Section 3.4. Such approval must be limited to the use of the appropriate science and technology and must not otherwise limit agency discretion to test for any drug tested under Section 3.2(a).

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 and biomarker test analytes and cutoffs for undiluted (neat) oral fluid?

The Secretary will publish the drug and biomarker test analytes and cutoffs (*i.e.,* the ''drug testing panel'' and ''biomarker testing panel'') for initial and confirmatory drug and biomarker tests in the **Federal Register** each year. The drug and biomarker testing panels will also be available on the internet at *https://www.samhsa.gov/workplace.*

This drug testing panel will remain in effect until the effective date of a new drug testing panel published in the **Federal Register**:

Initial test analyte	Initial test cutoff [1]	Confirmatory test analyte	Confirmatory test cutoff
Marijuana (THC) [2]	4 ng/mL [3]	THC	2 ng/mL.
Cocaine/Benzoylecgonine	15 ng/mL	Cocaine	8 ng/mL.
		Benzoylecgonine	8 ng/mL.
Codeine/Morphine	30 ng/mL	Codeine	15 ng/mL.
		Morphine	15 ng/mL.
Hydrocodone/Hydromorphone	30 ng/mL	Hydrocodone	15 ng/mL.
		Hydromorphone	15 ng/mL.
Oxycodone/Oxymorphone	30 ng/mL	Oxycodone	15 ng/mL.
		Oxymorphone	15 ng/mL.
6-Acetylmorphine	4 ng/mL [3]	6-Acetylmorphine	2 ng/mL.
Phencyclidine	10 ng/mL	Phencyclidine	10 ng/mL.
Amphetamine/Methamphetamine	50 ng/mL	Amphetamine	25 ng/mL.
		Methamphetamine	25 ng/mL.
MDMA [4]/MDA [5]	50 ng/mL.	MDMA	25 ng/mL.
		MDA	25 ng/mL.

[1] *For grouped analytes (i.e., two or more analytes that are in the same drug class and have the same initial test cutoff):*
Immunoassay: The test must be calibrated with one analyte from the group identified as the target analyte. The cross-reactivity of the immunoassay to the other analyte(s) within the group must be 80 percent or greater; if not, separate immunoassays must be used for the analytes within the group.
Alternate technology: Either one analyte or all analytes from the group must be used for calibration, depending on the technology. At least one analyte within the group must have a concentration equal to or greater than the initial test cutoff or, alternatively, the sum of the analytes present (i.e., equal to or greater than the laboratory's validated limit of quantification) must be equal to or greater than the initial test cutoff.
[2] An immunoassay must be calibrated with the target analyte, Δ-9-tetrahydrocannabinol (THC).
[3] *Alternate technology (THC and 6–AM):* The confirmatory test cutoff must be used for an alternate technology initial test that is specific for the target analyte (i.e., 2 ng/mL for THC, 2 ng/mL for 6–AM).
[4] Methylenedioxymethamphetamine (MDMA).
[5] Methylenedioxyamphetamine (MDA).

(a) The drug testing panel will include drugs authorized for testing in Federal workplace drug testing programs, with the required test analytes and cutoffs;

(b) The biomarker testing panel will include biomarkers authorized for testing in Federal workplace drug testing programs, with the required test analytes and cutoffs; and

(c) HHS-certified laboratories and Medical Review Officers must use the nomenclature (*i.e.,* analyte names and abbreviations) published in the **Federal Register** with the drug and biomarker testing panels to report Federal workplace drug test results.

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). An HHS-certified laboratory is not authorized to routinely perform additional drug and/or specimen validity tests at the request of an MRO without prior authorization from the Secretary or designated HHS representative, with the exception of the determination of d,l stereoisomers of amphetamine and methamphetamine. All tests must meet appropriate validation and quality control requirements in accordance with these Guidelines.

Section 3.6 What criteria are used to report an oral fluid specimen as adulterated?

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

Section 3.7 What criteria are used to report an oral fluid specimen as substituted?

An HHS-certified laboratory reports a primary (A) specimen as substituted when a biomarker is not detected or is present at a concentration inconsistent with that established for human oral fluid for both the initial (first) test and the confirmatory (second) test on two separate aliquots (*i.e.,* using the test analytes and cutoffs listed in the biomarker testing panel).

Section 3.8 What criteria are used to report an invalid result for an oral fluid specimen?

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

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

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

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

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

(e) A specimen validity test on two separate aliquots of the specimen indicates that the specimen is not valid for testing.

Subpart D—Collectors

Section 4.1 Who may collect a specimen?

(a) A collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

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

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

Section 4.2 Who may not collect a specimen?

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

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

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

(d) To avoid a potential conflict of interest, a collector must not be related to the employee (*e.g.,* spouse, ex-spouse, relative) or a personal friend of the employee (*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 the collection procedure described in these Guidelines;

(3) Is trained and qualified to use the specific oral fluid collection device. Training must include the following:

(i) All steps necessary to complete an oral fluid collection;

(ii) Completion and distribution of the Federal CCF;

(iii) Problem collections;

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

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

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

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

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

(b) A trained collector must complete refresher training at least every five years that includes the requirements in *Section 4.3*(a).

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

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

Section 4.4 What are the requirements to be a trainer for collectors?

(a) Individuals are considered qualified trainers for collectors for a specific oral fluid collection device and may train others to collect oral fluid specimens using that collection device when they have completed the following:

(1) Qualified as a trained collector and regularly conducted oral fluid drug test collections using that collection device for a period of at least one year or

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

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

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

Section 4.5 What must a Federal agency do before a collector is permitted to collect a specimen?

A Federal agency must ensure the following:

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

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

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

Subpart E—Collection Sites

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

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

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect an oral fluid specimen (*e.g.,* an accident investigation), another site may be used for the collection, providing the collection is performed by a collector who has been trained to collect oral fluid specimens in accordance with these Guidelines and the manufacturer's procedures for the collection device.

Section 5.2 What are the requirements for a collection site?

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

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

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

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

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

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

(f) 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 an oral fluid specimen?

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

Subpart F—Federal Drug Testing Custody and Control Form

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

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

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

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

(b) If the collector does not use the correct OMB-approved Federal CCF, the collector must document that it is a Federal agency specimen collection and provide the reason that the incorrect form was used. Based on the 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—Oral Fluid Specimen Collection Devices

Section 7.1 What is used to collect an oral fluid specimen?

A single-use collection device intended to collect an oral fluid specimen must be used. This collection device must maintain the integrity of such specimens during storage and transport so that the specimen contained therein can be tested in an HHS-certified laboratory for the presence of drugs or their metabolites.

Section 7.2 What are the requirements for an oral fluid collection device?

An oral fluid specimen collection device must provide:

(a) An indicator that demonstrates the adequacy of the volume of oral fluid specimen collected;

(b) One or two sealable, non-leaking tubes [depending on the device type, as described in Section 8.8(a)] that:

(1) 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 or their metabolites,

(2) are sufficiently transparent (*e.g.,* translucent) to enable a visual assessment of the contents (*i.e.,* oral fluid, buffer/diluent, collection pad) for identification of abnormal physical characteristics without opening the tube, and

(3) include the device lot expiration date on each specimen tube (*i.e.,* the expiration date of the buffer/diluent or, for devices without a buffer/diluent, the earliest expiration date of any device component);

(c) Components that ensure pre-analytical drug and drug metabolite stability; and

(d) Components that do not substantially affect the composition of drugs and/or drug metabolites in the oral fluid specimen.

Section 7.3 What are the minimum performance requirements for a collection device?

An oral fluid collection device must meet the following minimum performance requirements.

(a) Reliable collection of a minimum of 1 mL of undiluted (neat) oral fluid;

(b) If the collection device contains a diluent (or other component, process, or method that modifies the volume of the testable specimen):

(1) The volume of oral fluid collected should be at least 1.0 mL ±10 percent, and

(2) The volume of diluent in the device should be within ±2.5 percent of the diluent target volume;

(c) Stability (recoverable concentrations ≥80 percent of the concentration at the time of collection) of the drugs and/or drug metabolites for five days at room temperature (64–77 °F/18–25 °C) and under the manufacturer's intended shipping and storage conditions; and

(d) Recover ≥80 percent (but no more than 120 percent) of drug and/or drug metabolite in the undiluted (neat) oral fluid at (or near) the initial test cutoff listed in the drug testing panel.

Subpart H—Oral Fluid Specimen Collection Procedure

Section 8.1 What privacy must the donor be given when providing an oral fluid specimen?

The following privacy requirements apply when a donor is providing an oral fluid specimen:

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

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

Section 8.2 What must the collector ensure at the collection site before starting an oral fluid specimen collection?

The collector must take all reasonable steps to prevent the adulteration or substitution of an oral fluid specimen at the collection site.

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

The collector must take the following steps before beginning an oral fluid specimen collection:

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

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

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

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

(e) The collector asks the donor to remove any unnecessary outer garments (*e.g.,* coat, jacket) that might conceal items or substances that could be used to adulterate or substitute the oral fluid specimen. The collector must ensure that all personal belongings (*e.g.,* purse or briefcase) remain with the outer garments. The donor may retain the donor's wallet. The donor is not required to remove any items worn for faith-based reasons.

(f) If the donor will remain under the collector's direct observation until the end of the collection, including the 10-minute wait period described in Section 8.3(h), the collector proceeds to Section 8.3(g). If the collector will not keep the donor under direct observation from this point until the end of the collection, the collector asks the donor to empty the donor's pockets and display the contents to ensure no items are present that could be used to adulterate or substitute the specimen.

(1) If no items are present that can be used to adulterate or substitute the specimen, the collector instructs the donor to return the items to their pockets and continues the collection procedure.

(2) If an item is present whose purpose is to adulterate or substitute the specimen (*e.g.,* a commercial drug culture product or other substance for which the donor has no reasonable explanation), 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.

(3) If an item that could be used to adulterate or substitute the specimen (*e.g.,* common personal care products such as mouthwash, lozenges, capsules) appears to have been inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(4) If the donor refuses to show the collector the items in their pockets, the collector must keep the donor under direct observation until the end of the oral fluid collection.

(g) The collector requests that the donor open the donor's mouth, and the collector inspects the oral cavity to ensure that it is free of any items (*e.g.,* candy, gum, food, tobacco) that could impede or interfere with the collection of an oral fluid specimen or items that could be used to adulterate, substitute, or dilute the specimen.

(1) If an item is present that whose purpose is to adulterate or substitute the specimen (*e.g.,* a commercial drug culture product or other item for which the donor has no reasonable explanation), 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.

(2) If an item is present that could impede or interfere with the collection of an oral fluid specimen (including abnormally colored saliva), or the donor claims to have ''dry mouth,'' the collector gives the donor water (*e.g.,* up to 4 oz.) to rinse their mouth. The donor may drink the water. If the donor refuses to remove the item or refuses to rinse, this is a refusal to test.

(3) If the donor claims that they have a medical condition that prevents opening their mouth for inspection, the collector follows the procedure in Section 8.6(b)(2).

(h) The collector must initiate a 10-minute wait period prior to collecting the specimen. During these 10 minutes, the collector must:

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

(2) Provide the instructions for completing the Federal CCF for the donor's review, and informs the donor that these instructions and the collection device-specific instructions are available upon request.

(3) Answer any reasonable and appropriate questions the donor may have regarding the collection procedure; and

(4) Inform the donor that they must remain at the collection site (*i.e.,* in the area designated by the collector) during the wait period, and that failure to follow these instructions will be reported as a refusal to test.

Section 8.4 What steps does the collector take in the collection procedure before the donor provides an oral fluid specimen?

(a) The collector shall instruct the donor to wash and dry the donor's hands under the collector's observation, and to keep their hands within view and avoid touching items or surfaces after handwashing. If the donor refuses to wash their hands when instructed by the collector, this is a refusal to test.

(b) The collector will provide or the donor may select the specimen collection device(s) to be used for the collection. The device(s) must be clean, unused, and wrapped/sealed in original packaging and must be within the manufacturer's expiration date printed on the specimen tube. See Section 8.8(a) for types of specimen collection devices used for oral fluid split specimen collections.

(1) The collector will open the package in view of the donor.

(2) Both the collector and the donor must keep the unwrapped collection devices in view at all times until each collection device containing the donor's oral fluid specimen has been sealed and labeled.

(c) The collector verifies that each device is within the manufacturer's expiration date, and documents this action on the Federal CCF.

(d) The collector reviews with the donor the procedures required for a successful oral fluid specimen collection as stated in the manufacturer's instructions for the specimen collection device.

(e) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (*e.g.,* an attempt to prevent the device from collecting sufficient oral fluid; an attempt to bring into the collection site an adulterant or oral fluid substitute), the collector must report a refusal to test in accordance with Section 8.9.

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

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

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

(1) Under the observation of the collector, the donor is responsible for positioning the specimen collection device for collection. The collector must ensure the collection is performed correctly and that the collection device is working properly. If there is a failure to collect the specimen, the collector must begin the process again, beginning with Step 8.4(b), using a new specimen collection device (for both A and B specimens) and notes the failed collection attempt on the Federal CCF. If the donor states that they are unable to provide an oral fluid specimen during the collection process or after multiple failures to collect the specimen, the collector follows the procedure in Section 8.6.

(2) The donor and the collector must complete the collection in accordance with the manufacturer instructions for the collection device.

(3) The collector must inspect the specimen to determine if there is any sign indicating that the specimen may not be a valid oral fluid specimen (*e.g.,* unusual color, presence of foreign objects or material), documents any unusual findings on the Federal CCF, and takes action (*e.g.,* recollection) to obtain an acceptable specimen.

(b) If the donor fails to remain present through the completion of the collection, fails to follow the instructions for the collection device, refuses to begin the collection process after a failure to collect the specimen as required in Section 8.5(a)(1), refuses to provide a split specimen as instructed by the collector, 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.

Section 8.6 What procedure is used when the donor states that they are unable to provide an oral fluid specimen?

(a) If the donor states that they are unable to provide an oral fluid specimen during the collection process, the collector requests that the donor follow the collector instructions and attempt to provide an oral fluid specimen.

(b) The donor demonstrates their inability to provide a specimen when, after 15 minutes of using the collection device, there is insufficient volume or no oral fluid collected using the device.

(1) If the donor states that they could provide a specimen after drinking some fluids, the collector gives the donor a drink (up to 8 ounces) and waits an additional 10 minutes before beginning the specimen collection (a period of 1 hour must be provided or until the donor has provided a sufficient oral fluid specimen). If the donor simply needs more time before attempting to provide an oral fluid specimen, the donor may choose not to drink any fluids during the 1 hour wait time. The collector must inform the donor that the donor must remain at the collection site (*i.e.,* in an area designated by the collector) during the wait period.

(2) If the donor states that they are unable to provide an oral fluid specimen, the collector records the reason for not collecting an oral fluid specimen on the Federal CCF, notifies the Federal agency's designated representative for authorization to collect an alternate specimen, and sends the appropriate copies of the Federal CCF to the MRO and to the Federal agency's designated representative. The Federal agency may choose to provide the collection site with a standard protocol to follow in lieu of requiring the collector to notify the agency's designated representative for authorization in each case. If an alternate specimen is authorized, the collector may begin the collection procedure for the alternate specimen (see Section 8.7) in accordance with the Mandatory Guidelines for Federal Workplace Drug Testing Programs using the alternate specimen.

Section 8.7 If the donor is unable to provide an oral fluid specimen, may another specimen type be collected for testing?

Yes, if the alternate specimen type is authorized by Mandatory Guidelines for Federal Workplace Drug Testing Programs and specifically authorized by the Federal agency.

Section 8.8 How does the collector prepare the oral fluid specimens?

(a) All Federal agency collections are to be split specimen collections. An oral fluid split specimen collection may be:

(1) Two specimens collected simultaneously with two separate collection devices;

(2) Two specimens collected serially with two separate collection devices. The donor is not allowed to drink or rinse their mouth between the two collections. Collection of the second specimen must begin within two minutes after the completion of the first collection and recorded on the Federal CCF;

(3) Two specimens collected simultaneously using a single collection device that directs the oral fluid into two separate collection tubes; or

(4) A single specimen collected using a single collection device, that is subsequently subdivided into two specimens.

(b) A volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube

A'' and a volume of at least 1 mL of undiluted (neat) oral fluid is collected for the specimen designated as ''Tube B''.

(c) In the presence of the donor, the collector places a tamper-evident label/seal from the Federal CCF over the cap of each specimen tube. The collector records the date of the collection on the tamper-evident labels/seals.

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

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

(f) The collector asks the donor to read and sign a statement on the Federal CCF certifying that the specimens identified were collected from the donor. If the donor refuses to sign the certification statement, the collector notes the refusal on the Federal CCF and continues with the collection process.

(g) The collector signs and prints their name on the Federal CCF, completes the Federal CCF, and distributes the copies of the Federal CCF as required.

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

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

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

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

(a) Notifying the Federal agency by means (*e.g.,* telephone, email, or secure fax) that ensures that the notification is immediately received,

(b) Documenting the refusal to test including the reason on the Federal CCF, and

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

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

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

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

(c) A Federal agency must investigate reported collection site deficiencies (*e.g.,* specimens reported ''rejected for testing'' by an HHS-certified laboratory) and take appropriate action which may include a collection site self-assessment (*i.e.,* using the Collection Site Checklist for the Collection of Oral Fluid Specimens for Federal Agency Workplace Drug Testing Programs) or an inspection of the collection site. The inspections of these additional collection sites may be included in the 5 percent or maximum of 50 collection sites inspected annually.

Subpart I—HHS Certification of Laboratories

Section 9.1 Who has the authority to certify laboratories to test oral fluid specimens for Federal agencies?

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

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

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

(a) A laboratory seeking HHS certification must:

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

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

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

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

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

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

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

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

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

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

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

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

(1) Stop testing federally regulated specimens;

(2) Ensure the security of federally regulated specimens and records throughout the required storage period described in Sections 11.18, 11.19, and 14.8;

(3) Ensure access to federally regulated specimens and records in accordance with Sections 11.21 and 11.22 and subpart P of these Guidelines; and

(4) Follow the HHS suspension and revocation procedures when imposed by the Secretary, follow the HHS

procedures in subpart P of these Guidelines 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 the drug testing panel and may be sent to the laboratory as undiluted (neat) oral fluid. The PT samples must satisfy one of the following parameters:

(i) The concentration of a drug or metabolite will be at least 20 percent above the initial test cutoff 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 when the PT sample is designated as a retest sample; or

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

(2) A PT sample may contain an interfering substance, an adulterant, or other substances for special purposes, or may satisfy the criteria for a substituted specimen or invalid result.

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

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

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

(a) An applicant laboratory that seeks certification under these Guidelines to perform oral fluid 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 ±20 percent or ±2 standard deviations [whichever is larger] from the appropriate reference or peer group means) for at least 80 percent of the total drug challenges over the three sets of PT samples;

(5) For the confirmatory drug tests, do not obtain any drug concentration that differs by more than ±50 percent from the appropriate reference or peer group mean;

(6) For each confirmatory drug test, correctly identify and determine the concentrations (*i.e.,* no more than ±20 percent or ±2 standard deviations [whichever is larger] from the appropriate reference or peer group means) for at least 50 percent of the drug challenges for an individual drug over the three sets of PT samples;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over the three sets of PT samples;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the three sets of PT samples;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over the three sets of PT samples that satisfy the specified criteria; and

(10) Do not report any PT sample as adulterated with a compound that is not present in the sample or substituted when the appropriate reference or peer group mean for a biomarker is within the acceptable range.

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

Section 9.7 What are the PT requirements for an HHS-certified oral fluid laboratory?

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

(5) For the confirmatory drug tests, do not obtain any drug concentration that differs by more than ±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 ±20 percent or ±2 standard deviations (whichever is larger) from the appropriate reference or peer group means over two consecutive PT cycles;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over two consecutive PT cycles;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over two consecutive PT cycles;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over two consecutive PT cycles that satisfy the specified criteria; and

(10) Do not report any PT sample as adulterated with a compound that is not present in the sample or substituted when the appropriate reference or peer group mean for a biomarker is within the acceptable range.

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

Section 9.8 What are the 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) Each inspector conducts an independent evaluation and review of the HHS-certified laboratory's procedures, records, and facilities using guidance provided by the Secretary.

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

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

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

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

(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 of these Guidelines, 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 of these Guidelines 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 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 of these Guidelines.

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 *https://www.samhsa.gov/workplace.*

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

Subpart J—Blind Samples Submitted by an Agency

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

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

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

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

Section 10.2 What are the requirements for blind samples?

(a) Drug positive blind samples must be validated by the supplier in the selected manufacturer's collection device as to their content using appropriate initial and confirmatory tests.

(1) Drug positive blind samples must contain one or more of the drugs or metabolites listed in the drug testing panel.

(2) Drug positive blind samples must contain concentrations of drugs between 1.5 and 2 times the initial drug test cutoff.

(b) Drug negative blind samples (*i.e.,* certified to contain no drugs) must be validated by the supplier in the selected manufacturer's collection device as negative using appropriate initial and confirmatory tests.

(c) The supplier must provide information on the blind samples' content, validation, expected results, and stability to the collection site/collector sending the blind samples to the laboratory, and must provide the information upon request to the MRO, the Federal agency for which the blind sample was submitted, or the Secretary.

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

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

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

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

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

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

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

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

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

(e) The Secretary shall investigate the blind sample error. A report of the Secretary's investigative findings and the corrective action taken in response to identified deficiencies must be sent to the Federal agency. The Secretary shall ensure notification of the finding as appropriate to other Federal agencies and coordinate any necessary actions to prevent the recurrence of the error.

Subpart K—Laboratory

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

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

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

(1) Chain of custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

(9) Computers, software, and laboratory information management systems.

(c) All procedures in the SOP manual must be compliant with these Guidelines and all guidance provided by the Secretary.

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

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

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

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

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

laboratory. The SOP must be reviewed and documented by the RP annually.

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

(e) Initiate and implement all remedial actions necessary to maintain satisfactory operation and performance of the HHS-certified laboratory in response to the following: quality control systems not within performance specifications; errors in result reporting or in analysis of performance testing samples; and inspection deficiencies. The RP must ensure that specimen results are not reported until all corrective actions have been taken and that the results provided are accurate and reliable.

Section 11.3 What scientific qualifications must the RP have?

The RP must have documented scientific qualifications in analytical toxicology.

Minimum qualifications are:

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

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

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

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

(e) Qualify as a certifying scientist.

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

(a) HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. If the RP(s) are concurrently absent, an alternate RP must be present and qualified to fulfill the responsibilities of the RP.

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

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

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

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

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

(c) To nominate an individual as an RP or alternate RP, the HHS-certified laboratory must submit the following documents to the Secretary: the candidate's current resume or curriculum vitae, copies of diplomas and licensures, a training plan (not to exceed 90 days) to transition the candidate into the position, an itemized comparison of the candidate's qualifications to the minimum RP qualifications described in the Guidelines, and have official academic transcript(s) submitted from the candidate's institution(s) of higher learning. The candidate must be found qualified during an on-site inspection of the HHS-certified laboratory.

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

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

(a) A certifying scientist must have:

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

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

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

(b) A certifying technician must have:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Section 11.9 What are the requirements for an initial drug test?

(a) An initial drug test may be:

(1) An immunoassay or

(2) An alternate technology (*e.g.,* spectrometry, spectroscopy).

(b) An HHS-certified laboratory must validate an initial drug test before testing specimens.

(c) Initial drug tests must be accurate and reliable for the testing of specimens when identifying drugs or their metabolites.

(d) An HHS-certified laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.11.

Section 11.10 What must an HHS-certified laboratory do to validate an initial drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each initial drug test:

(1) The ability to differentiate negative specimens from those requiring further testing;

(2) The performance of the test around the cutoff, using samples at several concentrations between 0 and 150 percent of the cutoff;

(3) The effective concentration range of the test (linearity);

(4) The potential for carryover;

(5) The potential for interfering substances; and

(6) The potential matrix effects if using an alternate technology.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) Each initial drug test using an alternate technology must be re-verified periodically or at least annually.

Section 11.11 What are the batch quality control requirements when conducting an initial drug test?

(a) Each batch of specimens must contain the following controls:

(1) At least one control certified to contain no drug or drug metabolite;

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

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

(4) At least one control that appears as a donor specimen to the analysts.

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

Section 11.12 What are the requirements for a confirmatory drug test?

(a) The analytical method must use mass spectrometric identification (*e.g.,* gas chromatography-mass spectrometry [GC–MS], liquid chromatography-mass spectrometry [LC–MS], GC–MS/MS, LC–MS/MS) or equivalent.

(b) A confirmatory drug test must be validated before it can be used to test federally regulated specimens.

(c) Confirmatory drug tests must be accurate and reliable for the testing of an oral fluid specimen when identifying and quantifying drugs or their metabolites.

Section 11.13 What must an HHS-certified laboratory do to validate a confirmatory drug test?

(a) An HHS-certified laboratory must demonstrate and document the following for each confirmatory drug test:

(1) The linear range of the analysis;

(2) The limit of detection;

(3) The limit of quantification;

(4) The accuracy and precision at the cutoff;

(5) The accuracy (bias) and precision at 40 percent of the cutoff;

(6) The potential for interfering substances;

(7) The potential for carryover; and

(8) The potential matrix effects if using liquid chromatography coupled with mass spectrometry.

(b) Each new lot of reagent must be verified prior to being placed into service.

(c) HHS-certified laboratories must re-verify each confirmatory drug test method periodically or at least annually.

Section 11.14 What are the batch quality control requirements when conducting a confirmatory drug test?

(a) At a minimum, each batch of specimens must contain the following calibrators and controls:

(1) A calibrator at the cutoff;

(2) At least one control certified to contain no drug or drug metabolite;

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

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

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

Section 11.15 What are the analytical and quality control requirements for conducting specimen validity tests?

An HHS-certified laboratory may perform specimen validity tests in accordance with Sections 3.1 and 3.5.

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

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

(c) Controls must be analyzed concurrently with specimens.

Section 11.16 What must an HHS-certified laboratory do to validate a specimen validity test?

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test, and must re-verify the test periodically, or at least annually. Each new lot of reagent must be verified prior to being placed into service.

Section 11.17 What are the requirements for an HHS-certified laboratory to report a test result?

(a) Laboratories must report a test result to the agency's MRO within an average of 5 working days after receipt of the specimen. Reports must use the Federal CCF and/or an electronic report, as described in items o and p 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 Section 11.17(g)(1) through (5).

(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 the cutoffs listed in the drug testing panel.

(d) A primary (A) oral fluid specimen is reported 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.

(e) A primary (A) oral fluid specimen is reported substituted when a biomarker is not present or is present at a concentration inconsistent with that established for human oral fluid.

(f) For a specimen that has an invalid result for one of the reasons stated in Section 11/17(g)(1) through (5), 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.

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

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

(2) Interference with the confirmatory drug test occurs on at least two separate aliquots of the specimen and the HHS-certified laboratory is unable to identify the interfering substance;

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

(4) The physical appearances of the A and B specimens are clearly different (note: A is tested); or

(5) A specimen validity test on two separate aliquots of the specimen indicates that the specimen is not valid for testing.

(h) 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.

(i) An HHS-certified laboratory must report all positive, adulterated, substituted, and invalid test results for an oral fluid specimen. For example, a specimen can be positive for a drug and adulterated.

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

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

(l) An HHS-certified laboratory must report results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

(m) When the concentration of a drug or drug metabolite exceeds the validated linear range of the confirmatory test, HHS-certified laboratories may report to the MRO that the quantitative value exceeds the linear range of the test or that the quantitative value is greater than ''insert the actual value for the upper limit of the linear range,'' or laboratories may report a quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen to achieve a result within the method's linear range and multiplying the result by the appropriate dilution factor.

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

(o) HHS-certified laboratories must 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.

(p) 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 11.18 How long must an HHS-certified laboratory retain specimens?

(a) An HHS-certified laboratory must retain specimens that were reported as positive, adulterated, substituted, or as an invalid result for a minimum of 1 year.

(b) Retained oral fluid specimens must be kept in secured storage in accordance with the collection device manufacturer's specifications (*i.e.,* frozen at −20 °C or less, or refrigerated), to ensure their availability for retesting during an administrative or judicial proceeding.

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

Section 11.19 How long must an HHS-certified laboratory retain records?

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

(b) A Federal agency may request the HHS-certified laboratory to maintain a documentation package (as described in Section 11.21) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The Federal agency's request to the laboratory must be in writing and must specify the period of time to maintain the documentation package.

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

Section 11.20 What statistical summary reports must an HHS-certified laboratory provide for oral fluid testing?

(a) HHS-certified laboratories must provide to each Federal agency for which they perform testing a semiannual statistical summary report that must be submitted by mail, fax, or email 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 11.21 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 11.22 What HHS-certified laboratory information is available to a Federal employee?

Federal applicants or employees who are subject to 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 11.21(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 11.23 What types of relationships are prohibited between an HHS-certified laboratory and an MRO?

An HHS-certified laboratory must not enter into any relationship with a Federal agency's MRO that may be construed as a potential conflict of interest or derive any financial benefit by having a Federal agency use a specific MRO.

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

Subpart L—Instrumented Initial Test Facility (IITF)

Section 12.1 May an IITF test oral fluid specimens for a Federal agency's workplace drug testing program?

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

Subpart M—Medical Review Officer (MRO)

Section 13.1 Who may serve as an MRO?

(a) A currently licensed physician who has:
(1) A Doctor of Medicine (M.D.) or Doctor of Osteopathy (D.O.) degree;
(2) Knowledge regarding the pharmacology and toxicology of illicit drugs;
(3) The training necessary to serve as an MRO as set out in Section 13.3;
(4) Satisfactorily passed an initial examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs; and
(5) At least every five years from initial certification, completed requalification training on the topics in Section 13.3 and satisfactorily passed a requalification examination administered by a nationally recognized entity or a subspecialty board that has been approved by the Secretary to certify MROs.

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

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

entities and subspecialty boards that have been approved. This notification is also available on the internet at *https://www.samhsa.gov/workplace.*

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 including any changes to the drug and biomarker testing panels 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 11.17(f) to determine whether testing at another HHS-certified laboratory may be warranted.

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

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

(2) Interview the donor when required;

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

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

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

(f) The MRO must conduct a medical examination or a review of the examining physician's findings and make a determination of refusal to test or cancelled test when a collector reports that the donor was unable to provide a specimen and an alternate specimen was not collected, as addressed in Sections 8.6 and 13.6.

Section 13.5 What must an MRO do when reviewing an oral fluid specimen's test results?

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

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

(1) The MRO reports all verified positive and/or refusal to test results to the Federal agency.

(2) If an invalid result was reported in conjunction with a positive, adulterated, or substituted result, 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 Section 13.5(e) only when:

(i) The MRO verifies the positive, adulterated, or substituted result as negative based on a legitimate medical explanation as described in Section 13.5(c)(2) and (d)(1), or based on codeine and/or morphine concentrations less than 150 ng/mL as described in Section 13.5(c)(3)(i); or

(ii) The split (B) specimen is tested and reported as a failure to reconfirm the positive, adulterated or substituted result reported for the primary (A) specimen as described in Section 14.6(m).

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

(1) If the donor admits unauthorized use of the drug(s) that caused the positive result, the MRO reports the test result as positive to the agency. The MRO must document the donor's admission of unauthorized drug use in the MRO records and in the MRO's report to the Federal 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 a drug (*e.g.,* products containing marijuana) is not a legitimate medical explanation for a positive drug test result. See exceptions for positive codeine and morphine results in Section 13.5(c)(3).

(iii) A physician's authorization or medical recommendation for a Schedule 1 controlled substance is not a legitimate medical explanation for a positive drug test result.

(3) If the donor is unable to provide a legitimate medical explanation for the positive result, the MRO reports the positive result to the agency, for all drugs except codeine and/or morphine as follows:

(i) For codeine and/or morphine less than 150 ng/mL, the MRO must report the result as negative to the agency, unless the donor admits unauthorized use of the drug(s) that caused the positive result as described in Section 13.5(c)(1).

(ii) For codeine and/or morphine equal to or greater than 150 ng/mL and no legitimate medical explanation, the MRO shall report a positive result to the agency. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.

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

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

(2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a refusal to test to the Federal agency because the oral fluid specimen was adulterated or substituted.

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

(1) If the donor provides a legitimate explanation (*e.g.,* a prescription medicine), the MRO reports a test cancelled result with the reason for the invalid result and informs the Federal agency that a recollection is not required because there is a legitimate explanation for the invalid result.

(2) If the donor is unable to provide a legitimate explanation, the MRO reports a test cancelled result with the reason for the invalid result and directs the Federal agency to immediately collect another specimen from the donor.

(i) If the second specimen collected provides a valid result, the MRO follows the procedures in Section 13.5(a) through (d).

(ii) If the second specimen collected provides an invalid result, the MRO reports this specimen as test cancelled and recommends that the agency collect another authorized specimen type (*e.g.,* urine). If the Federal agency does not authorize collection of another specimen type, the MRO consults with the agency to arrange a clinical evaluation as described in Section 13.7, to determine whether there is a legitimate medical reason for the invalid result.

(f) When the HHS-certified laboratory reports a rejected for testing result for the primary (A) specimen, the MRO reports a test cancelled result to the agency and recommends that the agency collect another specimen from the donor.

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

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

(b) When the Federal agency did not authorize the collection of an alternate specimen, the MRO consults with the Federal agency. The Federal agency immediately directs the donor to obtain, within five days, an evaluation from a licensed physician, acceptable to the MRO, who has expertise in the medical issues raised by the donor's failure to provide a specimen. The MRO may perform this evaluation if the MRO has appropriate expertise.

(1) For purposes of this section, a medical condition includes an ascertainable physiological condition. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time.

(2) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

(i) That the donor was required to take a federally regulated drug test, but was unable to provide a sufficient amount of oral fluid to complete the test;

(ii) The consequences of the appropriate Federal agency regulation for refusing to take the required drug test;

(iii) That, after completing the evaluation, the referral physician must agree to provide a written statement to the MRO with a recommendation for one of the determinations described in Section 13.6(b)(3) and the basis for the recommendation. The statement must not include detailed information on the employee's medical condition beyond what is necessary to explain the referral physician's conclusion.

(3) As the MRO, if another physician performed the evaluation, you must consider and assess the referral physician's recommendations in making your determination. You must make one of the following determinations and report it to the Federal agency in writing:

(i) A medical condition as defined in Section 13.6(b)(1) has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid, but is not a permanent or long-term disability. As the MRO, you must report a test cancelled result to the Federal agency.

(ii) A permanent or long-term medical condition as defined in Section 13.6(b)(1) has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of oral fluid and is highly likely to prevent the employee from providing a sufficient amount of oral fluid for a very long or indefinite period of time. As the MRO, you must follow the requirements of Section 13.7, as appropriate. If Section 13.7 is not applicable, you report a test cancelled result to the Federal agency and recommend that the agency authorize collection of an alternate specimen type (*e.g.,* urine) for any subsequent drug tests for the donor.

(iii) There is not an adequate basis for determining that a medical condition has or, with a high degree of probability, could have precluded the employee from providing a sufficient amount of oral fluid. As the MRO, you must report a refusal to test to the Federal agency.

(4) When a Federal agency receives a report from the MRO indicating that a test is cancelled as provided in Section 13.6(b)(3)(i), the agency takes no further action with respect to the donor. When a test is canceled as provided in Section 13.6(b)(3)(ii), the agency takes no further action with respect to the donor other than designating collection of an alternate specimen type (*i.e.,* authorized by the Mandatory Guidelines for Federal Workplace Drug Testing Programs) for any subsequent collections, in accordance with the Federal agency plan. The donor remains in the random testing pool.

13.7 What happens when an individual is unable to provide a sufficient amount of oral fluid for a Federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which the donor has a medical condition that precludes the donor from providing a sufficient specimen for a Federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test and the condition involves a permanent or long-term disability and the Federal agency does not authorize collection of an alternate specimen. As the MRO in this situation, you must do the following:

(1) You must determine if there is clinical evidence that the individual is an illicit drug user. You must make this determination by personally conducting, or causing to be conducted, a medical evaluation and through consultation with the donor's physician and/or the physician who conducted the evaluation under Section 13.6.

(2) If you do not personally conduct the medical evaluation, you must ensure that one is conducted by a licensed physician acceptable to you.

(b) If the medical evaluation reveals no clinical evidence of drug use, as the MRO, you must report the result to the Federal agency as a negative test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient oral fluid specimen

impossible, and for the determination that no signs and symptoms of drug use exist. The MRO recommends that the agency authorize collection of an alternate specimen type (*e.g.,* urine) for any subsequent collections.

(c) If the medical evaluation reveals clinical evidence of drug use, as the MRO, you must report the result to the Federal agency as a cancelled test with written notations regarding results of both the evaluation conducted under Section 13.6 and any further medical examination. This report must state that a permanent or long-term medical condition [as defined in Section 13.6(b)(1)] exists, making provision of a sufficient oral fluid specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (*e.g.,* the Federal agency is not authorized to allow the donor to begin or resume performing official functions, because a negative test is needed for that purpose).

Section 13.8 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.,* fax, computer). Transmissions of the reports must ensure confidentiality. The MRO and external service providers must ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

(b) A verified result may not be reported to the agency until the MRO has completed the review process.

(c) The MRO must send a copy of either the completed MRO copy of the Federal CCF or the separate letter/memorandum report for all positive, adulterated, and substituted results.

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

(e) The MRO must report drug test results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 13.9 Who may request a test of a split (B) specimen?

(a) For a positive, adulterated, or substituted result reported on a primary (A) specimen, a donor may request through the MRO that the split (B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first HHS-certified laboratory.

(b) The donor has 72 hours from the time the MRO notified the donor that the donor's specimen was reported positive, adulterated, or substituted to request a test of the split (B) specimen. The MRO must inform the donor that the donor has the opportunity to request a test of the split (B) specimen when the MRO informs the donor that a positive, adulterated, or substituted result is being reported to the Federal agency on the primary (A) specimen.

Section 13.10 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.

Section 13.11 What reports must an MRO provide to the Secretary for oral fluid testing?

(a) An MRO must send to the Secretary or designated HHS representative a semiannual report of Federal agency specimens that were reported as positive for a drug or drug metabolite by a laboratory and verified as negative by the MRO. The report must not include any personally identifiable information for the donor and must be submitted by mail, fax, or other secure electronic transmission method within 14 working days after the end of the semiannual period (*i.e.,* in January and July). The semiannual report must contain the following information:

(1) Reporting period (inclusive dates);

(2) MRO name, company name, and address;

(3) Federal agency name; and

(4) For each laboratory-reported positive drug test result that was verified as negative by the MRO:

(i) Specimen identification number;

(ii) Laboratory name and address;

(iii) Positive drug(s) or drug metabolite(s) verified as negative;

(iv) MRO reason for verifying the positive drug(s) or drug metabolite(s) as negative (*e.g.,* a donor prescription [the MRO must specify the prescribed drug]);

(v) All results reported to the Federal agency by the MRO for the specimen; and

(vi) Date of the MRO report to the Federal agency.

(b) An MRO must provide copies of the drug test reports that the MRO has sent to a Federal agency when requested to do so by the Secretary.

(c) If an MRO did not verify any positive laboratory results as negative during the reporting period, the MRO should file a report that states that the MRO has no reportable results during the applicable reporting period.

Section 13.12 What are a Federal agency's responsibilities for designating an MRO?

(a) Before allowing an individual to serve as an MRO for the agency, a Federal agency must verify and document the following:

(1) that the individual satisfies all requirements in Section 13.1, including certification by an MRO certification organization that has been approved by the Secretary, as described in Section 13.2; and

(2) that the individual is not an employee, agent of, or have any financial interest in an HHS-certified laboratory that tests the agency's specimens, as described in Section 13.10.

(b) The Federal agency must verify and document that each MRO reviewing and reporting results for the agency:

(1) completes training on any revisions to these Guidelines, including any changes to the drug and biomarker testing panels, prior to their effective date;

(2) at least every five years, maintains their certification by completing requalification training and passing a requalification examination; and

(3) provides biannual reports to the Secretary or designated HHS representative as required in Section 13.11;

(c) The Federal agency must ensure that each MRO reports drug test results to the agency in accordance with Sections 13.8 and 14.7.

(1) Before allowing an MRO to report results electronically, the agency must obtain documentation from the MRO to confirm that the MRO and any external service providers ensure the confidentiality, integrity, and availability of the data and limit access to any data transmission, storage, and retrieval system.

Subpart N—Split Specimen Tests

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

(a) The donor may request, verbally or in writing, through the MRO that the split (B) oral fluid specimen be tested at a different (*i.e.,* second) HHS-certified oral fluid laboratory when the primary

(A) specimen was determined by the MRO to be positive, adulterated, or substituted.

(b) A donor has 72 hours to initiate the request after being informed of the result by the MRO. The MRO must document in the MRO's records the verbal request from the donor to have the split (B) specimen tested.

(c) If a split (B) oral fluid specimen cannot be tested by a second HHS-certified laboratory (*e.g.,* insufficient specimen, lost in transit, split not available, no second HHS-certified laboratory to perform the test), the MRO reports a cancelled test to the Federal agency and the reason for the cancellation. The MRO directs the Federal agency to ensure immediate recollection of another oral fluid specimen from the donor, with no notice given to the donor of this collection requirement until immediately before the collection.

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

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

(a) The testing of a split (B) specimen for a drug or metabolite is not subject to the testing cutoffs established.

(b) The HHS-certified laboratory is only required to confirm the presence of the drug or metabolite that was reported positive in the primary (A) specimen.

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

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

(b) The second HHS-certified laboratory may only conduct the confirmatory specimen validity test(s) needed to reconfirm the adulterated result reported by the first HHS-certified laboratory.

Section 14.4 How does an HHS-certified laboratory test a split (B) oral fluid specimen when the primary (A) specimen was reported substituted?

The second HHS-certified laboratory may only conduct the confirmatory biomarker test(s) needed to reconfirm the substituted result reported by the first HHS-certified laboratory.

Section 14.5 Who receives the split (B) specimen result?

The second HHS-certified laboratory must report the result to the MRO using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 14.6 What action(s) does an MRO take after receiving the split (B) oral fluid specimen result from the second HHS-certified laboratory?

The MRO takes the following actions when the second HHS-certified laboratory reports the result for the split (B) oral fluid specimen as:

(a) *Reconfirmed the drug(s), adulteration, and/or substitution result.* The MRO reports reconfirmed to the agency.

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

(c) *Failed to reconfirm a single or all drug positive results and the specimen was substituted.* If the donor provides a legitimate medical explanation for the substituted result, the MRO reports a failed to reconfirm result (specifying the drug[s]) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to reconfirm result (specifying the drug[s]) and a refusal to test (substituted) to the agency. The MRO gives the donor 72 hours to request that Laboratory A test the primary (A) specimen using its confirmatory test for the biomarker.

(1) If the primary (A) specimen's test results confirm that the specimen was substituted, the MRO reports a refusal to test (substituted) to the agency.

(2) If the primary (A) specimen's results fail to confirm that the specimen was substituted, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program about the failed to reconfirm and cancelled test.

(d) *Failed to reconfirm a single or all drug positive results and the specimen was not adulterated or substituted.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s]), cancels both tests, and notifies the HHS office responsible for coordination of the drug-free workplace program.

(e) *Failed to reconfirm a single or all drug positive results and the specimen had an invalid result.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s] and the reason for the invalid result), cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure, and notifies the HHS office responsible for coordination of the drug-free workplace program.

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

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

(h) *Failed to reconfirm one or more drugs, reconfirmed one or more drugs, and the specimen was not adulterated or substituted.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s]). The MRO tells the agency that it may take action

based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program regarding the test results for the specimen.

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

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

(k) *Failed to reconfirm substitution or adulteration and the specimen had an invalid result.* The MRO reports to the agency a failed to reconfirm result (not adulterated: specifying the adulterant or not substituted, and the reason for the invalid result), cancels both tests, directs the agency to immediately collect another specimen using a direct observed collection procedure and notifies the HHS office responsible for coordination of the drug-free workplace program.

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

(m) *Failed to reconfirm a single or all drug positive results and failed to reconfirm the adulterated or substituted result.* The MRO reports to the agency a failed to reconfirm result (specifying the drug[s] and not adulterated: specifying the 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.

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

(o) *Failed to reconfirm at least one drug and failed to reconfirm the adulterated result.* The MRO reports to the agency a reconfirmed result (specifying the drug[s]) and a failed to reconfirm result (specifying the drug[s and not adulterated: specifying the adulterant). The MRO tells the agency that it may take action based on the reconfirmed drug(s) although Laboratory B failed to reconfirm one or more drugs and failed to reconfirm the adulterated result.

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

(q) *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 (not adulterated: specifying the 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.

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

Section 14.7 How does an MRO report a split (B) specimen test result to an agency?

(a) The MRO must report all verified results to an agency using the completed MRO copy of the Federal CCF or a separate report using a letter/memorandum format. The MRO may use various electronic means for reporting (*e.g.,* fax, 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.

(e) The MRO must report drug test results using the HHS-specified nomenclature published with the drug and biomarker testing panels.

Section 14.8 How long must an HHS-certified laboratory retain a split (B) specimen?

A split (B) specimen is retained for the same period of time that a primary (A) specimen is retained and under the same storage conditions, in accordance with Section 11.18. 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 an oral fluid specimen as rejected for testing?

The following discrepancies are considered to be fatal flaws. The HHS-certified laboratory must stop the testing process, reject the specimen for testing, and indicate the reason for rejecting the specimen on the Federal CCF when:

(a) The specimen ID number on the primary (A) or split (B) specimen label/seal does not match the ID number on the Federal CCF, or the ID number is missing either on the Federal CCF or on either specimen label/seal;

(b) The primary (A) specimen label/seal is missing, misapplied, broken, or shows evidence of tampering and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(c) The primary (A) specimen was collected using an expired device (*i.e.,* the device expiration date precedes the collection date) and the split (B) specimen cannot be re-designated as the primary (A) specimen;

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

(e) The collector failed to document observation of the volume indicator(s) at the time of collection for a collection device containing a diluent.

(f) There is an insufficient amount of specimen for analysis in the primary (A) specimen and the split (B) specimen cannot be re-designated as the primary (A) specimen;

(g) 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;

(h) The specimen was received at the HHS-certified laboratory without a CCF;

(i) The CCF was received at the HHS-certified laboratory without a specimen;

(j) The collector performed two separate collections using one CCF; 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 hold the specimen and attempt to obtain a memorandum for record to recover the collector's signature. 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 report for at least 5 business days, the HHS-certified laboratory cannot obtain a memorandum for record from the collector, the laboratory must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

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

(a) The following omissions and discrepancies on the Federal CCF that are received by the HHS-certified laboratory should not cause an HHS-certified laboratory to reject an oral fluid specimen or cause an MRO to cancel a test:

(1) An incorrect laboratory name and address appearing at the top of the form;

(2) Incomplete/incorrect/unreadable employer name or address;

(3) MRO name is missing;

(4) Incomplete/incorrect MRO address;

(5) A transposition of numbers in the donor's Social Security Number or employee identification number;

(6) A telephone number is missing/incorrect;

(7) A fax number is missing/incorrect;

(8) A ''reason for test'' box is not marked;

(9) A ''drug tests to be performed'' box is not marked;

(10) The specimen type box (Oral Fluid) is not marked (*i.e.,* by the collector or laboratory);

(11) A ''collection'' box is not marked;

(12) The ''each device within expiration date'' box is not marked;

(13) The collection site address is missing;

(14) The collector's printed name is missing but the collector's signature is properly recorded;

(15) The time of collection is not indicated;

(16) The date of collection is not indicated;

(17) Incorrect name of delivery service;

(18) 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

(19) The donor's name inadvertently appears on the HHS-certified laboratory copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.

(b) The following omissions and discrepancies on the Federal CCF that are made at the HHS-certified laboratory should not cause an MRO to cancel a test:

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

(2) The accessioner fails to print their name;

(3) The certifying scientist or certifying technician fails to print their name;

(4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;

(c) The above omissions and discrepancies should occur no more than once a month. The expectation is that each trained collector and HHS-certified laboratory will make every effort to ensure that the Federal CCF is properly completed and that all the information is correct. When an error occurs more than once a month, the MRO must direct the collector or HHS-certified laboratory (whichever is responsible for the error) to immediately take corrective action to prevent the recurrence of the error.

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

(a) An MRO must attempt to correct the following errors:

(1) The donor's signature is missing on the MRO copy of the Federal CCF and the collector failed to provide a comment that the donor refused to sign the form;

(2) The certifying scientist failed to sign the Federal CCF for a specimen being reported drug positive, adulterated, invalid, or substituted; or

(3) The electronic report provided by the HHS-certified laboratory does not contain all the data elements required for the HHS standard laboratory electronic report for a specimen being reported drug positive, adulterated, invalid result, or substituted.

(b) If the error in Section 15.4(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 the error in Section 15.4(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 the error in Section 15.4(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 Section 16.8(e), (f), and (g).

(e) *Written Decision.* The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation and will attempt to issue the decision within 7–10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

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

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