

[Federal Register: November 25, 2008 (Volume 73, Number 228)]
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From the Federal Register Online via GPO Access [<http://edocket.access.gpo.gov/2008/E8-26726.htm>]
[DOCID:fr25no08-140]

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Part V

Department of Health and Human Services

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs; Notice

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Mandatory Guidelines for Federal Workplace Drug Testing Programs

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Revised Mandatory Guidelines.

SUMMARY: This Final Notice of Revisions to the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Revisions to Mandatory Guidelines) addresses collection and testing of urine specimens, the requirements for the certification of Instrumented Initial Test Facilities (IITFs), and the role of and standards for collectors and Medical Review Officers (MROs). Additional notices of Proposed Revisions to the Mandatory Guidelines addressing the use of point of collection testing (POCT), oral fluid testing, sweat patch testing, hair testing, and associated issues will be published at a later date. With regard to the use of alternative specimens including hair, oral fluid, and sweat patch specimens in Federal Workplace Drug Testing Programs, significant issues have been raised by Federal agencies during the review process which require further examination, and may require additional study and analysis. As part of the review process for these alternative tests, the Department of Health and Human Services ("HHS" or "Department") plans to issue a notice in the Federal Register requesting information and assistance from the general public to provide or identify data and research findings that address specific areas of interest.

DATES: Effective Date: March 25, 2008.

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SUPPLEMENTARY INFORMATION:

Background

The Guidelines were first published in the Federal Register on April 11, 1988, (53 FR 11970), and have since been revised in the Federal Register on June 9, 1994, (59 FR 29908), on September 30, 1997, (62 FR 51118), on November 13, 1998 (63 FR 63483), and on April 13, 2004, (69 FR 19644). The Guidelines establish the scientific and technical guidelines for Federal workplace drug testing programs and establish standards for certification of laboratories engaged in drug testing for Federal agencies under authority of section 503 of Public Law 100-71, 5 U.S.C. Section 7301 note, and Executive Order (E.O.) 12564.

The Department also published Proposed Revisions to Mandatory Guidelines in the Federal Register on April 13, 2004, (69 FR 19673). These Proposed Revisions to Mandatory Guidelines described changing the Guidelines into a plain language format, expanding the Federal drug testing program to include use of alternative specimens including testing hair, oral fluid, and sweat patch specimens, allowing the use of "point of collection testing" (POCTs) for urine and oral fluid specimens, establishing the requirements for certifying "instrumented initial test facilities" (IITFs) to test specimens, and providing specific standards for collectors, POCT testers, and MROs. There was a 90-day public comment period during which 285 commenters submitted comments on the proposed changes to the Guidelines. These commenters were individuals and public and private entities. The comments are available for public view on the Department's Internet Web site (<http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://workplace.samhsa.gov>).

Section 503 of Public Law 100-71, 5 U.S.C. Section 7301 note, required the Department to establish scientific and technical guidelines and amendments in accordance with Executive Order 12564, and to publish Mandatory Guidelines which establish comprehensive standards for all aspects of laboratory drug testing and procedures, including standards that require the use of the best available technology for ensuring the full reliability and accuracy of drug tests and strict procedures governing the chain of custody of specimens collected for drug testing. These revisions to the Mandatory Guidelines promote and establish standards that use the best available technology for ensuring the full reliability and accuracy of urine drug tests, while reflecting the ongoing process of review and evaluation of legal, scientific, and societal concerns.

The submitted public comments and additional comments raised by Federal Agencies during subsequent internal review of the proposed changes to the Guidelines raised significant scientific, legal, and public policy concerns about the use of alternative specimens and POCT devices in Federal agency workplace drug testing programs. Since each alternative specimen and drug testing using POCT devices

poses different concerns, the Department established a staggered timeline for issuing final guidance that allows for further study and research. In assessing the complexity of the task, the Department has decided to publish these final Guidelines with regard to collection and testing urine specimens, establishing the requirements for the certification of IITFs, and establishing specific standards for collectors and MROs. The Department considered several options for issuing one or more Final Notices in the Federal Register that may require additional public comment periods, concerning the use of alternative specimens and drug testing technologies such as POCT devices. Since the scientific, legal, and public policy information for drug testing oral fluid, hair, and sweat patch specimens, and using POCT devices is not as complete as it is for the laboratory-based urine drug testing program, developing Final Notices concerning the use of these is more challenging. As described in the notice of Proposed Revisions to Mandatory Guidelines issued April 13, 2004, the performance of alternative specimens in pilot performance testing (PT) programs has been encouraging, with individual laboratory and group performance improving over time. However, there are still three areas of concern. First, the data from the pilot PT programs to date show that not all participants have developed the capability to test for all required drug classes, nor to perform such tests with acceptable accuracy. Second, some drug classes are more difficult to detect than others, for any given type of specimen. Third, the specific drug classes that are difficult to detect vary by type of specimen. As a result, it will require additional study to assist agencies in determining how to select the appropriate type of specimen to be collected from a specific donor, when the use of a specific drug is suspected. Nevertheless, HHS believes that the addition of alternative specimens to the Federal Workplace Drug Testing Program would complement urine drug testing and aid in combating the risks posed from available methods of suborning urine drug testing through adulteration, substitution, and dilution. Thus, HHS will continue to pursue testing using alternative specimens. HHS anticipates issuing further revisions to the Mandatory Guidelines addressing the use of oral fluid, sweat patch, and hair, and the use of POCT devices for urine and oral fluid. These revisions will be published in the Federal Register, with opportunity for public comment.

All written comments were reviewed and taken into consideration in the

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preparation of these revised Guidelines. The preamble only addresses sections of the draft Guidelines regarding urine testing that were commented on during the public comment period or that the Department is changing. Most section numbers for the Guidelines issued in April 2004 were changed in these Guidelines due to the removal of those sections concerning alternative specimens and POCT as well as for clarity. To make it easier for the public, the preamble refers to the new section number and, where appropriate, the corresponding section number in the Proposed Revisions to Mandatory Guidelines issued in April 2004. Similar comments are considered together in the discussion.

Reason for the Effective Date

An effective date of 18 months from the date of publication of these revised Mandatory Guidelines was chosen to permit the following activities:

(1) It will take at least 12 months for manufacturers of immunoassay test kits to modify or manufacture immunoassay test kits and ensure compliance with any applicable statutory and regulatory requirements before commercialization of the modified kits.

(2) It will take the HHS-certified laboratories at least one month to validate and implement the new test kits.

(3) It will take 2 to 3 months for the National Laboratory Certification Program (NLCP) to challenge the HHS-certified laboratories with performance testing (PT) samples to ensure that the test kits and test results satisfy the required performance criteria.

The effective time frame of 18 months will encompass many activities that will overlap or occur at the same time within different industries and Federal agencies.

Summary of Public Comments and the HHS Response

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

Initial Test Kit Issues

In the proposed Guidelines, the Department requested comments on issues regarding the testing for amphetamine analogs using one or two immunoassay test kits because the laboratory or IITF would be required to test specimens for the target analytes listed under amphetamines. Two commenters believed that two separate initial test kits would be needed to appropriately screen specimens for amphetamines as specified in Section 3.4. One commenter believed three separate initial test kits may be required. Six commenters believed that one initial test kit could be used to screen for amphetamine, methamphetamine, and their analogs. For the most part, the commenters provided justifications for their comments. The Department has evaluated the comments and has concluded that using either a single initial test kit or multiple initial test kits is acceptable depending on the specificity and sensitivity that the single initial test kit has with amphetamine and methamphetamine and its cross-reactivity with methylenedioxymethamphetamine (MDMA).

Subpart A--Applicability

The Department has revised Section 1.1 to state that the requirements in these Guidelines also apply to collectors and MROs. This revision ensures that collectors and MROs are notified of the applicable requirements under these Guidelines.

In Section 1.5, where terms are defined, the Department has added several new definitions for terms that appear in the Guidelines, and revised several definitions that needed clarification even though no comments were received from the public.

The Department has changed the term to be defined from “adulterated” to “adulterated specimen.” The meaning of the term has not changed. Only the wording has been changed to make the definition clearer.

Definitions were added for “alternate responsible person” and “alternate responsible technician”, the individuals who are pre-approved by HHS to assume responsibility for the HHS-certified drug testing laboratory or IITF, respectively, when the responsible person or responsible technician is absent for an extended period.

The definition for “cancelled test” was reworded for clarification. The definition is the same.

The term “carryover” was defined. Carryover, as used in these Guidelines, refers to the condition that results when the test result for one sample has been affected by a preceding sample during analysis. For example, if the concentration of a drug in one sample is very high and cannot be completely eliminated from the analytical instrument before the next sample is tested, the residual drug in the analytical instrument contributes to the concentration of that drug in the next sample.

The definition for “certifying scientist” was revised to indicate that a certifying scientist can report any test result reported from an HHS-certified laboratory. The proposed definition referred to “non-negative or invalid result.” Since the term “non-negative” was deleted from these Guidelines, the definition for certifying scientist needed to be revised.

The definition for “certifying technician” was revised to state that a certifying technician can report on the chain of custody and scientific reliability of negative, negative/dilute, and rejected for testing results. This revised definition clarifies which types of results a certifying technician can report. The proposed definition incorrectly permitted the certifying technician to report on the chain of custody and scientific reliability of only negative test results.

The term “confirmatory validity test” was changed to “confirmatory specimen validity test.” The term “validity test” was changed to “specimen validity test” throughout the Guidelines, to be consistent with current terminology used by the Department.

The definition for a “cutoff” was revised to apply to specimen validity tests, as well as drug tests. The term is used in both contexts.

The definition for “dilute specimen” was revised to state that the term applies to a urine specimen with creatinine and specific gravity values that are lower than expected but still physiologically possible. This change shows that a dilute specimen is different from a substituted specimen.

The definition for “failed to reconfirm” was revised to clarify

that the term applies when a second laboratory tests a split (Bottle B) specimen and is unable to corroborate the original test result reported by the primary laboratory.

The definition for “follow-up test” was removed. The definition for “follow-up test” is provided in Federal agency drug testing plans and does not need to be repeated in the Guidelines.

The definition for an “initial validity test” was changed to “initial specimen validity test” throughout the Guidelines to be consistent with current terminology used by the Department. The term was also revised to include an “invalid result” because an “invalid result” requires using an initial specimen validity test as would an adulterated, diluted, or substituted test result.

To avoid confusion, the definitions for an “instrumented initial test facility” and for a “laboratory” were revised to show that these are permanent locations.

The definition for “invalid result” was revised to clarify that this type of result is reported when the test results

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satisfy the criteria established in Section 3.8. The definition in the draft issuance did not include all of the criteria described in Section 3.8.

A definition for “limit of detection” (LOD) has been added to these Guidelines because the Guidelines require the laboratory to determine the LOD for each confirmatory drug test during assay validation. In addition, to validate specimen validity tests, laboratories and IITFs are required to demonstrate and document appropriate assay characteristics, which may include the LOD.

A definition for “limit of quantitation” (LOQ) has been added to these Guidelines because the Guidelines require the laboratory to determine the LOQ for each confirmatory drug test during assay validation. In addition, to validate tests used to determine specimen validity, laboratories and IITFs are required to demonstrate and document appropriate assay characteristics, which may include the LOQ. Lastly, laboratories and IITFs are required to use the established LOQ as the decision point for adulterants without a program-specified cutoff.

A definition for a “lot” has been added to these Guidelines because throughout the Guidelines there are requirements to validate or verify the performance characteristics of various items (e.g., drug test kits, reagents, quality control material) and to establish an expiration date. The term “lot” refers to the item(s) manufactured from the same starting materials within a specified period of time which have essentially the same performance characteristics and the same expiration date.

The definition for a “negative result” was revised to clarify that the specimen must not only be negative for drugs but must also be a valid urine specimen. Since these Guidelines require that specimen validity tests be conducted on each specimen, this definition states that a “negative result” indicates that a specimen is not only negative for drugs but also that the specimen validity tests conducted on the specimen indicate that the specimen is a valid specimen.

The definition for a “non-negative” result was removed from the list of definitions and replaced with more specific reporting terms as follows: Positive result, substituted specimen, adulterated specimen, or invalid specimen result.

The definition for a “performance testing (PT) sample” was revised to show that it refers to samples that are program-generated and sent to a testing facility. The proposed definition did not indicate the source of the samples.

The definition for a “post-accident test” was removed. The definition for “post-accident test” is provided in Federal agency drug testing plans and does not need to be repeated in the Guidelines.

The definition for a “pre-employment test” was removed. The definition for “pre-employment test” is provided in Federal agency drug testing plans and does not need to be repeated in the Guidelines.

The definition for a “quality control (QC) sample” was revised to clarify that the term refers to calibrators or controls.

The definition for a “random test” was removed. The definition for “random test” is provided in Federal agency drug testing plans and does not need to be repeated in the Guidelines.

The definition for a “reasonable suspicion/cause test” was removed. The definition for “reasonable suspicion/cause test” is provided in Federal agency drug testing plans and does not need to be repeated in the Guidelines.

The definition for “reconfirmed” was revised to clarify that the definition applies to a split specimen (Bottle B) tested by a second laboratory.

The definition for “return to duty test” was removed. The definition for “return to duty test” is provided in Federal agency drug testing plans and does not need to be repeated in the Guidelines.

The definition for “rejected for testing” was revised to clarify that this result may be reported by an IITF, as well as a laboratory.

Three commenters noted the terms “sample” and “specimen” were used interchangeably throughout the Guidelines and suggested that the definitions be defined and the text updated accordingly. The Department agrees and has revised the definitions for these terms and has revised the Guidelines text to consistently use the terms as they are defined in this section. “Sample” refers to a performance testing (PT) sample, a quality control sample, or a representative portion of a donor specimen. “Specimen” refers to the donor specimen (i.e., urine provided by the donor for the drug test).

The term “split specimen” was replaced by “split specimen collection”. The definition of a “split specimen collection” states that one urine specimen of sufficient volume is collected and then divided into two separate specimen bottles. A “split specimen collection” does not permit collecting two different urine specimens at two different times that are, respectively, transferred to a Bottle A and a Bottle B.

The definition for “substituted” was changed to “substituted specimen” and revised to define this as a specimen submitted in place of the donor’s urine, as evidenced by creatinine and specific gravity values outside physiologically producible ranges of human urine.

Section 1.6 describes what an agency is required to do to protect employee records. The policy in this section is the same as the policy in the Proposed Revisions to Mandatory Guidelines. The Department has included a discussion on the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

The Department has included a new Section 1.7, to clarify refusals to test and who ultimately determines if the conditions for verifying them are met (i.e., the collector, the MRO, the Federal agency).

Subpart B--Specimens

Section 2.1 states that urine is the only specimen that can be collected by a Federal agency under the Guidelines for its workplace drug testing program to clarify that Federal agencies are prohibited from collecting any other type of specimen.

Section 2.2 describes the circumstances under which a Federal agency may collect a specimen. The Department has included this section to ensure that the circumstances described are consistent with the reasons for collecting a specimen as listed on the Federal CCF.

Section 2.3 requires each urine specimen to be collected as a split specimen. This policy is the same as the policy described in the Proposed Revisions to Mandatory Guidelines. Five commenters opposed the part that the single urine specimen collection procedure was being eliminated. The Department disagrees with the commenters and has eliminated the single urine specimen collection procedure, not because the procedure is forensically or scientifically unsupportable, but because the split specimen procedure ensures that the donor will have access to a split specimen that was not opened by the laboratory testing the primary specimen. Additionally, there are a number of Federal employees working for agencies that have employees subject to both Federal drug testing guidelines and Department of Transportation workplace drug testing regulations. Requiring the use of a split specimen collection procedure will ensure that employees working in these dual regulation situations are treated the same.

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Subpart C--Drug and Specimen Validity Tests

Section 3.1 describes the tests that are performed on each urine specimen. The policy in this section applies to each specimen collected by a Federal agency regardless of the circumstance for which it was collected as described in Section 2.2. The Department believes that the wording of the policy in the current and Proposed Revisions to Mandatory Guidelines may be incorrectly interpreted such that the required tests only apply to specimens collected from Federal agency applicants and specimens collected at random. However, this is not the case. The wording in this section has been revised to state that each specimen collected will be tested for the same drugs and specimen validity tests. This section was also revised to describe the specimen validity tests that must be performed on each urine specimen. The

requirements and explanations described for the specimen validity tests are the same as those described in the current and Proposed Revisions to Mandatory Guidelines.

Section 3.2 provides guidance on how a Federal agency may test a specimen for additional drugs. Three commenters requested additional guidance on how a Federal agency would request permission to test for an additional drug on a case-by-case basis. The Department believes the policy in Section 3.2(a) adequately describes how a Federal agency would request to test a donor's specimen for a suspected Schedule I or Schedule II drug that is not part of the Federal program.

After further review of Section 3.2(a), however, the Department recognized that the Guidelines do not address how to proceed if the Federal agency is requesting to test for a Schedule I or II drug for which an immunoassay test is not available. The Department thus has added that when the need to test for an additional drug occurs and there is no immunoassay test available, an HHS-certified laboratory should be permitted to test for the drug by testing two separate aliquots of the specimen using the same confirmatory drug test. The confirmatory drug test used by the laboratory must satisfy the requirements in Section 11.13, the laboratory must validate the confirmatory drug test in accordance with the requirements in Section 11.14, and must satisfy the quality control requirements as stated in Section 11.15. The Department believes that testing the specimen twice using a validated confirmatory drug test is scientifically and forensically acceptable. Additionally, when a specimen is reported as positive, adulterated, or substituted, the Department allows the donor to request that Bottle B be tested at another HHS-certified laboratory by the confirmatory method. The testing of the split specimen by a second HHS-certified laboratory to reconfirm the drug reported positive by the first laboratory is sufficient to protect the donor's interests.

Section 3.3 states that urine specimens collected for Federal agency workplace drug testing programs may only be tested for the purpose of detecting drug use and to determine the validity of the specimen unless otherwise authorized by law. Several commenters expressed concern over the possibility that DNA testing could be conducted on a specimen. The Department states in Section 3.3(a) that “Federal agency specimens * * * must only be tested for drugs and to determine their validity unless otherwise authorized by law.” The Department is satisfied that the policy, as stated, prohibits DNA testing on a specimen but has removed the phrase “unless otherwise authorized by law” from this section to clarify that Federal agency specimens must only be tested for drugs and to determine their validity.

Section 3.4 lists the drugs and drug metabolites and the initial and confirmatory cutoff concentrations used to test and report urine specimens as negative or positive for a drug. The initial and confirmatory cutoff concentrations are the same as in the Proposed Revisions to Mandatory Guidelines, but the tables have been combined to make it easier for the readers.

Several commenters suggested including the scientific rationale used to support the proposed changes to the cocaine metabolite (benzoylecgonine) and amphetamine cutoff concentrations. Three commenters disagreed with the proposal to lower the amphetamines initial test cutoff concentration. Two of the three commenters were concerned that the lower cutoff will result in higher costs and more false initial test positives due to medications available over the counter. The third commenter stated that their laboratory currently has customers who use the lower amphetamine cutoff concentration and have no more confirmed positives than compared to a 1000 ng/mL initial test cutoff, but who do have more unconfirmed specimens.

The Department believes the revised cutoff concentrations will increase the window of detection for these drugs, i.e., the number of hours after a drug is ingested by an individual that the concentration of the drug or drug metabolite in urine will likely remain above the cutoff concentration. Lower cutoff concentrations will increase the number of urine specimens that are identified as containing cocaine metabolites and amphetamines and, thereby, will increase the deterrent effect of the program and improve identification of employees using illicit substances. Based on results reported by laboratories in the current urine PT program, the Department believes that certified laboratories (and IITFs after they are certified) will have the ability to report accurate test results using these revised cutoff concentrations. There is no evidence available to the Department to indicate that lowering these cutoff concentrations will increase the possibility that a donor who has not actually used cocaine or amphetamines will be identified as a drug user. The Department also points out that the individual can always challenge the result with the MRO.

Several commenters raised questions regarding the proposed options for HHS-certified laboratories and IITFs to perform an initial test for 6-AM. The commenters stated that the policy options were unclear as presented in Section 3.4, and recommended that HHS provide additional guidance to prevent

inconsistent treatment of specimens. The Department has revised the table and footnotes in Section 3.4 to clarify that all specimens tested for opiates must be tested for 6-AM. This policy allows a laboratory to confirm and report 6-AM by itself, in contrast to the current Guidelines policy which requires 6-AM to be tested and reported in conjunction with a positive morphine result. Data from laboratories indicate that 6-AM is present in specimens even when the morphine concentration is below 2000 ng/mL.

Sections 3.5, 3.6, 3.7, and 3.8 describe the criteria for reporting a urine specimen as adulterated, substituted, dilute, and invalid, respectively. Each section was revised to clarify that only a certified laboratory may report a specimen as adulterated, substituted, or invalid; that only a certified laboratory may report a specimen as dilute when creatinine is equal to or less than 5 mg/dL; and that a laboratory or an IITF may report a specimen as dilute when creatinine is greater than 5 mg/dL. For an adulterated or invalid urine specimen, one commenter requested the rationale for changing from the 20 mcg/mL chromium (VI) [Cr (VI)] initial validity test cutoff in a previous draft (several preliminary versions of the Guidelines were posted on the

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SAMHSA workplace Web site before the Proposed Revisions to Mandatory Guidelines were published in the Federal Register to 50 mcg/mL in these Guidelines. One commenter recommended using the 20 mcg/mL Cr (VI) cutoff instead of 50 mcg/mL and provided supporting data. Although the Department agrees with the data provided, the 50 mcg/mL cutoff is consistent with the capabilities of current assays' sensitivity and specificity. Additionally, most, but not all, oxidants are quantified at concentrations greater than 50 mcg/mL when they are used as urine adulterants. Unpublished evaluations of samples spiked with Cr (VI) have shown that for Cr (VI) to be effective as an adulterant, the urine concentration is usually much greater than 100 mcg/mL. For these reasons, the Department believes that the 50 mcg/mL Cr (VI) cutoff is sufficient to identify adulteration with Cr (VI) and is appropriate. One commenter recommended using the limit of quantitation (LOQ) instead of the limit of detection (LOD) as the decision point for adulterant tests without a program specified cutoff. The commenter stated that an LOQ ensures that the adulterant has been both appropriately identified and quantified. The Department agrees and has revised the testing requirements in Sections 3.5 and 3.8 to require that the adulterant's concentration be equal to or greater than the LOQ that was determined by the HHS-certified laboratory.

The Department has revised Section 3.7 to clarify that a dilute result may only be reported in conjunction with either a positive test result or a negative test result. When a urine specimen is determined to be adulterated or when an invalid result is being reported, the Department does not consider finding a dilute result for such a specimen as being correct. It is assumed that an adulterated or invalid urine specimen has been tampered with and, if it also happens to satisfy the dilute criteria, the dilute result would actually be meaningless. Additionally, by definition, when a urine specimen is reported as substituted it cannot be a dilute specimen. Therefore, a dilute result cannot be reported in conjunction with a substituted result.

Subpart D—Collectors

Section 4.1 describes who may collect a specimen for a Federal agency. Three commenters recommended allowing direct supervisors to routinely collect specimens for federal agency applicant tests. The Department disagrees and has always prohibited an immediate supervisor or hiring official from routinely acting as a collector, unless no other collector is available and only when the supervisor or hiring official is a trained collector.

Section 4.2 describes who may not collect a specimen. Seven commenters were opposed to the policy which prohibits testing facility employees from collecting specimens if they could link the donor's identity to the test results. The Department has always prohibited testing facility (HHS-certified laboratory) employees from collecting specimens if they could link the donor's identity to the test results and believes that this policy is appropriate. The Department revised this section to prohibit an employee who is in a testing designated position and subject to the Federal agency drug testing rules from serving as a collector for co-workers who are in the same testing pool or who work together with that employee on a daily basis, and to prohibit an individual from collecting his or her own urine for a federally regulated drug test.

Section 4.3 describes the requirements for an individual to be a collector for a Federal agency. Seven commenters disagreed with requiring collectors to read and understand the Guidelines and felt this should be limited to the sections pertaining to the collection of specimens. The Department agrees and has revised the policy in Section 4.3(a) to reflect that a collector must be knowledgeable of the collection procedure described in the Guidelines. Four commenters suggested that there should be standardized collector training requirements and documentation requirements for all collectors. The Department has revised Section 4.3 to provide more details on the requirements for collector training and the documentation requirements. The Department believes the requirements as described in this section are sufficient and appropriate to ensure that the collector can properly collect a specimen and correctly complete the Federal Drug Testing Custody and Control Form (Federal CCF).

Several commenters believe it is not sufficient to allow the agency to select the observer if there is no collector of the same gender available, as stated in the Proposed Revisions to Mandatory Guidelines. To address this concern, the Department has included a new Section 4.4 that specifies training requirements for an individual to serve as an observer for a direct observed collection (as described in Section 8.9). The training requirements are designed to ensure that any individual serving as an observer has been trained in procedures for a direct observed collection, although he or she may not be a trained collector. Other training elements are included to ensure that the observer interacts with the donor in a professional manner, respecting the donor's modesty and privacy, and that he or she maintains the confidentiality of collection information. The Department also revised this section to allow the collector or collection site supervisor to select the observer.

Section 4.5 describes the requirements for an individual to be a trainer for collectors. Three commenters noted that the Guidelines did not address approval and monitoring of the "train the trainer" courses. Currently there are organizations (e.g., manufacturers, private entities, contractors, Federal agencies) that offer "train the trainer" courses. The Department does not believe that it is necessary or appropriate to approve the content of the "train the trainer" courses. If a trainer does not properly train individuals to be collectors, collector errors will result as the Guidelines are enforced and will demonstrate the need to retrain those trainers.

Section 4.6 describes what a Federal agency must do before an individual is permitted to collect specimens. Five commenters disagreed with the requirement for an organization that manages/employs collectors to retain the collector training documents, saying this would be burdensome. The commenters recommend that collectors be responsible for their own documentation. The Department agrees that many collectors currently retain their training records and has revised the policy to indicate that a collector (who may be self-employed) or organization (e.g., collector training company, third party administrator, Federal agency that employs its own collectors) must maintain a copy of the record that documents his or her training. The Department has also revised the question to require the Federal agency to ensure that the requirements of this section are satisfied before a collector is permitted to collect specimens rather than placing the burden on an organization to satisfy the requirements. The Federal agency is always responsible for ensuring that a collector is properly trained.

Subpart E--Collection Sites

Section 5.1 describes a collection site as a permanent or temporary facility. The requirement for a collection site to have provisions for donor privacy during the collection procedure has been moved from Section 5.1 to Section

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5.2, which describes the specific requirements for a facility that is being used as a collection site.

Two commenters recommended including additional criteria in Section 5.2 for a collection site to have a secure working area and donor privacy. The Department agrees and is requiring the collection site in Section 5.2(a) to have provisions to ensure donor privacy. Privacy requirements are set forth in Section 8.1. In addition, Section 5.2(b) has been revised to reflect the need for a suitable clean working area that is not accessible to the donor. The Department believes the clean working area must not be accessible to the donor because, if given an opportunity, a donor may attempt to tamper with records, documents, or supplies. The Department also added Section 5.2(g) to require facilities to have the ability to limit donor access to potential contaminants, adulterants, or diluents.

Section 5.3 describes how long records must be stored by collection sites. The record storage requirements in this section are the same as those described in the Proposed Revisions to Mandatory Guidelines. The Department revised the section to specify the records that must be retained.

Subpart F--Federal Drug Testing Custody and Control Forms

Section 6.1 states that an OMB-approved Federal CCF must be used to document the collection of a urine specimen. The requirement in this section is the same as the requirement described in the Proposed Revisions to Mandatory Guidelines.

Section 6.2 describes what happens if the correct Federal CCF is not available or is not used. The Department recognizes that occasionally a current Federal CCF will not be available or a non-Federal form or expired Federal CCF will be used by mistake. The Department does not want this discrepancy to cause a laboratory or IITF to automatically reject the specimen for testing, or cause an MRO to automatically cancel the test. If the collector discovers the error before the specimen is packaged for shipment to a laboratory or IITF, the collector must note on the form that the specimen is a Federal agency specimen and give the reason for using the incorrect form. When this information is provided on the form, the laboratory or IITF simply proceeds with testing the specimen as a Federal agency specimen. If the laboratory, IITF, or MRO discovers that an incorrect form was used and there is no explanation given, the laboratory, IITF, or MRO must attempt to obtain a Memorandum For Record (MFR) from the collector explaining why an incorrect form was used. If a MFR cannot be obtained from the collector, the laboratory or IITF must report a rejected for testing result (i.e., when they discovered the error) and the MRO reports a cancelled test result.

Subpart G--Specimen Collection Containers

Section 7.1 describes the items to be used to collect a urine specimen. The Department added volume requirements for specimen containers to this section to ensure that the containers used would be of a sufficient size to hold the required amount of urine for primary and split specimens.

Section 7.2 describes the requirement that the collection items used must not affect the specimen collected. The requirement in this section is the same as the requirement described in the Proposed Revisions to Mandatory Guidelines. However, the proposed statements regarding FDA clearance for these collection items has been removed. FDA has regulatory oversight of a collection item as a "device" within the meaning of Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the FDCA) (21 U.S.C. 321(h)), and a manufacturer must comply with all statutory and regulatory requirements for these devices.

Subpart H--Specimen Collection Procedure

Section 8 establishes the procedures for collection of a urine specimen. The Department revised and reorganized the urine collection procedures in the Proposed Revisions to Mandatory Guidelines for clarity and to address issues raised as described below.

Section 8.1 states the privacy requirements for specimen collections. The procedure used to collect a urine specimen must ensure that a donor is given a sufficient amount of privacy under normal circumstances. That is, a donor is allowed to provide a urine specimen in the privacy of a restroom or an enclosed stall. Four commenters raised concerns with the privacy requirements that should be given a donor. The Department evaluated these comments and believes that it is more appropriate to address the privacy requirements in subpart H (which addresses the collection procedure) rather than discussing the privacy requirements in subpart E (which specifies the requirements for a collection site). Section 8.1(a) addresses the comments submitted by stating who may be present during a collection procedure. Section 8.1(b) states that the collector may be a different gender than the donor, but the observer of a direct observed collection procedure must be the same gender, and a monitor for a monitored collection must be the same gender unless the monitor is a medical professional. Section 8.1(c) clarifies that the privacy given to a donor is visual privacy because there may be situations where it is not possible to prevent the collector from hearing sounds in the enclosure where the donor is providing the specimen.

Section 8.2 describes what a collector must do before starting a specimen collection procedure. One commenter noted that the proposed requirement to have “no other source of water (e.g., no shower or sink) in the enclosure where urination occurs” may not address temporary collection sites. The commenter recommended that the procedure be revised to state that the collector must disable or secure other sources of water in the restroom before starting the collection procedure. One commenter noted that many public restrooms are equipped with toilets that have sensors for automatic flushing. The Department agrees and has revised this section to read “There must be no other source of water (e.g., no shower or sink) in the enclosure where urination occurs that is not secured during the collection.” If the enclosure used by the donor to provide a specimen has a sink or other source of water besides the toilet that cannot be disabled or secured, the collector must perform a monitored collection in accordance with Section 8.11. The monitor will listen for any sounds that may suggest possible attempts by the donor to tamper with the specimen.

Section 8.3 describes the preliminary steps in the collection process. Four commenters recommended that the Guidelines describe the type of identification the collector provides to the donor. The Department has revised Section 8.3(c) and included some examples of the type of identification that may be provided (e.g., driver's license, employee badge issued by the employer, any other picture identification issued by a Federal, State, or local government agency). Two commenters suggested that the collector must point out to the donor, but not require the donor to read, the collection procedure instructions on the back of the Federal CCF. The Department agrees with the comment and has revised Section 8.3(f) to direct the collector only to inform the donor where the donor can find the instructions for the collection on the back of the Federal CCF. The collector will allow the donor to read the procedure if the donor prefers. One commenter suggested that

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the donor be given the collector's full name, name of the collector's supervisor, name of the company conducting the test, and the MRO's name, telephone, and address. The Department agrees with this comment. With the exception of the name of the collector's supervisor, the rest of the commenter's request for information is recorded on the donor's copy of the Federal CCF. If some of the information is missing on the Federal CCF, it is the responsibility of the collector to obtain the information and to complete the Federal CCF in accordance with the instructions for the use of the Federal CCF for Federal agency workplace drug testing programs.

Section 8.4 describes the steps that the collector takes in the collection process before the donor provides a urine specimen. The steps are the same as in the Proposed Revisions to Mandatory Guidelines, but include additional detail.

Section 8.5 specifically addresses the situation where a donor states that he or she is unable to provide a urine specimen. Over 50 commenters expressed concern with the Department's urine collection policy. They stated that some individuals have what the commenters refer to as a “shy bladder.” The commenters noted that these individuals may be physically unable to provide a urine specimen upon demand, and forcing them to drink fluids creates a great deal of stress and may not change their ability to provide a specimen. The commenters were concerned with how a collector interacts with a donor who is unable to provide a sufficient amount of urine to perform a drug test. The Department's urine collection policy was designed to prevent an individual from intentionally circumventing the requirement to provide a urine specimen during a required collection. The policy is not intended to cause harm to anyone who has a condition that prevents them from providing a urine specimen when requested. The Department has always expected a collector to treat the donor with respect when the donor is unable to provide a specimen within a reasonable period of time (3 hours is considered reasonable). To address the concern, however, the Department has revised the urine specimen collection procedure. If the donor states that he or she cannot provide a specimen, the collector requests the donor to go into the restroom (stall) and attempt to provide a specimen. This attempt demonstrates the donor's inability to provide a specimen when the donor comes out of the stall with an empty collection container. At that time, if the donor states that he or she could provide a specimen after drinking some fluids, the collector allows the donor to drink some liquid (as stated in Section 8.5(b)(1)) and continues with the collection procedure. If the donor states that he or she simply needs more time, without a need to drink fluids, before attempting to provide a urine specimen, the collector gives the donor up to 3 hours to provide a urine specimen. If the donor states that he or she is unable to provide a urine specimen even after 3 hours, the collector

records the reason for not collecting a urine specimen on the Federal CCF, notifies the Federal agency's designated representative, and sends the Federal CCF to the MRO and the Federal agency for further evaluation of the donor. The requirement for the further evaluation of the donor by an MRO will prevent individuals from being falsely accused of a refusal to test.

Sections 8.5(b)(1) and 8.6(e)(2) describe the amount of fluid that a donor may be given at the collection site in order to collect a sufficient amount of urine. The reason why a limit is imposed at all is the concern for the welfare of the donor, as well as the concern that the urine specimen may become diluted. Several commenters expressed concern with the amount of fluids given to a donor at the collection site. The Proposed Revisions to Mandatory Guidelines instruction to the collector to give the donor a reasonable amount of liquid to drink is flexible in the amount given (note that the parenthetical in the Guidelines is stated as an example, not as a requirement). However, in response to the comment, the Department has changed the example in the Proposed Revisions to Mandatory Guidelines ("an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 24 ounces") to read "an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen." This change retains the flexibility that has always existed in the Federal program and sets a reasonable time limit within which most donors would be able to provide an acceptable amount of urine. Although the Department has changed the guidance on the amount of fluid given the donor, the Department does not require anyone to drink more fluid than he or she could comfortably drink. A statement has also been added to these sections to clearly state that the donor is not required to drink any fluids during this waiting time. The Department believes that most individuals who are unable to provide a sufficient specimen simply need some additional time to provide the required specimen without having a need to drink fluids.

Section 8.6 describes the steps that the collector takes in the collection process after the donor provides a urine specimen. One commenter recommended that the collector be instructed to inspect the stall for signs of tampering before the donor is permitted to flush the toilet. While this practice is acceptable, the Department has not included this detail in the Guidelines. Sections 8.2 and 8.3 include pre-collection procedures to prevent or detect specimen tampering. Furthermore, Section 8.4(b) instructs the collector to perform a recollection under direct observation if the donor's conduct indicates a possible attempt to adulterate or substitute the specimen.

Section 8.6 also includes procedures for the collector to measure the specimen temperature, visually inspect the specimen, and determine the specimen volume. Three commenters recommended deleting the proposed requirements for a collector to send a Bottle A specimen to the testing facility when there is an insufficient volume of urine collected for the split (Bottle B) specimen as required because this contradicted the proposed policy that a failure to provide 30 mL of urine for the second specimen collection prompts the collector to obtain guidance on the action to be taken. The Department agrees and has revised the collection procedures to stop the collection when the donor does not provide at least 45 mL, the amount required for a split specimen collection, after two attempts. When this occurs, the collector notifies the Federal agency's designated representative immediately, and notes on the Federal CCF the donor's failure to provide sufficient urine. The Federal CCF is sent to the Federal agency and the MRO. Subsequent actions by the MRO are described in Sections 13.5 and 13.6.

Section 8.8 is a new section that combines the reasons that appear in different sections of the current Guidelines regarding when a direct observed collection is used. The reasons are the same; they have simply been combined in one section. Section 8.8(c) requires the collector to notify a collection site supervisor to review and concur with the collector's decision to perform a direct observed collection procedure. Three commenters disagreed with this policy. One commenter recommended requiring an agency representative in addition to the supervisor to review and concur with

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the decision. The Department believes obtaining permission from a supervisor is necessary when a decision is needed to conduct a direct observed collection. The concurrence from a supervisor will ensure that the collector is justified in using a direct observed collection procedure. The Department also included in this section the actions a collector must take when the donor refuses to provide a specimen under direct observation.

Section 8.9 is a new section that describes how a direct observed collection procedure is conducted. The Proposed Revisions to Mandatory Guidelines discussed when a direct observed collection procedure

is permitted, but did not provide guidance on how it is to be conducted. The Department has included additional information regarding direct observed collections. This information has been available from the Department and has been used since the beginning of the Federal drug testing program. The Department believes that the procedure will ensure that all direct observed collection procedures are conducted the same way regardless of the reason for using the direct observed procedure. In response to submitted comments, in addition to requiring the observer to be the same gender as the donor, the Department has specified in Section 8.9 that individuals must be trained in direct observed collection procedures in order to serve as an observer. Training requirements are included in a new Section 4.4. The Department included two new sections, Sections 8.9 and 8.10, to address when and how monitored collections are performed.

Section 8.12 establishes how the collector reports a donor's refusal to test. The Proposed Revisions to Mandatory Guidelines discussed what constituted a refusal to test during the collection process, but did not provide guidance to the collector on how to report a refusal to test. Additional information regarding urine collection is available from the Department. In addition, the Department included an instruction for the collector to discard any urine collected when a refusal to test occurred during the collection process.

Section 8.13 establishes the responsibilities for Federal agencies regarding collection sites. Many commenters disagreed with requiring Federal agencies to inspect all of their collection sites. The commenters believe this requirement to inspect the hundreds of collection sites would be cost-prohibitive and logistically impossible, and there does not seem to be evidence that errors by collectors are common enough to justify such an inspection program. Other commenters suggested that, in lieu of annual inspections of all collection sites, HHS require agencies to inspect only collection sites which have generated "fatal flaws." The Department agrees that requiring Federal agencies to investigate and possibly inspect collection sites with "rejected for testing" errors ensures that collectors will receive appropriate training to prevent the recurrence of such errors. However, the Department maintains that random inspections are important to identify any collection procedure problems that may exist, but are not readily evident from the Federal CCF because the forms appear to be properly completed by the collector. The Department has revised the inspection requirements in this section accordingly. Federal agencies must inspect only 5 percent of the current number of collection sites, or up to a maximum of 50, selected randomly, of their collection sites each year. Additionally, Federal agencies are required to investigate reported collection site deficiencies (e.g., "rejected for testing" by either an HHS-certified laboratory or HHS-certified IITF) and take appropriate action which may include inspecting the collection site. The number of collection sites inspected because they have had "rejected for testing" results are not included in the 5 percent or maximum of 50 requirement.

Subpart I--HHS Certification of Laboratories and IITFs

The proposed section describing the goals and objectives of certifying laboratories and IITFs was removed from the Guidelines. Four commenters suggested that the discussion should be in the preamble rather than in the Guidelines. The Department agrees that the discussion in this section does not establish any specific analytical requirements and was removed from these Guidelines.

Section 9.1 (Section 9.2 in the Proposed Revisions to Mandatory Guidelines) states that the Secretary has the authority to certify laboratories. Four commenters disagreed with the right of the Secretary to review private sector specimen results tested under the Guidelines. The Department understands the concerns expressed by the commenters; however, the review of private sector specimen or non-regulated specimen results, only occurs for those private sector specimens that are tested in batches that contain federally-regulated specimens. This usually occurs with confirmatory test batches because laboratories assemble these batches by taking the initial test positive specimens from different initial test batches to make the confirmatory test cost effective and efficient. Therefore, the policy described in this section is the same policy as described in the Proposed Revisions to Mandatory Guidelines.

Section 9.2 (Section 9.3 of the Proposed Revisions to Mandatory Guidelines) describes the application process for a laboratory or IITF, procedures for maintaining certification, and what a laboratory or IITF must do when its certification is not maintained. In the Proposed Revisions to Mandatory Guidelines, the term "imminent harm" is used as a reason to require a laboratory to immediately stop testing Federal agency specimens. Three commenters objected to using the term "imminent harm" because they believe the term limits the Department's ability to suspend a laboratory or IITF. Although the Department has

successfully suspended a number of laboratories using “imminent harm” as the basis for an immediate suspension, the term has been removed from these Guidelines. The reasons for taking action against a laboratory or IITF are more appropriately discussed in Sections 9.12, 9.13, and 9.14. The Department has revised Section 9.2(c) to clarify the requirements when a laboratory or IITF does not maintain its HHS certification.

Section 9.3 (Section 9.5 of the Proposed Revisions to Mandatory Guidelines) describes the composition requirements for the PT samples that are used to challenge a laboratory or IITF’s drug and specimen validity tests. The requirements in this section are the same as those contained in the current Guidelines, except for the pH specifications in Section 9.3(b)(2). These specifications were revised to challenge the pH tests used by IITFs, as described in Section 12.14(c)(1), as well as laboratory pH screening tests with a narrow dynamic range, as described in Section 11.18(c)(1).

Section 9.4 (Section 9.9 of the Proposed Revisions to Mandatory Guidelines) describes the requirements that an applicant laboratory must satisfy when testing the 3 consecutive sets of PT samples sent to the laboratory during the initial certification process. Section 9.5 (Section 9.13 of the Proposed Revisions to Mandatory Guidelines) describes the requirements that a certified laboratory must satisfy when testing the quarterly sets of PT samples sent to the laboratory as part of the maintenance PT program. In both sections, the requirements are the same

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as in the current Guidelines with two exceptions concerning the evaluation of specific gravity results. The Department has retained the acceptable range of no more than 0.0003 specific gravity units from the mean for PT samples with a mean less than 1.0100, but has increased the acceptable range to 0.0004 specific gravity units when a PT sample’s mean is equal to or greater than 1.0100. The Department has retained the limit of 0.0006 specific gravity units from the mean for assessing errors for PT samples with a mean less than 1.0100, but has increased the limit to 0.0007 specific gravity units when the PT sample’s mean is equal to or greater than 1.0100. The Department has been evaluating the performance of the instruments used to measure specific gravity to 4 decimal places and believes increasing the precision limits for high specific gravity readings is reasonable and appropriate due to the nature of the refractive index and calibration methods using oil to calibrate the instruments.

Section 9.6 (Section 9.17 of the Proposed Revisions to Mandatory Guidelines) describes the PT requirements an applicant IITF must satisfy to conduct urine testing and Section 9.7 (Section 9.21 of the Proposed Revisions to Mandatory Guidelines) describes the PT requirements that an HHS-certified IITF must satisfy to conduct urine testing. Both sections were revised to be consistent with PT challenges for the initial testing part of a laboratory (i.e., requirements addressing confirmatory test challenges were deleted). One commenter noted the requirement to correctly identify and report the total drug challenges over 3 sets of PT samples was 80 percent for applicant and certified IITFs, while it is 90 percent for applicant and certified laboratories. The commenter recommended that the requirement be the same for IITFs and laboratories. The Department agrees and has revised the requirement in Section 9.6(a)(1) to be 90 percent for applicant IITFs for initial testing.

Section 9.8 (Section 9.22 of the Proposed Revisions to Mandatory Guidelines) describes the inspection requirements for an applicant laboratory or IITF and Section 9.9 (Section 9.23 of the Proposed Revisions to Mandatory Guidelines) describes the inspection requirements for an HHS-certified laboratory or IITF. The Proposed Revisions to Mandatory Guidelines required using at least two inspectors to inspect an applicant laboratory or IITF. Three commenters expressed concern with requiring at least two inspectors to inspect an applicant laboratory or IITF, while the Proposed Revisions to Mandatory Guidelines permit only one inspector to potentially be used to inspect an HHS-certified laboratory or IITF. The Department has revised Section 9.8 to require two inspectors rather than the proposed “at least two inspectors.” The Department believes that the inspection of an applicant laboratory or IITF must be conducted using two inspectors because this minimizes the possibility of a laboratory or IITF disputing the findings of one inspector as opposed to the findings from two inspectors. With regard to HHS-certified laboratories and IITFs, the Department retained the Proposed Revisions to Mandatory Guidelines requirement which states that an HHS-certified laboratory or IITF “is inspected by one or more inspectors”. The Department believes that one inspector is appropriate to inspect an HHS-certified laboratory or IITF when the facility is very small, has an extremely small workload, and

has a history of acceptable performance on testing the PT samples and on previous inspections. The Department believes that using one inspector is sufficient to conduct a thorough inspection and makes it cost-effective for very small HHS-certified laboratories and IITFs to remain in the certification program.

Section 9.10 specifies the criteria an individual must satisfy to be eligible for selection as an inspector for the Secretary under these Guidelines. This section also states that the Secretary of a Federal Agency may inspect an HHS-certified laboratory or IITF at any time. The requirements in this section are the same as in Section 9.24 of the Proposed Revisions to Mandatory Guidelines, but the section has been reworded for clarity.

Section 9.11 describes what happens when an applicant laboratory or IITF fails to satisfy the minimum requirements for either the PT program or the inspection program. The Department believes that an applicant laboratory or IITF must successfully satisfy all of the initial certification process requirements or be required to begin the process from the very beginning. That is, submit a new application with corrective actions indicated and then successfully satisfy the requirements for the 3 sets of PT samples. These requirements are the same as in the Proposed Revisions to Mandatory Guidelines, Section 9.25.

Section 9.12 describes what happens when a certified laboratory or IITF does not satisfy the minimum requirements for either the PT program or the inspection program. The policy in this section is the same as that contained in the current and Proposed Revisions to Mandatory Guidelines in Section 9.26.

Section 9.13 describes the factors that are considered when determining whether to revoke a laboratory's or IITF's certification. The factors described are the same as those contained in the current and Proposed Revisions to Mandatory Guidelines in Section 9.27.

Section 9.14 states that the Secretary may suspend a laboratory's or IITF's certification to protect the interests of the United States. This policy is the same as that contained in the current and Proposed Revisions to Mandatory Guidelines in Section 9.28.

Section 9.15 describes how the Secretary notifies a laboratory or IITF that action is being taken against the laboratory or IITF. The policy in this section is the same as the policy described in the current and Proposed Revisions to Mandatory Guidelines in Section 9.29.

Section 9.16 describes how a laboratory that has had its certification revoked can apply for recertification. The policy is the same policy as described in the current and Proposed Revisions to Mandatory Guidelines in Section 9.30.

Section 9.17 states that the list of HHS-certified laboratories and IITFs will be published monthly in the Federal Register. This policy is the same policy as described in the current and Proposed Revisions to Mandatory Guidelines in Section 9.31.

Subpart J--Blind Samples Submitted by an Agency

Section 10.1 describes the requirements for Federal agencies to submit blind samples to certified laboratories or IITFs. Four commenters expressed concern that the proposed requirement to submit only 1 percent blind samples was too low. The Department agrees and has revised Section 10.1(b) to require each agency to submit 3 percent blind samples each year rather than having one requirement for the first 90 days (3 percent) and a different requirement after 90 days (1 percent). The Department also notes that the HHS-certified laboratories and IITFs will also be evaluated using quarterly PT samples and will be receiving the 3 percent blind samples from several agencies to ensure that they are properly handling and testing donor specimens. The policy in Section 10.1(c) describing the percentage of negative, positive, and adulterated or substituted blind samples to be submitted was revised. The proposed 80 percent negative blind samples was changed to 75 percent

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negative blind samples, and 20 percent non-negative was changed to 15 percent positive and 10 percent adulterated or substituted.

Section 10.2 describes the specific requirements for each blind sample and the requirements are the same as those contained in the current and Proposed Revisions to Mandatory Guidelines.

Section 10.3 describes how a collector submits a blind sample to be tested. The requirements in this section are the same as those in the Proposed Revisions to Mandatory Guidelines. Section 10.4 describes what happens when an inconsistent result is reported on a blind sample. The requirements in this section are the same as those in the Proposed Revisions to Mandatory Guidelines.

Subpart K--Laboratory

Section 11.1 requires each certified laboratory to have a standard operating procedure manual and describes what information must be contained in the manual. The requirements in this section are the same as those in the current and Proposed Revisions to Mandatory Guidelines.

Section 11.2 describes the responsibilities of the individual who has responsibility for the day-to-day management of the urine drug testing laboratory. This individual is called the responsible person (RP). The responsibilities described in this section are the same as those described in the current and Proposed Revisions to Mandatory Guidelines, except the requirement that the RP qualify as a certifying scientist was moved to Section 11.3(e). The Department believes the requirement that the RP qualify as a certifying scientist is more appropriately included as a qualification rather than a responsibility.

Section 11.3 describes the scientific qualifications that an individual must have to serve as an RP. Three commenters believe the requirement for an RP to have experience with the collection and analysis of biological specimens is too general. The Department believes the qualification as stated in Section 11.3(b) is appropriate and does not need to specifically focus on collecting urine specimens. The primary purpose for this qualification is that the RP has experience and knowledge of the general procedures and issues that may arise with the collection and analysis of biological specimens (e.g., chain of custody, storage, handling, troubleshooting problems). The qualifications described in this section are the same as those described in the current and Proposed Revisions to Mandatory Guidelines.

Section 11.4 describes what happens when an RP is absent or leaves a certified laboratory. This section has been revised to require a laboratory to have multiple RPs or one RP and an alternate RP. The requirement in the Proposed Revisions to Mandatory Guidelines did not make it clear that the laboratory must have an alternate RP when there is only one RP. The Department believes this requirement and establishing time limits for the alternate RP to assume RP duties when an RP is absent from a laboratory will minimize the impact on the laboratory, and enable the laboratory's continued compliance with the Guidelines when the RP is absent. The Department has revised Section 11.4(c) to state that an alternate RP must be found acceptable during an on-site inspection of the laboratory. This requirement ensures that the alternate RP is pre-approved. The Department believes an individual must be pre-approved as an alternate RP to ensure that someone with the appropriate knowledge and qualifications can assume RP responsibilities when the RP is absent from the laboratory.

Section 11.5 describes the qualifications an individual must have to certify a result reported by an HHS-certified laboratory. An individual who certifies results may be either a certifying scientist (CS) or a certifying technician (CT) depending on the type of test result he or she is certifying. The Department has decided to retain the bachelor's degree or equivalent requirement for the certifying scientist qualifications as described in the current Guidelines. The Department believes the training and experience specified in the Proposed Revisions to Mandatory Guidelines for a CT are sufficient to ensure that the CT can properly certify a negative, negative/dilute, or rejected for testing result. One commenter stated that the qualifications for a CT in an HHS-certified laboratory were not consistent with the qualifications for a CT in an HHS-certified IITF as described in the Proposed Revisions to Mandatory Guidelines. The same requirements are specified for a CT in the laboratory and IITF sections (i.e., Sections 11.5(b) and 12.5, respectively). The Department has further clarified that qualifications for a CT are the same in a laboratory and in an IITF by revising the definition for a certifying technician in Section 1.5. The revised definition states that a CT can verify negative, negative/dilute, and rejected for testing results reported by a laboratory or IITF.

Section 11.6 describes the qualifications and training other laboratory personnel must have. The policy in this section is the same as the policy described in the current and Proposed Revisions to Mandatory Guidelines, except that the current and Proposed Revisions to Mandatory Guidelines do not specifically state that the training must be documented.

Section 11.7 describes the security measures that a certified laboratory must maintain. This section has been revised to require the authorized escort to enter his or her name in the record used to document the entry of authorized visitors. The current and Proposed Revisions to Mandatory Guidelines did not require such documentation.

Section 11.8 describes internal laboratory chain of custody requirements. The policy in this section is the same as the policy in the Proposed Revisions to Mandatory Guidelines.

Section 11.9 describes the tests an HHS-certified laboratory must conduct on a specimen received from an IITF. Three commenters expressed concern with requiring an HHS-certified laboratory to conduct

only the confirmatory test(s) on specimens received from an HHS-certified IITF. The commenters recommended that an HHS-certified laboratory test all specimens received from an HHS-certified IITF as if the specimens had not been previously tested. The commenters believe it is important that all analytical results supporting a positive, adulterated, substituted, or invalid result should be generated within the same facility. The Department agrees and has revised this section to require an HHS-certified laboratory to test each specimen received from an HHS-certified IITF in the same manner as if it had not been previously tested. This revision ensures that the final analytical results (both the initial and confirmatory data) and internal chain of custody documents are generated by one HHS-certified laboratory and can be properly reviewed and certified before the test result is released.

Section 11.10 describes the requirements for an initial drug test. One commenter stated that paragraph (c) of the Proposed Revisions to Mandatory Guidelines did not clearly state that the initial drug test kits must be "FDA-cleared." The Department agrees and clarified that drug tests must be approved, cleared, or otherwise recognized by FDA as accurate and reliable for the testing of a specimen for identifying drugs of abuse or their

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metabolites. Therefore, it is more appropriate to refer to "FDA requirements" rather than limit the language to "FDA-cleared". We note that only those test kits subject to FDA premarket notification requirements must be "FDA-cleared." One commenter believes that the purpose for conducting a second initial test was not clearly stated in paragraph (d). The Department agrees and has revised this paragraph to indicate that a second initial drug test may be used when the second initial drug test has a different specificity than the first initial drug test. The second initial test must satisfy the batch quality control requirements for an initial drug test.

Section 11.11 describes what a laboratory must do to validate an initial drug test before using it to test donor specimens. One commenter recommended that the requirements to validate an initial drug test should be more stringent. The Department believes these requirements are appropriate and that they give an HHS-certified laboratory the flexibility it needs to validate the initial drug tests based on the instruments they are using. The Department also moved the requirement from Section 11.13 to document the effect of carryover to this section, because it is more appropriate to evaluate the possibility of carryover when the initial drug test is validated. Knowing when and if carryover can affect donor specimen results allows a laboratory to determine when corrective action must be taken to control for carryover.

Section 11.12 describes the batch quality control requirements when conducting initial drug tests. The requirements in this section are the same as those described in the current and Proposed Revisions to Mandatory Guidelines.

Section 11.13 describes the requirements for a confirmatory drug test. Four commenters disagreed with allowing the use of other chromatographic separation and mass spectrometry techniques for the confirmatory drug tests. They believe that gas chromatography/mass spectrometry (GC/MS) has been the gold standard since the Federal Workplace Drug Testing Program began and should be the only accepted confirmatory method until other methods are proven to be reliable and scientifically supportable. The Department disagrees and believes that other methods, such as liquid chromatography/mass spectrometry (LC/MS), LC/MS/MS, and GC/MS/MS, have been proven to be reliable to test specimens. While GC/MS remains the most common confirmatory testing technology used in forensic drug testing laboratories, the Department does not want to prohibit laboratories from using technologies that provide forensically and scientifically supportable results. The Department proposed that these additional technologies be allowed in Federal workplace drug testing programs only after a thorough review of extensive information obtained through technical working groups consisting of drug testing and analytical chemistry experts. No comments were submitted that justified removal of these technologies from the proposed Guidelines. Since the proposed revisions to the Guidelines were published in April 2004, the use of these technologies has become even more widespread and there have been numerous studies employing these methods, providing additional data to demonstrate their forensic and scientific acceptability. These methods may offer some benefits over traditional GC/MS methods. For example, GC and LC provide a means to separate drugs of abuse from other compounds found in urine. The advantage of LC methods is that they may require less specimen preparation prior to analysis, thereby saving time and costs. Likewise MS and MS/MS methods are highly selective, reducing the chance that

other substances present in the urine might interfere with the analysis and prevent the laboratory from obtaining a valid result. MS/MS technology provides an advantage in that it is also more sensitive than GC/MS. A properly validated and controlled GC/MS method is sensitive enough to meet the requirements of these Guidelines for forensic urine drug testing. However, the increased sensitivity provided by MS/MS can enable laboratories to use less specimen volume, which may have implications in some cases (e.g., when there are multiple drugs present in a specimen). Furthermore, many laboratories have implemented instruments and test methods using these different chromatographic and/or mass spectrometric technologies for forensic applications other than federally regulated workplace testing. Therefore, laboratories that are currently certified or plan to seek certification under these Guidelines may already have the experience and capability to employ these methods in Federal workplace testing programs or they may want to add these newer technologies to their testing protocols.

Section 11.14 describes what a laboratory must do to validate a confirmatory drug test before using it to test donor specimens. The Department moved the requirement from Section 11.16 to document the effect of any carryover to this section, because it is more appropriate to evaluate the possibility of carryover when the confirmatory drug test method is validated. Knowing when and if carryover can affect donor specimen results allows a laboratory to determine when corrective action must be taken to control for carryover.

Section 11.15 describes the batch quality control requirements when conducting confirmatory drug tests. Three commenters recommended that this section be revised to allow using a multi-point calibration as well as a single-point calibration for each batch of specimens when conducting a confirmatory test. The Department agrees and has revised Section 11.15(a)(1) to read "A calibrator with its drug concentration at the cutoff". This revision allows multi-point calibration, while still requiring a cutoff calibrator.

Section 11.16 describes the analytical and quality control requirements for conducting specimen validity tests. The requirements are the same as those described in the current Guidelines, except that Section 11.16(b) specifically refers to the requirements specified in Section 11.18 rather than simply stating that appropriate calibrators and controls must be included. The Department believes this revision will ensure that each laboratory will use the same calibrators and controls when conducting specimen validity tests. Section 11.17 is a new section that describes what a certified laboratory must do to validate a specimen validity test. The Department is establishing these requirements to ensure that specimen validity tests, like drug tests, are validated before they are used for donor specimens. The policy has been intentionally written as a general requirement because each type of specimen validity test has different performance characteristics.

Section 11.18 describes the requirements for conducting each type of specimen validity test on a urine specimen. One commenter recommended allowing an HHS-certified laboratory to use a three decimal place refractometer as a preliminary specific gravity test to determine if the initial specific gravity test must be conducted. The Department agrees and has revised Section 11.18(b)(1) to allow a laboratory to use a refractometer measuring to at least three decimal places as a specific gravity screening test when the creatinine is greater than 5.0 mg/dL and less than 20 mg/dL. However, laboratories must use a four decimal

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place refractometer to measure specific gravity for specimens when the initial creatinine test result is equal to or less than 5.0 mg/dL or when the screening specific gravity test result using a three decimal place refractometer is less than 1.002. These criteria were selected for deciding whether a three or four decimal refractometer must be used because the test results are approaching the criteria for reporting a substituted specimen which may lead to adverse personnel action. The Department also added the quality control requirements for conducting the specific gravity screening test. One commenter recommended that colorimetric specific gravity assays be permitted for use as the initial specific gravity test. The Department disagrees because these assays lack the required accuracy and precision to serve as an initial specific gravity test. One commenter recommended that pH meters used for the initial and confirmatory pH tests should print a paper copy report or be interfaced with a Laboratory Information Management System (LIMS) or computer. The commenter noted that the Guidelines include this requirement for refractometers used to conduct the initial and confirmatory specific gravity tests, and the same forensic considerations apply for pH tests. The Department agrees and has added Section

11.18(c)(2) specifying that a pH meter used for the initial and confirmatory pH tests must report and display pH to at least one decimal place, and must be interfaced with a LIMS or computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the pH test results.

Section 11.19 describes the requirements for a certified laboratory to report results to an MRO. One commenter was opposed to requiring an HHS-certified laboratory to provide the concentration of a drug in a specimen at the time the test result is reported to the MRO. The Department disagrees and believes this policy is appropriate because, in keeping with the paperwork reduction and elimination acts, it eliminates the need for the MRO to generate a request in writing to obtain the concentrations for positive specimens. One commenter stated that reporting a positive and invalid result on the same specimen is confusing and recommended that the positive result and “the reason for the invalid result” be reported, rather than using the term “invalid result” along with the reason for the invalid result. The Department recognizes that requiring the laboratory to report both results to the MRO may be confusing; however, the MRO must discuss both results with the donor. The invalid result may only have an impact on the testing of the split specimen if requested by the donor. One commenter recommended that specific guidance be included on the content of any computer-generated report. The Department does not believe detailed guidance is needed, but has revised the appropriate Section 11.19(o) to state that the computer-generated report must contain sufficient information to ensure that the test result is properly associated with the Federal CCF that the MRO received from the collector. The Department added Section 11.19(g) to maintain the policy in the current Guidelines which requires the laboratory to contact the MRO prior to reporting specimens meeting certain “invalid result” criteria. This policy is important to ensure that the laboratory and the MRO discuss those specimens for which a positive or adulterated result could be determined, using different or additional tests at another certified laboratory. If additional testing does not appear to be feasible, the laboratory reports the invalid result. The MRO can initiate action immediately upon receipt of the report, in accordance with Section 13.4.

Section 11.20 describes how long a certified laboratory must retain a specimen. Section 11.20(c) was revised to require a Federal agency to specify a period of time rather than “an additional period of time” when requesting a laboratory to retain a specimen beyond the normal one year specimen storage period. Also, the statement that a laboratory must maintain any specimen under legal challenge for an indefinite period of time has been deleted. The laboratory must be instructed by the agency as to the period of time the specimen under legal challenge will need to be retained beyond the normal one year storage period.

Section 11.21 describes how long a certified laboratory must retain records. This section has been revised to specify the records that the HHS-certified laboratory must maintain when there is a legal challenge to the test result for a particular specimen. The revision allows a Federal agency to request a laboratory to maintain a copy of the documentation package for the specimen result being challenged for a specified period of time. The revision also permits the HHS-certified laboratory to retain records other than those included in the documentation package beyond the 2 year period of time that records are normally maintained.

Section 11.22 describes the statistical summary report that a certified laboratory must provide to an agency. The summary report is the same as the report described in the current and Proposed Revisions to Mandatory Guidelines. Four commenters expressed concern with requiring an HHS-certified laboratory to make qualified personnel available to testify in a proceeding against a Federal employee. They were concerned that several individuals may be required to testify, thereby disrupting the laboratory's ability to continue testing specimens. The Department agrees and has revised Section 11.22(d) to require an HHS-certified laboratory to make only one qualified individual available to testify. This change is consistent with what normally happens in proceedings where laboratory results are being challenged by a donor.

Section 11.23 describes the information a laboratory must make available to a Federal employee. The Department has revised this section to require that the curriculum vitae for the responsible person(s) be included along with the curriculum vitae for the certifying scientist that certified the test result.

Section 11.24 describes the type of relationship that is prohibited between a certified laboratory and an MRO. Three commenters recommended that this section be revised to include additional restrictions or requirements that can be found in other regulated programs. The Department believes the requirements are sufficient to ensure that an MRO would report a potential problem with an HHS-certified laboratory to a Federal agency or to the appropriate regulatory office within HHS. In addition, the requirements in this section have been used successfully by HHS in previous versions of the Guidelines. The section has been reworded to clarify the requirements.

Section 11.25 was added, addressing the type of relationship allowed between an HHS-certified laboratory and an IITF. This section was added for clarity, and is consistent with the requirements specified in the IITF sections of the Proposed Revisions to Mandatory Guidelines.

The Department removed the requirement that a certified laboratory must inform its private sector clients when it uses testing procedures different from those used for Federal agency specimens. Although this requirement has been a program policy for many years, the Department is confident that HHS-certified laboratories would not intentionally mislead their private sector clients into believing that regulated procedures

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would be used to test their specimens when, in fact, less stringent procedures are being used.

Subpart L--Instrumented Initial Test Facility (IITF)

Section 12.1 describes what an HHS-certified IITF must include in its standard operating procedure manual. The requirements in this section are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines, except a 2 year period was specified for retaining archived SOPs, consistent with the requirement for laboratories in Section 11.1.

Section 12.2 describes the responsibilities of the responsible technician (RT). The Department moved the requirement that the RT qualify as a certifying technician to Section 12.3(e), because this is a qualification rather than a responsibility. All other requirements in this section are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines.

Section 12.3 describes the qualifications that the RT must have. One commenter recommended that the qualifications for the RT be the same as those for an alternate RP working in an HHS-certified laboratory. The Department disagrees with the recommendation because the qualifications for an alternate RP include responsibilities and expertise in technical areas (i.e., confirmatory testing) that the RT does not need to know to fulfill the responsibilities as an RT. However, the requirements are similar to those of a CS at an HHS-certified laboratory in Section 11.5. The requirement that the RT qualify as a certifying technician ensures that the RT can properly review the same results that a certifying technician reviews and reports at an HHS-certified laboratory or IITF.

Section 12.4 describes what happens when the RT is absent or leaves an HHS-certified IITF. The Department has revised Section 12.4(c) to state that an alternate RT must be found acceptable during an on-site inspection of the IITF. This requirement ensures that the alternate RT is pre-approved. The Department believes an individual must be pre-approved as an alternate RT to ensure that someone with the appropriate knowledge and qualifications can assume RT responsibilities when the RT is absent from the IITF.

Section 12.5 describes the qualifications an individual must have to certify a result reported by an HHS-certified IITF. The requirements in this section are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines, and are the same as those for a CT in a laboratory, specified in Section 11.5(b).

Section 12.6 describes the qualifications and training other personnel must have who work in an IITF. The requirements in this section are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines, except that the Proposed Revisions to Mandatory Guidelines did not specifically state that the training must be documented.

Section 12.7 describes the security measures that an HHS-certified IITF must maintain. The Department has revised this section to require the authorized escort to enter his or her name in the record used to document the entry of authorized visitors. These requirements are the same as for an HHS-certified laboratory, as specified in Section 11.7. The change in this requirement clarifies that the record must always indicate all of the individuals who may have had access to specimens maintained in secure areas. It is not any different than requiring any employee (whether serving as an escort or not) to document every time he or she enters or leaves a secured area.

Section 12.8 describes internal IITF chain of custody requirements. The requirements in this section are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines.

Section 12.9 describes the requirements for an initial drug test used by an HHS-certified IITF. The Department has added this section to ensure that the drug tests used by an HHS-certified IITF satisfy the

same initial drug test requirements as required for HHS-certified laboratories.

Section 12.10 was added to describe validation requirements for initial drug tests in an HHS-certified IITF. The requirements are the same as for initial drug tests in an HHS-certified laboratory.

Section 12.11 describes the batch quality control requirements for initial drug tests in an IITF. These are the same as the requirements in the Proposed Revisions to Mandatory Guidelines, in that the requirements are the same as for an HHS-certified laboratory. For clarity, this section has been revised to list the required quality control samples, rather than referring to the relevant laboratory section.

A single section, Section 13.14, was included in the Proposed Revisions to Mandatory Guidelines to address specimen validity testing in IITFs, referring to the relevant laboratory sections. The Department has expanded the information into three sections to address the requirements in a manner consistent with the format of Subpart K for HHS-certified laboratories.

Section 12.12 addresses the IITF analytical and quality control requirements for specimen validity tests, specifying that testing is performed on a single aliquot. Since IITFs do not report adulterated, substituted, or invalid specimens, there is no need to perform two tests on separate aliquots, as required in a laboratory.

Section 12.13 describes the validation requirements for specimen validity tests. The requirements in this section are the same as for an HHS-certified laboratory.

Section 12.14 describes the requirements for an HHS-certified IITF to conduct each specimen validity test. One commenter recommended that an HHS-certified IITF be permitted to use a pH screening test to determine the pH rather than requiring the use of a pH meter. The Department agrees and has specified in this section that an HHS-certified IITF may use a pH screening test to determine if an initial pH validity test must be performed. The HHS-certified IITF will forward specimens with pH test results outside the acceptable range to an HHS-certified laboratory where the laboratory will conduct the initial pH validity test and, if needed, the confirmatory pH validity test. This policy permits an HHS-certified IITF to determine pH without a requirement to have a pH meter available for conducting the initial pH test.

Section 12.15 describes the requirements for an HHS-certified IITF to report a negative or rejected for testing result to an MRO. One commenter recommended that this section be revised to allow an HHS-certified IITF to report a urine specimen that is negative/dilute to the MRO. The Proposed Revisions to Mandatory Guidelines stated that only a negative result could be reported by an HHS-certified IITF to an MRO. The Department agrees and has revised the section to permit an HHS-certified IITF to report negative, negative/dilute (when creatinine is greater than 5 mg/dL), and rejected for testing results directly to the MRO. All other requirements in this section are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines.

Section 12.16 describes how an HHS-certified IITF handles a specimen that tested as positive, adulterated, substituted, or invalid at the IITF. The Department has revised this section by

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removing the proposed requirement for the HHS-certified IITF to record these types of results on the OMB-approved chain of custody form. The Department revised the Guidelines (Section 11.10) to require an HHS-certified laboratory to perform both initial and confirmatory testing for specimens received for testing from an IITF.

Section 12.17 describes how long an HHS-certified IITF must retain a specimen. The Department added this section to specifically state that an HHS-certified IITF is permitted to discard specimens that are reported negative, negative/dilute, or rejected for testing. This policy is the same as those for an HHS-certified laboratory.

Section 12.18 describes how long an HHS-certified IITF must retain records. The Department has revised Section 12.18(b) to specify the records that the HHS-certified IITF must maintain when there is a legal challenge to the test result for a particular specimen. The revision requires a Federal agency to specify the period of time that an IITF must maintain a copy of the documentation package (as described in Section 12.20) for the specimen result being challenged rather than requiring an indefinite period of time as stated in the Proposed Revisions to Mandatory Guidelines. Section 12.18(c) was added to permit an HHS-certified IITF to retain records other than those included in the documentation package beyond the 2 year period of time that records are normally maintained.

Section 12.19 describes the statistical summary report that an HHS-certified IITF must provide semiannually to an agency. One commenter noted that this section must be revised because an HHS-

certified IITF cannot report an invalid result. The Department agrees and has revised this section to clarify that an IITF indicates the number of specimens that were reported negative, negative/dilute, and rejected for testing on the statistical summary report. The Department also revised the section to clarify that an IITF indicates the number of specimens forwarded to an HHS-certified laboratory for additional drug and/or specimen validity testing. Three commenters raised concern with the proposed requirement that an HHS-certified IITF must make available qualified personnel to testify in a proceeding against a Federal employee when that proceeding is based on a test result reported by the HHS-certified IITF. The Department agrees and has revised the policy to specifically indicate that one qualified individual must be made available to testify. This change is consistent with what normally occurs in legal proceedings and is consistent with the policy that applies to an HHS-certified laboratory.

Section 12.20 describes the information an IITF must make available to a Federal employee. The Department has revised this section to require that the curriculum vitae for the responsible technician be included along with the curriculum vitae for the certifying technician that certified the test result.

Section 12.21 describes the type of relationship that is prohibited between an HHS-certified IITF and an MRO. The policy in this section is the same policy as described in the Proposed Revisions to Mandatory Guidelines. This section was reworded to clarify the requirements.

Section 12.22 describes the type of relationship that can exist between an HHS-certified IITF and an HHS-certified laboratory. Three commenters raised concern over allowing any type of relationship to exist between an HHS-certified IITF and an HHS-certified laboratory. The Department believes any relationship is acceptable because HHS-certified laboratories and IITFs are certified independently. Therefore, the Department has no objection if an HHS-certified laboratory wants to establish and own one or more HHS-certified IITFs.

Subpart M--Medical Review Officer (MRO)

Section 13.1 describes who may serve as an MRO. Several commenters disagreed with the proposed policy in Section 13.1(b) to require MRO organizations to submit their training programs for review and approval by HHS before their trained MROs would be permitted to serve as MROs for Federal agencies. Other commenters stated that the Guidelines should include objective criteria that will be used to assess and approve the MRO organization's training programs. The Department believes that approving these MRO training courses is necessary to ensure that MROs receive all the information needed to properly evaluate drug test results and that they demonstrate and document their knowledge of the drug testing program by passing an examination. With regard to the criteria used by HHS to assess these training courses, the training requirements in Section 13.2 will serve as the basis for approving each MRO organization's training course.

Section 13.2 describes the training requirements before a physician can serve as an MRO. The training requirements in this section will serve as the basis for approving an MRO organization's training course. HHS approval will focus on how well the course presents the materials for each requirement listed in this section and how well the organization documents each MRO's understanding of the material by examination.

Section 13.3 describes the responsibilities of an MRO. The Department revised this section to address the requirement for the MRO to medically evaluate donors who were unable to provide a sufficient amount of urine for a drug test, as described in Section 13.5 and to address the requirement for the MRO and laboratory to discuss specimens meeting certain "invalid result" criteria, as described in Section 11.19(g). One commenter pointed out that the preamble for the Proposed Revisions to Mandatory Guidelines required the MRO to review 5 percent of the negative results reported by staff to ensure that the staff is properly performing the review process, but the text did not specify the 5 percent requirement. The Department has revised Section 13.3(a) to include this requirement. Three commenters recommended deleting the sentence which stated that "The MRO must cancel the result for any agency's specimen that is not collected or tested in accordance with these Guidelines." The commenters believed it places a burden on MROs to be finders of fact concerning alleged irregularities at the collection site. The Department agrees and has deleted the sentence.

Section 13.4 describes what an MRO must do when reviewing a drug test result. Three commenters stated that the proposed section referring to invalid results reported by an HHS-certified IITF should be revised, because IITFs will not report such results. The Department agrees and has deleted any reference to an HHS-certified IITF reporting an invalid result in Section 13.4. If an HHS-certified IITF finds

a presumptive invalid result for a specimen, the IITF must forward the specimen to an HHS-certified laboratory for testing. Recent research supports that high temperature for an extended time may increase urine pH up to 9.5. This means that conditions during specimen transport and/or storage may cause pH to fall within the invalid range (i.e., greater than or equal to 9.0, but less than 11.0). The Department has added guidance to MROs in paragraph f of this section on interpreting an invalid result based on pH in the range of 9.0 to 9.5. This allows the MRO to consider time and temperature as an alternative, non-medical explanation for this invalid result. The Department has removed the sections addressing MRO actions in response to a second specimen collected

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after an invalid result for which there is no valid medical explanation. The Department will provide detailed guidance for MROs outside of these Guidelines.

The Department added new Sections 13.5 and 13.6 to describe action the MRO must take when a collector reports that a donor was unable to provide a sufficient urine specimen. Sections 8.5(b)(2) and 8.6(e)(2)(ii) require the collector to document when a donor did not provide a urine specimen or when a donor provided an insufficient amount (i.e., less than 45 mL). Section 13.5 provides a detailed description of what the MRO and the Federal agency must do to determine the reason for the donor's inability to provide a urine specimen.

Section 13.6 describes what the MRO and the Federal agency must do when a donor has a permanent or long-term medical condition that precludes him or her from providing a sufficient specimen when a negative result is required (i.e., for a Federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test).

Section 13.7 describes when the donor has the opportunity to request the testing of a split (Bottle B) specimen. The policy in this section is the same policy as described in the Proposed Revisions to Mandatory Guidelines.

Section 13.8 describes how an MRO reports a primary (Bottle A) specimen test result to an agency. The requirements in this section are the same as those described in the Proposed Revisions to Mandatory Guidelines.

Section 13.9 describes the type of relationship that is prohibited between an MRO and an HHS-certified laboratory or an HHS-certified IITF. The Department has revised the question and policy in this section to delete references to a POCT.

Subpart N--Split Specimen Tests

Section 14.1 describes when a split specimen may be tested. Several commenters disagreed with the requirement that the donor must request the testing of his or her split specimen in writing. The commenters believe the requirement places an unreasonable burden on the donor and may cause unnecessary delays in testing and reporting split specimen results. The Department agrees that requiring a written request may be an obstacle to getting the split specimen tested in a timely manner and, therefore, has revised Section 14.1(b) to allow the MRO to have a split specimen tested based on a verbal request from the donor. However, the MRO is required to document in his or her records (e.g., a donor interview sheet) that the donor made a verbal request. The Department believes this documentation is acceptable to ensure that the donor properly initiated the request within 72 hours after being informed of the result by the MRO. The Department has revised the proposed policy for MRO action when the split (Bottle B) specimen cannot be tested by a second laboratory (e.g., insufficient specimen, lost in transit, split not available, no second laboratory available to perform the test). The Proposed Revisions to Mandatory Guidelines (Section 15.1) had required the MRO to direct the agency to immediately collect another specimen in these cases. In response to comments received, the Department has revised this section, now Section 14.1(c), to require an immediate recollection under direct observation. This is consistent with the current Guidelines.

Sections 14.2, 14.3, and 14.4 describe the requirements to test split specimens when the primary specimens are tested positive, adulterated, or substituted, respectively. The requirements in these sections are the same as the requirements described in the current and Proposed Revisions to Mandatory Guidelines.

Section 14.5 requires the second certified laboratory to report the split specimen result directly to the MRO. The policy in this section is the same as the policy described in the Proposed Revisions to Mandatory Guidelines.

Section 14.6 describes the specific action(s) that an MRO must take after receiving the split specimen result from the second certified laboratory. The actions described in this section are the same as the actions described in the current and Proposed Revisions to Mandatory Guidelines.

Section 14.7 describes the different ways that an MRO can report split specimen results to an agency. The policies in this section are the same as those described in the Proposed Revisions to Mandatory Guidelines.

Section 14.8 describes how long a certified laboratory must retain a split (Bottle B) specimen. The policy in this section is the same as the policy described in the Proposed Revisions to Mandatory Guidelines.

Subpart O--Criteria for Rejecting a Specimen or Cancelling a Test

Section 15.1 describes those discrepancies (i.e., "fatal flaws") that require an HHS-certified laboratory or an HHS-certified IITF to report a urine specimen as rejected for testing. The fatal flaws described in this section are the same as those described in the Proposed Revisions to Mandatory Guidelines. Section 15.2 describes the discrepancies that require an HHS-certified laboratory or an HHS-certified IITF to report a urine specimen as rejected for testing unless the discrepancy is corrected. The discrepancies described in this section are the same as those described in the Proposed Revisions to Mandatory Guidelines.

Section 15.3 describes the deficiencies that are not sufficient to require an HHS-certified laboratory or an HHS-certified IITF to reject a urine specimen for testing or for an MRO to cancel a test. Several commenters stated the requirement in this section directing an MRO to track the frequency of omissions and discrepancies to determine when a collector, laboratory, or IITF should take immediate corrective action to prevent the recurrence of an error was unduly burdensome. The Department believes this requirement is necessary because the MRO is the only individual who reviews all of the information before making a final determination and reporting a test result to an agency. If a collector, laboratory, or IITF continues to make the same error even though the error may be insignificant, eliminating the error on future Federal CCFs is preferable than having it appear on every Federal CCF.

Section 15.4 describes the discrepancies that may require an MRO to cancel a test. Three commenters stated that this section contains correctable discrepancies that should be included in Section 15.2. The Department believes that the correctable discrepancies in this section cannot be included in Section 15.2 because they can only be identified as discrepancies by the MRO. The discrepancies in Section 15.2 are those that should be identified by the HHS-certified laboratory or HHS-certified IITF when the Federal CCFs and specimens are received for testing. Four commenters requested clarification in Section 15.4(c) and Section 15.4(d), respectively, on the consequences if the MRO does not obtain a statement from the certifying scientist that he or she inadvertently forgot to sign the Federal CCF and the HHS-certified laboratory or IITF did not retransmit a modified electronic report. The Department agrees and revised Sections 15.4(c) and (d) to require the MRO to cancel the test when the required corrective action was not taken.

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Subpart P--Laboratory or IITF Suspension/Revocation Procedures

The requirements in this entire subpart are the same as the requirements described in the Proposed Revisions to Mandatory Guidelines.

Executive Order 12866: Economic Impact

In accordance with Executive Order 12866, the Department submitted the Guidelines for review by the Office of Management and Budget (OMB). However, because the Guidelines will not have an annual impact of \$100 million or more, and will not have a material adverse effect on the

economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments, they are not subject to the detailed analysis requirements of Section 6(a)(3)(C) of Executive Order 12866.

The Department asked the Department of Transportation (DOT) for its estimate of the annual economic impact of the revised Guidelines on their regulated entities. Specifically, DOT requires that certain industries (e.g., Federal Motor Carrier Safety Administration) use the drug testing standards for HHS-certified laboratories and HHS-certified IITFs under these Guidelines. The Department notes that lowering testing cutoffs for existing drugs and establishing capability to test for new drugs, such as MDMA, will not impose additional costs or burdens on DOT-regulated entities, since most laboratories currently use similar testing standards on many non-regulated client specimens. It is estimated that there may be 10 percent more users of amphetamines and cocaine identified using the lowered cutoffs and testing for new drugs. The incidence and prevalence of amphetamines and cocaine use are very low (approximately 19,000 amphetamines positive and approximately 40,000 cocaine positive specimens in more than 6,500,000 tests conducted in 2007) in the DOT-regulated industries, and identification of 10 percent more positives should not impose a significant economic impact or burden for either the testing or the MRO review of the results.

Paperwork Reduction Act of 1995

These revised Guidelines contain information collections which are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA)(44 U.S.C. 3507(d)). The title, description and respondent description of the information collections are shown in the following sections 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: Mandatory Guidelines for Federal Workplace Drug Testing Programs.

Description: The Mandatory Guidelines establish the scientific and technical guidelines for Federal workplace drug testing programs and establish standards for certification of laboratories engaged in drug testing for Federal agencies under authority of section 503 of Public Law 100-71, 5 U.S.C. 7301 note, and Executive Order 12564. Federal agencies test applicants to sensitive positions, individuals involved in accidents, individuals for cause, and random testing of persons in sensitive positions. The program has depended on urine testing since 1988; the reporting, recordkeeping, and disclosure requirements associated with urine testing are approved under OMB control number 0930-0158.

In an effort to shorten the time for negative results to be reported to the Federal agency, the changes also establish criteria for an IITF that will only perform initial tests.

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

The burden estimates in the tables below are based on the following number of respondents: 38,000 Federal agency applicants who apply for employment in testing designated positions, 100 collectors, 50 urine testing laboratories, 25 IITFs, and 100 MROs.

Estimate of Annual Reporting Burden

Section	Purpose	Number of respondents	Responses/respondent	Hours/response	Total hours
9.2(a)(1)	Lab or IITF required to submit application for certification.	28	1	3	84
9.10(a)(3)	Materials to submit to become an HHS inspector.	25	1	2	50
11.4(c)	Lab submits qualifications of new RPs and alternate RPs to HHS.	75	1	2	150
11.22(a)	Specifications for lab semi-annual statistical report of test results to each Federal agency.	75	2	0.5	75
12.4(c)	IITF submits qualifications of new RTs and alternate RTs to HHS.	50	1	2	100
12.19(a)	Specifics contents of IITF semi-annual statistical report to Federal agencies served.	25	5	0.5	63
14.7	Specifics that MRO must report verified split specimen test results to Federal agency.	100	5	0.05 (3 min)	25
16.1(b); 16.5(a)	Specifies content of request for informal review of suspension/proposed revocation of certification.	1	1	3	3
16.4	Specifies information appellant provides in first written submission when lab or IITF 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 contents of appellant request for expedited review of suspension or proposed revocation.	1	1	3	3
16.9(c)	Specifics contents of review file and briefs.	1	1	50	50
Total		384			654

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The following reporting requirements are also in the Proposed Revisions to Mandatory Guidelines, but have not been addressed in the above reporting burden table: Collector must report any unusual donor behavior or unusual physical appearance of the urine specimen on the Federal CCF (Sections 8.4(3) and 8.6(d)(1)); collector annotates the Federal CCF when a specimen is a blind sample (Section 10.3(a)); and MRO notifies the Federal agency and HHS when an error occurs on a blind sample (Section 10.4(c)). SAMHSA has not calculated a separate reporting burden for these requirements because they are included in the burden hours estimated for collectors to complete Federal CCFs and for MROs to report results to Federal agencies.

Estimate of Annual Disclosure Burden

Section	Purpose	Number of respondents	Responses/respondent	Hours/response	Total hours
4.5(c)	Collector is given name and phone of Federal agency point of contact.	100	1	0.05 (3 min)	5
11.23(b)	Information on drug test that lab must provide to donor through MRO.	50	10	3	1500
12.20(b)	Drug test information that IITF must provide to donor through MRO.	25	10	2	500
13.7(b)	MRO must inform donor of right to request split specimen test when a positive, adulterated, or substituted result is reported.	100	5	3	1500
Total		275			3505

The following disclosure requirements are also included in the Proposed Revisions to Mandatory 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 (Sections 8.3(e) and (g)). SAMHSA

believes having the collector explain the collection procedure to the donor and to answer any questions is a standard business practice and not a disclosure burden.

Estimate of Annual Recordkeeping Burden

Section	Purpose	Number of respondents	Responses/respondent	Hours/response	Total hours
8.3, 8.4, 8.5, 8.6, and 8.7	Collector completes Federal CCF for specimen collected.	100	380	0.07 (4 min)	2660
11.8 and 11.19(a) and (o)	Lab completes Federal CCF upon receipt of specimen and before reporting result.	50	760	0.05 (3 min)	1900
12.8(a) and 12.15(f)	IITF completes Federal CCF upon receipt of specimen and before reporting result.	25	1520	0.05 (3 min)	1900
13.3(c)(4)	MRO completes the Federal CCF before reporting result.	100	380	0.05 (3 min)	1900
14.1(b)	MRO documents donor's request to have split specimen tested.	300	1	0.05 (3 min)	15
Total		575			8375

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The revised Mandatory Guidelines contain a number of recordkeeping requirements that SAMHSA considers not to be an additional recordkeeping burden. In subpart D, a trainer is required to document the training of an individual to be a collector (Section 4.3(a)(4)(ii)) 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 8.6(d)(1)) requires collectors to enter any information on the Federal CCF of any unusual findings during the urine specimen collection procedure. These recordkeeping requirements are an integral part of the collection procedure and are essential to documenting the chain of custody for the specimens collected. The burden for these entries is included in the recordkeeping burden estimated to complete the Federal CCF and is, therefore, not considered an additional recordkeeping burden. Subparts K and L describe a number of recordkeeping requirements for laboratories and IITFs associated with their testing procedures, maintaining chain of custody, and keeping records (i.e., Sections 11.1(a), 11.1(d), 11.2(b), 11.2(c), 11.2(d), 11.6(a), 11.7(c), 11.8(b), 11.8(c), 11.8(e), 11.11, 11.14, 11.17, 11.21, 12.1(a), 12.1(d), 12.2(b), 12.2(c), 12.2(d), 12.6(b), 12.7(c), 12.8(b), 12.10, 12.13, and 12.18). These recordkeeping requirements are necessary for any laboratory or IITF to conduct forensic drug testing and to ensure the scientific supportability of the test results. Therefore, they are considered to be standard business practice and are not considered a burden for this analysis. This same opinion applies to the recordkeeping requirements for MROs in Section 13.3(c)(5).

Thus the total annual response burden associated with the testing of urine specimens by the laboratories and IITFs is estimated to be 13,768 hours (that is, the sum of the total hours from the above tables). This is in addition to the 1,786,809 hours currently approved by OMB under control number 0930-0158 for urine testing under the current Mandatory Guidelines.

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

OMB is required to make a decision concerning the collection of information contained in these Guidelines between 30 and 60 days after publication of this document in the Federal Register. Therefore, a comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication.

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

Dated: July 23, 2008.
Terry L. Cline,
Administrator, SAMHSA.
Dated: July 29, 2008.
Michael O. Leavitt,
Secretary.

The Mandatory Guidelines as revised are hereby adopted in accordance with Section 503 of Public Law 100-71 and Executive Order 12564.

Mandatory Guidelines for Federal Workplace Drug Testing Programs

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Subpart A--Applicability

Section 1.1 To whom do these Guidelines apply?

- (a) These Guidelines apply to:
- (1) Executive Agencies as defined in 5 U.S.C. 105;
 - (2) The Uniformed Services, as defined in 5 U.S.C. 2101(3) (but excluding the Armed Forces as defined in 5 U.S.C. 2101(2));
 - (3) Any other employing unit or authority of the Federal Government except the United States Postal Service, the Postal Rate Commission, and employing units or authorities in the Judicial and Legislative Branches; and
 - (4) The Intelligence Community, as defined by Executive Order 12333, is subject to these Guidelines only to the extent agreed to by the head of the affected agency;
 - (5) Laboratories and instrumented initial test facilities (IITFs) that provide drug testing services to the Federal agencies;
 - (6) Collectors that provide specimen collection services to the Federal agencies; and
 - (7) Medical Review Officers (MROs) that provide drug testing review and interpretation of results services to the Federal agencies.
- (b) The Guidelines do not apply to drug testing under authority other than Executive Order 12564, including testing of persons in the criminal justice system, such as, arrestees, detainees, probationers, incarcerated persons, or parolees.¹

Section 1.2 Who is responsible for developing and implementing these Guidelines?

¹ Although HHS has no authority to regulate the transportation industry, the Department of Transportation (DOT) does have such authority. DOT is required by law to develop requirements for its regulated industry that "incorporate the Department of Health and Human Services scientific and technical guidelines dated April 11, 1988, and any amendments to those guidelines. * * * " See, e.g., 49 U.S.C. 20140(c)(2). In carrying out its mandate, DOT requires by regulation at 49 CFR Part 40 that its federally-regulated employers use only HHS-certified laboratories in the testing of employees, 49 CFR 40.81, and incorporates the scientific and technical aspects of the HHS Mandatory Guidelines.

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

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

Section 1.3 How does a Federal agency request a change from these Guidelines?

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

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

Section 1.4 How are these Guidelines revised?

(a) In order to ensure the full reliability and accuracy of drug and specimen validity tests, the accurate reporting of test results, and the integrity and efficacy of Federal drug testing programs, the Secretary may make changes to these Guidelines to reflect improvements in the available science and technology.

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

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

The following definitions are adopted:

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

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

Aliquot. A fractional part of a specimen used for testing, representing the whole specimen.

Alternate Responsible Person. The person who assumes professional, organizational, educational, and

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administrative responsibility for the day-to-day management of the HHS-certified laboratory when the responsible person is unable to fill these obligations.

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

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

Calibrator. A solution of known concentration in the appropriate matrix that is used to define expected outcomes of a measurement procedure or to compare the response obtained with the response of a test specimen aliquot/sample. The concentration of the analyte of interest in the calibrator is known within limits ascertained during its preparation. Calibrators may be used to establish a calibration curve over a concentration range.

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

Carryover. The effect that occurs when a sample's result (e.g., drug concentration) has been affected by a preceding sample during analysis.

Certifying Scientist (CS). The individual responsible for verifying the chain of custody and scientific reliability of any 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, negative/dilute, and rejected for testing results reported by a laboratory or IITF.

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

Chain of Custody Document. A form used to document the security of the specimen and all aliquots of a specimen. The document, which may account for an individual specimen, aliquot, or batch, must include the names and signatures of all individuals who handled the specimen or aliquots and the date and purpose of the access.

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

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

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

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

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

Cutoff. The decision point or value used to establish and report a specimen as negative, positive, adulterated, substituted, or invalid.

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

Donor. The individual from whom a specimen is collected.

Failed to Reconfirm. The result reported for a split specimen when the second laboratory is unable to corroborate the original result reported for the primary 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, custody, and transport of a specimen from the time the specimen is collected until it is received by the testing site (i.e., certified laboratory, instrumented initial test facility). The form may also be used to report the test result to the Medical Review Officer.

HHS. The Department of Health and Human Services.

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

Initial Specimen Validity Test. The first test used to determine if a specimen is adulterated, diluted, substituted, or invalid. **Instrumented Initial Test Facility (IITF).** A permanent location where 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 testing, reporting of results, and recordkeeping is performed under the supervision of a responsible person.

Limit of Detection. The lowest concentration at which a measurand can be identified, but (for quantitative assays) the concentration cannot be accurately calculated.

Limit of Quantitation. For quantitative assays, the lowest concentration at which the identity and concentration of the measurand can be accurately established.

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

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

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

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 laboratory or IITF that is used 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 cutoff concentration.

Quality Control (QC) Sample. A calibrator or control used to verify that an analytical test is providing accurate test results.

Reconfirmed. The result reported for a split specimen when the second laboratory is able to corroborate the original result reported for the primary specimen.

Rejected for Testing. The result reported by an HHS-certified laboratory or HHS-certified IITF when no tests are performed for a specimen because of a fatal flaw or an unrecovered correctable

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error (as described in 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 the HHS-certified laboratory.

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

Sample. A performance testing sample, quality control material used for testing, or a representative portion of a donor specimen.

Secretary. The Secretary of Health and Human Services or the Secretary's designee. The Secretary's designee may be a contractor or other recognized organization which acts on behalf of the Secretary in implementing these Guidelines.

Specimen. Fluid or material collected from a donor at the collection site for the purpose of a drug test. Urine is the only specimen allowed for Federal workplace drug testing programs.

Split Specimen Collection. A collection in which the urine collected is divided into two separate specimen bottles, the primary specimen (Bottle A) and the split specimen (Bottle B).

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

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

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

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

In addition, the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, 45 CFR Parts 160 and 164, Subparts A and E, is applicable to certain health care providers with whom a Federal agency may contract. If a health care provider is a HIPAA covered entity, the provider must protect the individually identifiable health information it maintains in accordance with the requirements of the Privacy 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 HIPAA Privacy Rule, please visit <http://frwebgate.access.gpo.gov/cgi-bin/leaving.cgi?from=leavingFR.html&log=linklog&to=http://www.hhs.gov/ocr/hipaa>.

Section 1.7 What is a refusal to take a federally regulated drug test, and what are the consequences?

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

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

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

(3) Fail to provide a urine specimen for any drug test required by these Guidelines or Federal agency regulations (with the exception of a donor who leaves the collection site before the collection process begins for a pre-employment test);

(4) In the case of a direct observed or monitored collection, fail to permit the observation or monitoring of your provision of a specimen when required as described in sections 8.8 and 8.10;

(5) Fail to provide a sufficient amount of urine when directed, and it has been determined, through a required medical evaluation, that there was no adequate medical explanation for the failure as determined by the process described in section 13.5;

(6) Fail or decline to take an additional drug test or collection as directed by the Federal agency or collector (i.e., as described in section 8.6);

(7) Fail to undergo a medical examination or evaluation, as directed by the MRO as part of the verification process (i.e., section 13.5) 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; or

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

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

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

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

(b) As a Federal agency applicant or employee, if the MRO reports that you have a verified adulterated or substituted test result, you have refused to take a drug test.

(c) As a Federal agency applicant or employee, refusal to submit to testing will result in initiation of disciplinary action, up to and including dismissal.

(d) As a collector or an MRO, when a donor refuses to participate in the part of the testing process in which you are involved, you must terminate the portion of the testing process in which you are involved, document the refusal on the Federal CCF, and immediately notify the Federal agency's designated representative by any means (e.g., telephone or secure fax machine) that ensures that the refusal notification is immediately received. As a referral physician (e.g., physician evaluating whether medical condition preventing the donor from providing a sufficient amount of urine for a drug test or evaluating a claim of a legitimate medical explanation in a specimen validity testing situation), you must notify the MRO, who in turn will notify the Federal agency.

(1) As the collector, you must note the refusal on the Federal CCF and sign and date the CCF in accordance with section 8.12.

(2) As the MRO, you must note the refusal and the reason on the MRO copy of the Federal CCF and sign and date the CCF.

Subpart B--Specimens

Section 2.1 What type of specimen may be collected?

Urine is the only specimen a Federal agency may collect under the

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Guidelines for its workplace drug testing program.

Section 2.2 Under what circumstances may specimens be collected?

A Federal agency may collect a 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 specimen collected?

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

Section 2.4 What volume of urine is collected?

A donor is expected to provide at least 45 mL of urine for a specimen to be tested at an HHS-certified laboratory or IITF.

Section 2.5 How does the collector split the urine collected?

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

Subpart C--Urine Drug and Specimen Validity Tests

Section 3.1 Which drug and specimen validity tests are conducted on a urine specimen?

A Federal agency:

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

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

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

(1) Determine the creatinine concentration on every specimen;

(2) Determine the specific gravity on every specimen for which the creatinine concentration is less than 20 mg/dL;

(3) Determine the pH on every specimen; and

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

(d) If a specimen exhibits abnormal physical 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 standards, unusual response), or contains an unidentified substance that interferes with the confirmatory analysis, then additional testing may be performed.

Section 3.2 May a specimen be tested for additional drugs?

(a) A specimen may be tested for additional drugs, on a case-by-case basis, when a Federal agency is conducting a specimen collection for reasonable suspicion, post accident, or unsafe practice testing. A specimen collected from a Federal agency employee may be tested by the Federal agency for any drugs listed in Schedule I or II of the Controlled Substances Act (other than the drugs listed in Section 3.1, or when used pursuant to a valid prescription or when used as otherwise authorized by law). The Federal agency must request the HHS-certified laboratory to test for the additional drug, include a justification to test a specific specimen for the drug, and ensure that the HHS-certified laboratory has the capability to test for the drug and has established properly validated initial and confirmatory analytical methods. If an initial test procedure is not available upon request for a suspected Schedule I or Schedule II drug, the Federal agency can request an HHS-certified laboratory to test for the drug by directing two separate aliquots of the specimen for the confirmatory analytical method. Additionally, the split (Bottle B) specimen will be available for testing if the donor requests a retest at another HHS-certified laboratory.

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

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

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

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

Section 3.4 What are the cutoff concentrations for drug tests?

Initial test analyte	Initial test cutoff concentration	Confirmatory test analyte	Confirmatory test cutoff concentration
Marijuana metabolites	50 ng/mL	THCA	15 ng/mL
Cocaine metabolites	150 ng/mL	Benzoylcegonine	100 ng/mL
Opiate metabolites Codeine/Morphine ²	2000 ng/mL	Codeine Morphine	2000 ng/mL 2000 ng/mL
6-Acetylmorphine	10 ng/mL	6-Acetylmorphine	10 ng/mL
Phencyclidine	25 ng/mL	Phencyclidine	25 ng/mL
Amphetamines ³ AMP/MAMP ⁴	500 ng/mL	Amphetamine Methamphetamine ⁵	250 ng/mL 250 ng/mL
MDMA ⁶	500 ng/mL	MDMA MDA ⁷ MDEA ⁸	250 ng/mL 250 ng/mL 250 ng/mL

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Section 3.5 What criteria are used to report a specimen as adulterated?

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

(a) The pH is less than 3 or equal to or greater than 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;

(b) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;

(c) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the limit of quantitation (LOQ) of the confirmatory test on the second aliquot;

(d) The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration equal to or greater

² Morphine is the target analyte for codeine/morphine testing.

³ Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.

⁴ Methamphetamine is the target analyte for amphetamine/methamphetamine testing.

⁵ To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.

⁶ Methylenedioxyamphetamine (MDMA).

⁷ Methylenedioxyamphetamine (MDA).

⁸ Methylenedioxyethylamphetamine (MDEA).

than the LOQ) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(e) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory test (e.g., GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

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

(g) The presence of a surfactant is verified by using a surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry) with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

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

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

An HHS-certified laboratory reports a primary (Bottle A) specimen as substituted when the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests on two separate aliquots (i.e., the same colorimetric test may be used to test both aliquots) and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200 on both the initial and confirmatory specific gravity tests on two separate aliquots (i.e., a refractometer is used to test both aliquots).

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

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

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

(b) In addition, an HHS-certified laboratory reports a primary (Bottle A) specimen as dilute when the creatinine concentration is equal to or greater than 2 mg/dL but less than or equal to 5 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030.

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

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

(a) Inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(b) The pH is equal to or greater than 3 and less than 4.5 or equal to or greater than 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(c) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial (first) test and the second test or using either initial test and the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (e.g.,

multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(d) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial (first) test and the second test on two separate aliquots;

(e) The possible presence of a halogen (e.g., bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOQ for both the initial (first) test and the second test on

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two separate aliquots or relying on the odor of the specimen as the initial test;

(f) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial (first) test and the second test on two separate aliquots;

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

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

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

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

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

or

(l) The specimen has been tested and the physical appearances of Bottles A and B (e.g., color) are clearly different.

Subpart D--Collectors

Section 4.1 Who may collect a specimen?

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

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

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

Section 4.2 Who may not collect a specimen?

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

(b) A Federal agency applicant or employee must not collect his or her own urine.

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

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

Section 4.3 What are the requirements to be a collector?

(a) An individual may serve as a collector when the individual:

- (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 or additional information provided by the Secretary relating to these Guidelines;
- (3) Has received training from a qualified trainer for collectors on the following subjects:
 - (i) All steps necessary to complete a collection correctly and the proper completion and transmission of the Federal CCF;
 - (ii) Problem collections;
 - (iii) Fatal flaws, correctable flaws, and how to correct problems in collections; and
 - (iv) The collector's responsibility for maintaining the integrity of the collection process, ensuring the privacy of individuals being tested, 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 quantity of urine scenario, one temperature out of range scenario, and one scenario in which the donor refuses to sign the Federal CCF and initial the specimen bottle tamper-evident seal.
 - (ii) A qualified trainer for collectors must monitor and evaluate the individual being trained, in person or by a means that provides real-time observation and interaction between the trainer and the individual being trained, and attest in writing that the mock collections are "error-free".
 - (b) A trained collector must complete refresher training on the requirements in paragraph a of this section no less frequently than every five years from the date on which he or she was first trained.
 - (c) The collector must maintain the documentation of his or her training and provide it to a Federal agency when requested.
 - (d) An individual may not collect specimens for a Federal agency until his or her training as a collector has been properly documented.

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

- (a) An individual may serve as an observer for a direct observed collection when the individual has satisfied the requirements:
 - (1) Is knowledgeable about the direct observed collection procedure described in Section 8.9 of these Guidelines;
 - (2) Is knowledgeable about any guidance provided by the Federal agency's Drug-Free Workplace Program or additional information provided by the Secretary relating to the direct observed collection procedure described in these Guidelines;
 - (3) Has received training on the following subjects:
 - (i) All steps necessary to perform a direct observed collection correctly; and
 - (ii) The observer's responsibility for maintaining the integrity of the collection process, ensuring the privacy of individuals being tested, ensuring that the observation is done in a professional manner that minimizes the discomfort to the employee so observed, ensuring the security of the specimen by maintaining visual contact with the collection container until it is delivered to the collector, and avoiding conduct or statements that could be viewed as offensive or inappropriate.
 - (b) The observer must be the same gender as the donor.
 - (c) The observer is not required to be a trained collector.

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

- (a) An individual is considered to be a qualified trainer for collectors and may train others to collect specimens when the individual has:
 - (1) Qualified as a trained collector and regularly conducted drug test collections for a period of at least one year; or

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- (2) Successfully 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 in accordance with the collector requirements in Section 4.3(a) no less frequently than every five years from the date on which he or she was first trained.

(c) A qualified trainer for collectors must maintain the documentation of his or her training and provide it to a Federal agency when requested.

Section 4.6 What must a Federal agency do before an individual is permitted to collect a specimen?

A Federal agency must:

(a) Ensure that the individual that serves as a collector has satisfied the requirements described in Section 4.3;

(b) Ensure that 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 record(s) that document the individual's training as a collector; and

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

Subpart E--Collection Sites

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

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

(b) In the event that an agency-designated collection site is not accessible and there is an immediate requirement to collect a specimen (e.g., an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.11.

Section 5.2 What are the requirements for a collection site?

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

(a) Provisions to ensure donor privacy during the specimen collection procedure in accordance with Section 8.1;

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

(c) A secure temporary storage capability to maintain a specimen until it is transferred to an HHS-certified laboratory or IITF;

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

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

(f) The ability to store records securely; and

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

Section 5.3 How long must collection site records be stored?

Collection site records (e.g., collector copies of the OMB-approved Federal CCF) must be stored for a minimum of 2 years by the collector or the collector's employer.

Section 5.4 How does the collector ensure the security 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 site during the collection procedure;

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

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

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

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

(6) Ensure that the Federal CCF is enclosed with the specimens and sealed for shipment to an HHS-certified laboratory or IITF; and

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

Subpart F--Federal Drug Testing Custody and Control Form

Section 6.1 What form is used for collecting a specimen?

An OMB-approved Federal CCF must be used to document the collection of each urine specimen at the collection site.

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

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

(b) If the collector realizes that an incorrect form was used before the specimen bottles are packaged for transit to the laboratory or IITF, the collector must show on the form that it is a Federal agency specimen collection and give the reason why an incorrect form was used. Based on the information provided by the collector, the laboratory or IITF must handle and test the specimen as a Federal agency specimen.

(c) If the laboratory, IITF, or MRO discovers that an incorrect form was used by the collector, the laboratory, IITF, or MRO must obtain a memorandum for the record from the collector stating the reason why the correct Federal CCF was not used to collect the Federal agency specimen. If after 5 business days a memorandum for the record cannot be obtained, the laboratory or IITF reports a rejected for testing result and the MRO cancels the test.

Subpart G--Specimen Collection Containers

Section 7.1 What is used to collect a urine specimen?

(a) A single-use collection container/cup that is capable of holding at least 55 mL; and

(b) Two specimen bottles which can be sealed for transport; one of which can hold at least 35 mL and the other at least 20 mL.

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Section 7.2 Are there any restrictions on the containers and bottles used to collect urine specimens?

Collection containers/cups and specimen bottles must not substantially affect the specimen collected.

Subpart H--Specimen Collection Procedure

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

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

(a) Only authorized personnel and the donor may be present at the collection site while the collector is collecting a specimen.

(b) The collector does not need to be the same gender as the donor. The observer for a direct observed collection (i.e., as described in Section 8.9) must be the same gender as the donor. The monitor for a monitored collection (i.e., as described in Section 8.11) must be the same gender as the donor, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place).

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

Section 8.2 What must the collector do at the collection site before starting a specimen collection procedure?

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

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

(b) Securing any other source of water (e.g., no shower or sink) in the enclosure where urination occurs that is not secured during the collection. If the enclosure used by the donor to provide a specimen has a source of water that cannot be disabled or secured, a monitored collection must be conducted in accordance with Section 8.10.

Section 8.3 What are the preliminary steps in the collection process?

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

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

(b) When the donor arrives at the collection site, the collector begins the testing process without undue delay. For example, the collection is not delayed because the donor says he or she is not ready or is unable to urinate or 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, any other picture 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 shall not proceed with the collection.

(d) The collector must provide identification (e.g., employee badge, employee list) to the donor if the donor asks.

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

(f) The collector informs the donor that he or she may read the instructions for completing the custody and control form which are located on the back of the Federal CCF.

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

(h) The collector asks the donor to remove any unnecessary outer garments such as a coat or jacket that might conceal items or substances that could be used to adulterate or substitute the urine specimen:

(1) The collector must ensure that all personal belongings such as a purse or briefcase remain with the outer garments; the donor may retain his or her wallet.

(2) The collector asks the donor to empty his or her pockets and display the items to ensure that no items are present that could be used to adulterate or substitute the specimen;

(3) If nothing is present that can be used to adulterate or substitute a specimen, the donor places the items back into the pockets and the collection procedure continues;

(4) If an item is found that appears to have been brought to the collection site with the intent to adulterate or substitute the specimen, a direct observed collection procedure is used in accordance with Section 8.9. If the item appears to be inadvertently brought to the collection site, the collector must secure the item and continue with the normal collection procedure.

(5) If the donor refuses to show the collector the items in his or her pockets, this is considered a "refusal to test." The collector must stop the collection and report the refusal to test as described in Section 8.12.

(i) The collector shall instruct the donor to wash and dry his or her hands prior to urination. After washing hands, the donor must remain in the presence of the collector and must not have access to any water fountain, faucet, soap dispenser, cleaning agent, or any other materials which could be used to adulterate or substitute the specimen.

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

(a) The collector gives the donor or allows the donor to select a specimen collection container. The collector instructs the donor to provide his or her specimen in the privacy of a stall or otherwise partitioned area that allows for individual privacy. The collector directs the donor to provide a specimen of at least 45 mL, to not flush the toilet, and to return with the specimen as soon as the donor has completed the void.

(1) Except in the case of a direct observed collection (i.e., as described in Section 8.9) or a monitored collection (i.e., as described in Section 8.11), neither the collector nor anyone else may go into the room with the donor.

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

(b) The collector notes any unusual behavior or appearance of the donor on the Federal CCF. If the collector detects any conduct that clearly indicates an attempt to tamper with a specimen (e.g., substitute urine in plain view or an attempt to bring into the collection site an adulterant or urine substitute), the collector must conduct an immediate collection under direct observation in accordance with Section 8.8. The collector must note the conduct and the fact that the collection was observed on the CCF.

Section 8.5 What procedure is used when the donor states that he or she is unable to provide a specimen?

(a) If the donor states that he or she is unable to provide a specimen during the collection process, the collector requests that the donor enter the restroom (stall) and attempt to provide a specimen.

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(b) The donor demonstrates his or her inability to provide a specimen when he or she comes out of the stall with an empty collection container.

(1) If the donor states that he or she could provide a specimen after drinking some fluids, the collector gives the donor a reasonable amount of liquid to drink for this purpose (e.g., an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). If the donor simply needs more time before attempting to provide a urine specimen, the donor is not required to drink any fluids during this waiting time.

(2) If the donor states that he or she is unable to provide a urine specimen, the collector records the reason for not collecting a urine specimen on the Federal CCF, notifies the Federal agency's designated representative, and sends the appropriate copies of the Federal CCF to the MRO and to the Federal agency's designated representative. The collector stops the collection procedure and requests that the donor leave the collection site.

Section 8.6 What steps does the collector take in the collection process after the donor provides a urine specimen?

The collector must take the following steps after the donor provides the urine specimen:

(a) After providing the specimen, the donor gives the specimen collection container to the collector. Both the donor and the collector must keep the specimen container in view at all times until the collector seals the specimen bottles as described in Section 8.7.

(b) After the donor has given the specimen to the collector, whenever practical, the donor shall be allowed to wash his or her hands and the donor may flush the toilet.

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

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

(2) If the temperature of the specimen is outside the range of 32[deg]-38[deg] C/90[deg]-100[deg] F, that is a reason to believe that the donor may have adulterated or substituted the specimen. Another specimen must be collected under direct observation in accordance with Section 8.8. The collector will forward both specimens (i.e., from the first and second collections) to an HHS-certified laboratory for testing and records a comment on the Federal CCF.

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

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

(2) When there is any reason to believe that a donor may have adulterated or substituted the specimen, another specimen must be obtained as soon as possible under direct observation in accordance with Section 8.8. The collector will forward both specimens (i.e., from the first and second collections) to an HHS-certified laboratory for testing and records a comment on the Federal CCF.

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

(1) If the volume is at least 45 mL, the collector will proceed with steps described in Section 8.7.

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

(i) The collector may give the donor a reasonable amount of liquid to drink for this purpose (e.g., an 8 ounce glass of water every 30 minutes, but not to exceed a maximum of 40 ounces over a period of 3 hours or until the donor has provided a sufficient urine specimen). However, the donor is not required to drink any fluids during this waiting time.

(ii) If the donor provides a sufficient urine specimen (i.e., at least 45 mL), the collector proceeds with steps described in Section 8.7.

(iii) If the employee has not provided a sufficient specimen (i.e., at least 45 mL) within three hours of the first unsuccessful attempt to provide the specimen, the collector stops the collection procedure and:

(A) Notes on the Federal CCF that the donor has not provided a sufficient volume of urine for the drug test;

(B) Notifies the Federal agency's designated representative;

(C) Discards the insufficient specimen;

(D) Requests that the donor leave the collection site;

(E) Sends the appropriate copies of the Federal CCF to the MRO and to the Federal agency.

(f) If the donor fails to remain present through the completion of the collection, declines to have a direct observed collection as required in steps (c)(2) or (d)(2) above, or refuses to provide a second specimen as required in step (e)(2) above, the collector stops the collection and reports the refusal to test in accordance with Section 8.12.

Section 8.7 How does the collector prepare the specimens?

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

(b) The collector, in the presence of the donor, pours the urine from the collection container into two specimen bottles to be labeled Bottle A and Bottle B. The collector pours at least 30 mL of urine into Bottle A and at least 15 mL into Bottle B, and caps each bottle.

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

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

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

(f) The collector signs and prints his or her name on the Federal CCF, completes the Federal CCF, and distributes the copies of the CCF as required.

(g) The collector seals the specimens (Bottle A and Bottle B) and Federal CCF in a package in accordance with instructions on the back of the Federal CCF for transfer to an HHS-certified laboratory or IITF.

(h) If the specimen bottles and Federal CCF are not immediately prepared for transfer to an HHS-certified laboratory or IITF, they must be appropriately safeguarded until the transfer occurs.

(i) The collector must discard any urine left over in the collection container after both specimen bottles have been appropriately filled and sealed. There is one exception to this requirement: The collector may use excess urine to conduct clinical tests (e.g., protein, glucose) if the collection was conducted in conjunction with a

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physical examination required by a Federal agency regulation. Neither the collector nor anyone else may conduct further testing (such as specimen validity testing) on the excess urine.

Section 8.8 When is a direct observed collection conducted?

A direct observed collection procedure must be conducted when:

(a) The agency has authorized a direct observed collection because:

(1) The donor's previous drug test result was reported by an MRO as positive, adulterated, or substituted; or

(2) The certified laboratory reports to the MRO that a specimen is invalid, and the MRO reported to the agency that there was not an adequate medical explanation for the result; or

(3) The MRO reported to the agency that the primary bottle (A) specimen was positive, adulterated, or substituted result had to be cancelled because the test of the split specimen could not be tested and/or the split specimen bottle (B) failed to reconfirm; or

(b) At the collection site, an immediate collection of a second urine specimen is required because:

(1) The temperature of the specimen collected during a routine collection is outside the acceptable temperature range;

(2) The collector suspects that the donor has tampered with the specimen during a routine collection (e.g., abnormal physical characteristic such as unusual color and/or odor, and/or excessive foaming when shaken);

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

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

(c) The collector must contact a collection site supervisor to review and concur in advance with any decision by the collector to obtain a specimen under direct observation.

(d) If the donor declines to have a direct observed collection, the collector reports a refusal to test (i.e., as described in Section 8.12).

Section 8.9 How is a direct observed collection conducted?

A direct observed collection procedure is the same as that for a routine collection, except an observer watches the donor urinate into the collection container. The observer must be the same gender as the donor with no exception to this requirement. If there is no collector available of the same gender as the donor, the collector or collection site supervisor shall select an observer trained in direct observed specimen collection as described in Section 4.4. The observer may be an individual that is not a trained collector.

At the point in a routine collection where the donor enters the restroom with the collection container, a direct observed collection includes the following additional steps:

- (a) The observer enters the restroom with the donor;
- (b) The observer must directly watch the urine go from the donor's body into the collection container (the use of mirrors or video cameras is not permitted);
- (c) The observer must not touch or handle the collection container unless the observer is also serving as the collector;
- (d) After the donor has completed urinating into the collection container:
 - (1) If the same person serves as the observer and collector, he or she may receive the collection container from the donor while they are both in the restroom;
 - (2) If the observer is not serving as the collector, the donor and observer leave the restroom and the donor hands the collection container directly to the collector. The observer must maintain visual contact of the collection container until the donor hands the container to the collector.
- (e) The collector checks the box for an observed collection on the Federal CCF and writes the name of the observer and the reason for an observed collection on the Federal CCF; and
- (f) The collector then continues with the routine collection procedure in Section 8.7.

Section 8.10 When is a monitored collection conducted?

- (a) In the event that an agency-designated collection site is not available and there is an immediate requirement to collect a specimen (e.g., an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.11.
- (b) If the enclosure used by the donor to provide a specimen has a source of water that cannot be disabled or secured, a monitored collection must be conducted.
- (c) If the donor declines to permit a collection to be monitored when required, the collector reports a refusal to test (i.e., as described in Section 8.12).

Section 8.11 How is a monitored collection conducted?

A monitored collection is the same as that for a routine collection, except that a monitor accompanies the donor into the restroom to check for signs that the donor may be tampering with the specimen. The monitor remains in the restroom, but outside the stall, while the donor is providing the specimen. A person of the same gender as the donor shall serve as the monitor, unless the monitor is a medical professional (e.g., nurse, doctor, physician's assistant, technologist, or technician licensed or certified to practice in the jurisdiction in which the collection takes place). The monitor may be an individual other than the collector and need not be a qualified collector.

- (a) The collector secures the restroom being used for the monitored collection so that no one except the employee and the monitor can enter the restroom until after the collection has been completed.
- (b) The monitor enters the restroom with the donor.
- (c) The monitor must not watch the employee urinate into the collection container. If the monitor hears sounds or makes other observations indicating an attempt by the donor to tamper with a specimen, there must be an additional collection under direct observation in accordance with Section 8.8.
- (d) The monitor must not touch or handle the collection container unless the monitor is also the collector.
- (e) After the donor has completed urinating into the collection container:
 - (1) If the same person serves as the monitor and collector, he or she may receive the collection container from the donor while they are both in the restroom;
 - (2) If the monitor is not serving as the collector, the donor and monitor leave the restroom and the donor hands the collection container directly to the collector. The monitor must ensure that the employee takes the collection container directly to the collector as soon as the employee has exited the enclosure.
- (f) If the monitor is not serving as the collector, the collector writes the name of the monitor on the Federal CCF.
- (g) The collector then continues with the routine collection procedure in Section 8.7.

Section 8.12 How does the collector report a donor's refusal to test?

The collector stops the collection, discards any urine collected, and reports the refusal to test by:

- (a) Notifying the Federal agency by means (e.g., telephone, e-mail, or secure fax) that ensures that the notification is immediately received,
- (b) Documenting the refusal to test on the Federal CCF, and

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

Section 8.13 What are a Federal agency's responsibilities for a collection site?

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

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

(c) A Federal agency must investigate reported collection site deficiencies (e.g., specimens reported "rejected for testing" by an HHS-certified IITF or HHS-certified laboratory) and take appropriate action which may include inspecting the collection site. The inspections of these additional collection sites may not be included in the 5 percent or maximum of 50 collection sites inspected annually.

Subpart I--HHS Certification of Laboratories and IITFs

Section 9.1 Who has the authority to certify laboratories and IITFs to test specimens for Federal agencies?

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

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

Section 9.2 What is the process for a laboratory or IITF to become certified and maintain HHS certification and the process when certification is not maintained?

(a) A laboratory or IITF seeking HHS certification must:

- (1) Submit a completed OMB-approved application form (i.e., the applicant laboratory or IITF provides detailed information on both the administrative and analytical procedures to be used for Federal agency specimens after it is certified);
- (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 a letter of certification from the Secretary before being able to test specimens for Federal agencies.

(b) To maintain HHS certification, a laboratory or IITF must:

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

(2) Respond in an appropriate, timely, and complete manner to required corrective action in the event of problems identified in either the maintenance PT or inspection program or in operations and reporting; and

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

(c) A laboratory or IITF that does not maintain its HHS certification must:

(1) Stop testing Federal agency specimens;

(2) Ensure the security of Federal agency specimens and records throughout the required storage period described in Sections 11.20, 11.21, 12.18, and 14.8;

(3) Ensure access to Federal agency specimens and records in accordance with Sections 11.23, 12.20, and subpart N; and

(3) When suspension and revocation procedures are imposed by the Secretary, follow the HHS procedures in subpart P that will be used for all actions associated with the suspension and/or revocation of HHS-certification.

Section 9.3 What are the qualitative and quantitative specifications of a performance test (PT) sample?

(a) PT samples used to evaluate drug tests will be formulated as follows:

(1) A PT sample may contain one or more of the drugs and metabolites in the drug classes listed in Section 3.4 and satisfy one of the following parameters:

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

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

(iii) The concentration of drug or metabolite may be at another concentration for a special purpose.

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

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

(b) PT samples used to evaluate specimen validity tests shall satisfy, but are not limited to, one of the following criteria:

(1) The nitrite concentration will be at least 20 percent above the cutoff;

(2) The pH will be between 1.5 and 5.0 or between 8.5 and 12.5;

(3) The concentration of an oxidant will be at a level sufficient to challenge a laboratory's ability to identify and confirm the oxidant;

(4) The creatinine concentration will be between 0 and 20 mg/dL; or

(5) The specific gravity will be less than or equal to 1.0050 or between 1.0170 and 1.0230.

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

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

Section 9.4 What are the PT requirements for an applicant laboratory?

(a) An applicant laboratory that seeks certification under these Guidelines must satisfy the following criteria on 3 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 3 sets of PT samples;

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(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over the 3 sets of PT samples;

(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 the 3 sets of PT samples;

(5) For the confirmatory drug tests, must not obtain any drug concentration on a PT sample 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 that the concentrations for at least 50 percent of the drug challenges are no more than 20 percent or 2 standard deviations (whichever is larger) from the appropriate reference or peer group means over the 3 sets of PT samples;

(7) Correctly identify at least 80 percent of the total specimen validity testing challenges over the 3 sets of PT samples;

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the 3 sets of PT samples;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over the 3 sets of PT samples that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than 20 percent or 2 standard deviations from the appropriate reference or peer group mean; and

(ii) pH values are no more than 0.3 pH units from the appropriate reference or peer group mean using a pH meter; and

(iii) Specific gravity values are no more than 0.0003 specific gravity units from the appropriate reference or peer group mean when the mean is less than 1.0100 and specific gravity values are no more than 0.0004 specific gravity units from the appropriate reference or peer group mean when the mean is equal to or greater than 1.0100;

(10) Must not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than 50 percent for nitrite and creatinine concentrations, 0.8 pH units using a pH meter, 0.0006 specific gravity units when the mean is less than 1.0100, or 0.0007 specific gravity units when the mean is equal to or greater than 1.0100; and

(11) Must not report any sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the appropriate reference or peer group mean is within the acceptable pH range, or substituted when the appropriate reference or peer group means for both creatinine and specific gravity are within the acceptable range.

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.5 What are the PT requirements for an HHS-certified laboratory?

(a) A laboratory certified under these Guidelines must satisfy the following criteria on the maintenance PT samples to maintain its certification:

(1) Have no false positive results;

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

(3) Correctly identify at least 80 percent of the drug challenges for each initial drug test over 2 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 2 consecutive PT cycles;

(5) For the confirmatory drug tests, obtain no more than one drug concentration on a PT sample that differs by more than 50 percent from the appropriate reference or peer group mean over 2 consecutive PT cycles;

(6) For each confirmatory drug test, correctly identify and determine that the concentrations for at least 50 percent of the drug challenges for an individual drug are no more than 20 percent or 2 standard deviations (whichever is larger) from the appropriate reference or peer group means over 2 consecutive PT cycles;

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

(8) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over 2 consecutive PT cycles;

(9) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total challenges over 2 consecutive PT cycles that satisfy the following criteria:

(i) Nitrite and creatinine concentrations are no more than 20 percent or 2 standard deviations from the appropriate reference or peer group mean;

(ii) pH values are no more than 0.3 pH units from the appropriate reference or peer group mean using a pH meter; and

(iii) Specific gravity values are no more than 0.0003 specific gravity units from the appropriate reference or peer group mean when the mean is less than 1.0100 and specific gravity values are no more than 0.0004 specific gravity units from the appropriate reference or peer group mean when the mean is equal to or greater than 1.0100;

(10) Obtain no more than one quantitative value over 2 consecutive PT cycles on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than 50 percent for nitrite and creatinine concentrations, 0.8 pH units using a pH meter, 0.0006 specific gravity units when the mean is less than 1.0100, or 0.0007 specific gravity units when the mean is equal to or greater than 1.0100; and

(11) Do not report any PT sample as adulterated with a compound that is not present in the sample, adulterated based on pH when the appropriate reference or peer group mean is within the acceptable pH range, or substituted when the appropriate reference or peer group means for both creatinine and specific gravity are within the acceptable range.

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

Section 9.6 What are the PT requirements for an applicant IITF?

(a) An applicant IITF that seeks certification under these Guidelines must satisfy the following criteria on 3 consecutive sets of PT samples:

(1) Correctly identify at least 90 percent of the total drug challenges over the 3 sets of PT samples;

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over the 3 sets of PT samples;

(3) Correctly identify at least 80 percent of the total specimen validity test challenges over the 3 sets of PT samples;

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over the 3 sets of PT samples;

(5) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total specimen validity test challenges over the 3 sets of PT samples that satisfy the following criteria:

(i) Creatinine concentrations are no more than 20 percent or 2 standard

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deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than 0.001 specific gravity units from the appropriate reference or peer group mean; and

(6) Must not obtain any quantitative value on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than 50 percent for creatinine concentration, or 0.002 specific gravity units for specific gravity.

(b) Failure to satisfy these requirements will result in disqualification.

Section 9.7 What are the PT requirements for an HHS-certified IITF?

(a) An IITF certified under these Guidelines must satisfy the following criteria on the maintenance PT samples to maintain its certification:

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

(2) Correctly identify at least 80 percent of the drug challenges for each individual drug test over 2 consecutive PT cycles;

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

(4) Correctly identify at least 80 percent of the challenges for each individual specimen validity test over 2 consecutive PT cycles;

(5) For quantitative specimen validity tests, obtain quantitative values for at least 80 percent of the total specimen validity test challenges over 2 consecutive PT cycles that satisfy the following criteria:

(i) Creatinine concentrations are no more than 20 percent or 2 standard deviations (whichever is larger) from the appropriate reference or peer group mean; and

(ii) Specific gravity values are no more than 0.001 specific gravity units from the appropriate reference or peer group mean; and

(6) Obtain no more than one quantitative value over 2 consecutive PT cycles on a specimen validity test PT sample that differs from the appropriate reference or peer group mean by more than 50 percent for creatinine concentration, or 0.002 specific gravity units for specific gravity.

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

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

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

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

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

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

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

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

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

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

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

(a) An individual may be selected as an inspector for the Secretary if he or she satisfies the following criteria:

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

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

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

(4) Attends approved training; and

(5) Performs acceptably as an inspector on an inspection of an HHS-certified laboratory or IITF under these Guidelines.

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

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

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

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

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

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

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

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

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

(a) The Secretary shall revoke certification of any laboratory or IITF certified in accordance with these Guidelines if the Secretary determines that revocation is necessary to ensure the full reliability and accuracy of drug and specimen validity tests and the accurate reporting of test results.

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

(1) Unsatisfactory performance in analyzing and reporting the results of

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drug and specimen validity tests; for example, a laboratory reporting a false positive result for an employee's drug test;

(2) Unsatisfactory participation in performance testing evaluations or inspections;

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

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

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

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

Section 9.14 What factors are considered in determining whether to suspend a laboratory or IITF?

(a) Whenever the Secretary has reason to believe that revocation may be required and that immediate action is necessary in order to protect the interests of the United States and its employees, the Secretary may immediately suspend (either partially or fully) a laboratory's or IITF's certification to conduct drug and specimen validity testing for Federal agencies.

(b) The period and terms of suspension shall be determined by the Secretary and shall depend upon the facts and circumstances of the suspension and the need to ensure accurate and reliable drug and specimen validity testing of Federal employee specimens.

Section 9.15 How does the Secretary notify a laboratory or IITF that action is being taken against the laboratory or IITF?

(a) When a laboratory or IITF is suspended or the Secretary seeks to revoke certification, the Secretary shall immediately serve the laboratory or IITF with written notice of the suspension or proposed revocation by facsimile, mail, personal service, or registered or certified mail, return receipt requested.

This notice shall state the following:

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

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

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

(d) The Secretary will publish in the Federal Register the name, address, and telephone number of any laboratory or IITF that has its certification revoked or suspended under Section 9.13 or Section 9.14, respectively, and the name of any laboratory or IITF that has its suspension lifted. The Secretary shall provide to any member of the public upon request the written notice provided to a laboratory or IITF that has its certification suspended or revoked, as well as the reviewing official's written decision which upholds or denies the suspension or proposed revocation under the procedures of subpart P.

Section 9.16 May a laboratory or IITF that had its certification revoked be recertified to test Federal agency specimens?

Following revocation, a laboratory or IITF may apply for recertification. Unless otherwise provided by the Secretary in the notice of revocation under Section 9.13(a) or the reviewing official's decision under Section 16.9(e) or 16.14(a), a laboratory or IITF which has had its certification revoked may reapply for certification as an applicant laboratory or IITF.

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

- (a) The list of HHS-certified laboratories and IITFs is published monthly in the Federal Register.
- (b) An applicant laboratory or IITF is not included on the list.

Subpart J--Blind Samples Submitted by an Agency

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

(a) Each Federal agency is required to submit blind samples for its workplace drug testing program. The blind samples are to be sent to the HHS-certified laboratory or HHS-certified IITF to which the collector sends employee specimens for the Federal agency.

(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. Every effort should be made to ensure that some of the blind samples are submitted quarterly.

(c) Of the blind samples submitted each year by an agency, approximately 75 percent of the blind samples must be negative, 15 percent must be positive for one or more drugs, and 10 percent must either be adulterated or substituted.

Section 10.2 What are the requirements for a blind sample?

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

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

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

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

(e) A blind sample that is adulterated must have the characteristics to clearly show that it is an adulterated sample at the time it is validated by the supplier.

(f) A blind sample that is substituted must have the characteristics to clearly show that it is a substituted sample at the time it is validated by the supplier.

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

(a) A blind sample is submitted using the same Federal CCF as used for a donor specimen. The collector provides the required information to ensure that the Federal CCF has been properly completed as well as providing

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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 throughout the total number of donor specimens rather than submitting all of the blind samples as a single group.

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

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

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

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

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

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

Subpart K--Laboratory

Section 11.1 What 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 laboratory operations. When followed, it ensures that all specimens are tested using the same procedures and in a consistent manner.

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

(1) Chain of custody procedures;

(2) Accessioning;

- (3) Security;
- (4) Quality control/quality assurance programs;
- (5) Analytical methods and procedures;
- (6) Equipment and maintenance programs;
- (7) Personnel training;
- (8) Reporting procedures; and
- (9) Computers, software, laboratory information management systems.

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

(d) A copy of all procedures that have been replaced or revised and the dates on which they were in effect must be maintained for 2 years to allow the laboratory to retrieve the procedures that were used to test a specimen.

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

(a) Manage the day-to-day operations of the drug testing laboratory even where another individual has overall responsibility for an entire multi-specialty laboratory.

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

(c) Maintain a complete, current SOP manual that is available for personnel in the drug testing laboratory, and followed by those personnel. The SOP manual must be reviewed, signed, and dated by the RP(s) whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the drug testing laboratory.

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

(e) Implement all remedial actions necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing samples, and deficiencies identified during inspections. This individual must ensure that specimen results are not reported until all corrective actions have been taken and he or she can assure that the results provided are accurate and reliable.

Section 11.3 What scientific qualifications in analytical toxicology must the RP have?

The RP must have documented scientific qualifications in analytical toxicology. Minimum qualifications are:

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

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

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

(d) Be found to fulfill RP responsibilities and qualifications upon interview by HHS-trained inspectors during each on-site inspection of the laboratory; and

(e) Qualify as a certifying scientist.

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

(a) All HHS-certified laboratories must have multiple RPs or one RP and an alternate RP. When an RP or multiple RPs are absent at the same time, an alternate RP must be present and able to maintain the

responsibilities of the RP.

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

(2) The Secretary, in accordance with these Guidelines, will suspend a laboratory's 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) When an RP permanently leaves an HHS-certified laboratory:

(1) An HHS-certified laboratory may maintain its certification and continue testing Federal agency specimens under the direction of an alternate RP for a period of up to 180 days while seeking

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to hire and receive the Secretary's approval of the new permanent RP.

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

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

(d) The laboratory must fulfill other inspection and PT criteria as required prior to conducting Federal agency testing under a new RP.

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

(a) The 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 laboratory that are relevant to the results that the individual certifies; and

(3) Training and experience in reviewing and reporting forensic test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

(b) The certifying technician must have:

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

(2) Training and experience in reviewing and reporting forensic test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

Section 11.6 What qualifications and training must other laboratory personnel have?

(a) All laboratory staff (e.g., technicians, administrative staff) must have the appropriate training and skills for the tasks assigned.

(b) Each individual working in an HHS-certified laboratory must be properly trained (i.e., receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before he or she is permitted to work independently with regulated specimens and the 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 (such as, firefighters and medical rescue teams).

(c) A laboratory must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized escorted visitors accessing secured areas, and their authorized escorts.

Section 11.8 What are the internal laboratory chain of custody requirements for a specimen or an aliquot?

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

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

(c) The date and purpose must be documented on an appropriate chain of custody document each time a specimen or aliquot is handled or transferred, and every individual in the chain must be identified.

(d) Chain of custody must be maintained and documented by using either paper copy or electronic procedures.

(e) Each individual that handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody document when the specimen or aliquot is received.

Section 11.9 What test(s) does an HHS-certified laboratory conduct on a specimen received from an IITF?

An HHS-certified laboratory must test the specimen in the same manner as a specimen that had not been previously tested.

Section 11.10 What are the requirements for an initial drug test?

(a) An initial drug test must be an immunoassay test.

(b) A laboratory must validate an initial drug test before using it to test specimens.

(c) Initial drug test kits must be approved, cleared, or otherwise recognized by FDA as accurate and reliable for the testing of a specimen for identifying drugs of abuse or their metabolites.

(d) A laboratory may conduct a second initial drug test using a method with different specificity, to rule out cross-reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 11.12.

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

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

(1) The ability to differentiate positive and negative specimens;

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

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

(4) The effect of carryover that may occur between aliquots.

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

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

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

(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 25 percent above the cutoff;

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

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

(b) A minimum of 10 percent of the total specimens and quality control samples in each batch must be quality

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control samples (i.e., calibrators or controls).

Section 11.13 What are the requirements for a confirmatory drug test?

- (a) The analytical method used must combine chromatographic separation and mass spectrometric identification (e.g., GC/MS, liquid chromatography/mass spectrometry (LC/MS), GC/MS/MS, LC/MS/MS).
- (b) A confirmatory drug test must be validated before the laboratory can use it to test specimens.

Section 11.14 What must an HHS-certified laboratory do to validate a confirmatory drug test?

- (a) An HHS-certified laboratory must demonstrate and document for each confirmatory drug test:
 - (1) The linear range of the analysis;
 - (2) The limit of detection;
 - (3) The limit of quantitation;
 - (4) The accuracy and precision at the cutoff concentration;
 - (5) The accuracy and precision at 40 percent of the cutoff concentration; and
 - (6) The potential for interfering substances.
 - (7) The effect of carryover that may occur between aliquots.
- (b) An HHS-certified laboratory must re-verify its confirmatory drug test methods periodically or at least annually.

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

- (a) Each batch of specimens must contain, at a minimum, the following QC specimens:
 - (1) A calibrator with its drug concentration 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 below 40 percent of the cutoff.
- (b) A minimum of 10 percent of the total specimens and quality control samples in each batch must be quality control samples (i.e., calibrators or controls).

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

- (a) Each specimen validity test result must be based on performing an initial specimen validity test on one aliquot and a second or confirmatory test on a second aliquot;
- (b) Each specimen validity test must satisfy the QC requirements in Section 11.18; and
- (c) Controls must be analyzed concurrently with specimens.

Section 11.17 What must an HHS-certified laboratory do to validate a specimen validity test?

An HHS-certified laboratory must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test; and must re-verify the test periodically, or at least annually.

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

- (a) The requirements for measuring creatinine concentration are as follows:
 - (1) The creatinine concentration must be measured to one decimal place on both the initial creatinine test and the confirmatory creatinine test;
 - (2) The initial creatinine test must have a calibrator at 2 mg/dL;

(3) The initial creatinine test must have a control in the range of 1.0 mg/dL to 1.5 mg/dL, a control in the range of 3 mg/dL to 20 mg/dL, and a control in the range of 21 mg/dL to 25 mg/dL; and

(4) The confirmatory creatinine test (performed on those specimens with a creatinine concentration less than 2 mg/dL on the initial test) must have a calibrator at 2 mg/dL, a control in the range of 1.0 mg/dL to 1.5 mg/dL, and a control in the range of 3 mg/dL to 4 mg/dL.

(b) The requirements for measuring specific gravity are as follows:

(1) For specimens with initial creatinine test results greater than 5 mg/dL and less than 20 mg/dL, laboratories may perform a screening test using a refractometer that measures urine specific gravity to at least three decimal places to identify specific gravity values that are acceptable (equal to or greater than 1.003) or dilute (equal to or greater than 1.002 and less than 1.003). Specimens must be subjected to an initial specific gravity test using a four decimal place refractometer when the initial creatinine test result is less than or equal to 5 mg/dL or when the screening specific gravity test result using a three decimal place refractometer is less than 1.002. The screening specific gravity test must have the following controls:

- (i) A calibrator or control at 1.000;
- (ii) One control targeted at 1.002;
- (iii) One control in the range of 1.004 to 1.018.

(2) For the initial and confirmatory specific gravity tests, the refractometer must report and display specific gravity to four decimal places. The refractometer must be interfaced with a laboratory information management system (LIMS), computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the specific gravity test results;

(3) The initial and confirmatory specific gravity tests must have a calibrator or control at 1.0000; and

(4) The initial and confirmatory specific gravity tests must have the following controls:

- (i) One control targeted at 1.0020;
- (ii) One control in the range of 1.0040 to 1.0180; and
- (iii) One control equal to or greater than 1.0200 but not greater than 1.0250.

(c) Requirements for measuring pH are as follows:

(1) Colorimetric pH tests that have the dynamic range of 2 to 12 to support the 3 and 11 pH cutoffs and pH meters must be capable of measuring pH to one decimal place. Colorimetric pH tests, dipsticks, and pH paper (i.e., screening tests) that have a narrow dynamic range and do not support the cutoffs may be used only to determine if an initial pH specimen validity test must be performed;

(2) For the initial and confirmatory pH tests, the pH meter must report and display pH to at least one decimal place. The pH meter must be interfaced with a LIMS, computer, and/or generate a paper copy of the digital electronic display to document the numerical values of the pH test results;

(3) pH screening tests must have, at a minimum, the following controls:

- (i) One control below the lower decision point in use;
- (ii) One control between the decision points in use; and
- (iii) One control above the upper decision point in use;

(4) An initial colorimetric pH test must have the following calibrators and controls:

- (i) One calibrator at 3;
- (ii) One calibrator at 11;
- (iii) One control in the range of 2 to 2.8;
- (iv) One control in the range 3.2 to 4;
- (v) One control in the range of 4.5 to 9;
- (vi) One control in the range of 10 to 10.8; and
- (vii) One control in the range of 11.2 to 12;

(5) An initial pH meter test, if a pH screening test is not used, must have the following calibrators and controls:

- (i) One calibrator at 4;
- (ii) One calibrator at 7;
- (iii) One calibrator at 10;
- (iv) One control in the range of 2 to 2.8;
- (v) One control in the range 3.2 to 4;

- (vi) One control in the range of 10 to 10.8; and
- (vii) One control in the range of 11.2 to 12;
- (6) An initial or confirmatory pH meter test, if a pH screening test is used, must have the following calibrators and controls when the screening result indicates that the pH is below the lower decision point in use:
 - (i) One calibrator at 4;
 - (ii) One calibrator at 7;
 - (iii) One control in the range of 2 to 2.8; and
 - (iv) One control in the range 3.2 to 4; and
- (7) An initial or confirmatory pH meter test, if a pH screening test is used, must have the following calibrators and controls when the screening result indicates that the pH is above the upper decision point in use:
 - (i) One calibrator at 7;
 - (ii) One calibrator at 10;
 - (iii) One control in the range of 10 to 10.8; and
 - (iv) One control in the range of 11.2 to 12.
- (d) Requirements for performing oxidizing adulterant tests are as follows:
 - (1) The initial test must include an appropriate calibrator at the cutoff specified in Sections 11.19(d)(2), (3), or (4) for the compound of interest, a control without the compound of interest (i.e., a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration; and
 - (2) A confirmatory test for a specific oxidizing adulterant must use a different analytical method than that used for the initial test. Each confirmatory test batch must include an appropriate calibrator, a control without the compound of interest (i.e., a certified negative control), and a control with the compound of interest at a measurable concentration.
 - (e) The requirements for measuring the nitrite concentration are that the initial and confirmatory nitrite tests must have a calibrator at the cutoff concentration, a control without nitrite (i.e., certified negative urine), one control in the range of 200 mcg/mL to 250 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL.

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

- (a) An HHS-certified laboratory must report a test result directly to the agency's MRO within an average of 5 working days after receipt of the specimen using the Federal CCF and/or an electronic report. Before any test result is reported, it must be certified by a certifying scientist or a certifying technician, as appropriate.
- (b) A primary (Bottle A) specimen is reported negative when each initial drug test is negative or it is negative on a confirmatory drug test and each specimen validity test result indicates that the specimen is a valid urine specimen.
- (c) A primary (Bottle A) specimen is reported positive for a specific drug when the initial drug test is positive and the confirmatory drug test is positive in accordance with Section 3.4.
- (d) A primary (Bottle A) specimen is reported adulterated when:
 - (1) The pH is less than 3 or equal to or greater than 11 using either a pH meter or a colorimetric pH test for the initial test on the first aliquot and a pH meter for the confirmatory test on the second aliquot;
 - (2) The nitrite concentration is equal to or greater than 500 mcg/mL using either a nitrite colorimetric test or a general oxidant colorimetric test for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on the second aliquot;
 - (3) The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or a chromium (VI) colorimetric test (chromium (VI) concentration equal to or greater than 50 mcg/mL) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, atomic absorption spectrophotometry, capillary electrophoresis, inductively coupled plasma-mass spectrometry) with the chromium (VI) concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(4) The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with an equal to or greater than 200 mcg/mL nitrite-equivalent cutoff or an equal to or greater than 50 mcg/mL chromium (VI)-equivalent cutoff) or halogen colorimetric test (halogen concentration equal to or greater than the LOQ) for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, inductively coupled plasma-mass spectrometry) with a specific halogen concentration equal to or greater than the LOQ of the confirmatory test on the second aliquot;

(5) The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and a different confirmatory method (e.g., GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the LOQ of the analysis on the second aliquot;

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

(7) The presence of a surfactant is verified by using a surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for the initial test on the first aliquot and a different confirmatory test (e.g., multi-wavelength spectrophotometry) with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff on the second aliquot; or

(8) The presence of any other adulterant not specified in paragraphs d(2) through d(7) of this section is verified using an initial test on the first aliquot and a different confirmatory test on the second aliquot.

(e) A primary (Bottle A) specimen is reported substituted when the creatinine concentration is less than 2 mg/dL and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200 on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots.

(f) A primary (Bottle A) specimen is reported dilute when the creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030 on a single aliquot.

(g) For a specimen that has an invalid result for one of the reasons stated in items (h)4 through (h)12 below, the laboratory shall contact the MRO and both will decide if testing by another certified laboratory would be useful in being able to report a positive or

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adulterated result. If no further testing is necessary, the laboratory then reports the invalid result to the MRO.

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

(1) Inconsistent creatinine concentration and specific gravity results are obtained (i.e., the creatinine concentration is less than 2 mg/dL on both the initial and confirmatory creatinine tests and the specific gravity is greater than 1.0010 but less than 1.0200 on the initial and/or confirmatory specific gravity test, the specific gravity is less than or equal to 1.0010 on both the initial and confirmatory specific gravity tests and the creatinine concentration is equal to or greater than 2 mg/dL on either or both the initial or confirmatory creatinine tests);

(2) The pH is equal to or greater than 3 and less than 4.5 or equal to or greater than 9 and less than 11 using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

(3) The nitrite concentration is equal to or greater than 200 mcg/mL using a nitrite colorimetric test or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test for both the initial (first) test and the second test or using either initial test and the nitrite concentration is equal to or greater than 200 mcg/mL but less than 500 mcg/mL for a different confirmatory test (e.g., multi-wavelength spectrophotometry, ion chromatography, capillary electrophoresis) on two separate aliquots;

(4) The possible presence of chromium (VI) is determined using the same chromium (VI) colorimetric test with a cutoff equal to or greater than 50 mcg/mL chromium (VI) for both the initial (first) test and the second test on two separate aliquots;

(5) The possible presence of a halogen (e.g., bleach, iodine, fluoride) is determined using the same halogen colorimetric test with a cutoff equal to or greater than the LOQ for both the initial (first) test and the second test on two separate aliquots or relying on the odor of the specimen as the initial test;

(6) The possible presence of glutaraldehyde is determined by using the same aldehyde test (aldehyde present) or characteristic immunoassay response on one or more drug immunoassay tests for both the initial (first) test and the second test on two separate aliquots;

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

(8) The possible presence of a surfactant is determined by using the same surfactant colorimetric test with an equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff for both the initial (first) test and the second test on two separate aliquots or a foam/shake test for the initial test;

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

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

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

(12) The physical appearance of Bottles A and B are clearly different and Bottle A tested negative for drugs.

(i) An HHS-certified laboratory shall reject a primary (Bottle A) urine specimen for testing when a fatal flaw occurs as described in Section 15.1 or when a correctable flaw as described in Section 15.2 is not recovered. The laboratory will indicate on the Federal CCF that the specimen was rejected for testing and provide the reason for reporting the rejected for testing result.

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

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

(l) An HHS-certified laboratory must report numerical values of the specimen validity test results that support a specimen that is reported adulterated, substituted, or invalid (as appropriate).

(m) When the concentration of an analyte exceeds the linear range of the standard curve, an HHS-certified laboratory may report to the MRO that the quantitative value exceeds the linear range of the test, that the quantitative value is greater than "insert the actual value for the upper limit of the linear range," or may report an accurate quantitative value above the upper limit of the linear range that was obtained by diluting an aliquot of the specimen.

(n) An HHS-certified laboratory may transmit a result to the MRO by various electronic means (e.g., teleprinter, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. A laboratory must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(o) For all test results, an HHS-certified laboratory may fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF, and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test result is properly associated with the custody and control form that the MRO received from the collector. For positive, adulterated, substituted, and invalid results, the laboratory must fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF.

Section 11.20 How long must an HHS-certified laboratory retain a specimen?

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

(b) A retained specimen must be kept in a secured frozen storage (-20 [deg]C or less) to ensure its availability for any necessary retesting during an administrative or judicial proceeding.

(c) Within the 1-year storage period, a Federal agency may request a laboratory to retain a specimen for an additional specified period of time.

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

(a) An HHS-certified laboratory must retain all records generated to support test results for at least 2 years.

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

(c) The laboratory may retain records other than those included in the documentation package beyond the normal 2 year period of time to ensure that it can fully support the reported test result.

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Section 11.22 What statistical summary report must an HHS-certified laboratory provide?

(a) An HHS-certified laboratory must provide to each Federal agency for which testing is conducted a semiannual statistical summary report that contains the following information:

- (1) Reporting period (inclusive dates);
- (2) Laboratory name and address;
- (3) Federal agency name;
- (4) Total number of specimen results reported;
- (5) Number of specimens collected by reason for test;
- (6) Number of specimens reported negative and the number reported negative/dilute;
- (7) Number of specimens rejected for testing because of a fatal flaw and the number rejected for testing because of an uncorrected flaw;
- (8) Number of specimens reported positive;
- (9) Number of specimens reported positive for each drug;
- (10) Number of specimens reported adulterated;
- (11) Number of specimens reported substituted; and
- (12) Number of specimens reported as invalid result.

(b) The report must be submitted by mail, fax, or e-mail within 14 working days after the end of the semiannual period. The summary report must not include any personal identifying information.

(c) The HHS-certified laboratory must make available copies of an agency's test results when requested by the Secretary or by the Federal agency for which the laboratory is performing drug-testing services.

(d) The HHS-certified laboratory must make available a qualified individual to testify in a proceeding against a Federal employee when that proceeding is based on a test result reported by the HHS-certified laboratory.

Section 11.23 What laboratory information is available to a Federal employee?

(a) A Federal employee who is the subject of a drug test may, upon written request through the MRO and the Federal agency, have access to any records relating to his or her drug test, any records relating to the results of any relevant certification, review, or revocation of certification proceedings, and access to a documentation package.

(b) A standard documentation package provided by an HHS-certified laboratory must consist of the following items:

- (1) A cover sheet that provides a brief description of the drug testing procedures and specimen validity tests performed on the donor's specimen;
- (2) A table of contents page that lists by page number all documents and materials in the package;
- (3) A copy of the Federal CCF with any attachments, internal chain of custody records for the specimen, memoranda (if any) generated by the laboratory, and a copy of the electronic report (if any) generated by the laboratory;

(4) A brief description of the laboratory's initial drug and specimen validity test procedures, instrumentation, batch quality control requirements, and copies of the initial test data for the donor's specimen with all calibrators and controls identified and copies of all internal chain of custody documents related to the initial tests;

(5) A brief description of the laboratory's confirmatory drug and specimen validity test procedures, instrumentation, batch quality control requirements, and copies of the confirmatory test data for the donor's specimen with all calibrators and controls identified and copies of all internal chain of custody documents related to the confirmatory tests; and

(6) A copy of the resume or curriculum vitae for the RP(s) and the certifying scientist that certified the test result.

Section 11.24 What type of relationship is prohibited between an HHS-certified laboratory and an MRO?

A 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 laboratory for which the MRO is reviewing drug testing results. Additionally, an MRO shall not derive any financial benefit by having an agency use a specific drug testing laboratory or have any agreement with the laboratory that may be construed as a potential conflict of interest.

Section 11.25 What type of relationship can exist between an HHS-certified laboratory and an HHS-certified IITF?

An HHS-certified laboratory can enter into any relationship with an HHS-certified IITF.

Subpart L--Instrumented Initial Test Facility (IITF)

Section 12.1 What must be included in the HHS-certified IITF's standard operating procedure manual?

(a) An HHS-certified IITF must have a standard operating procedure (SOP) manual that describes, in detail, all IITF operations.

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

(1) Chain of custody procedures;

(2) Accessioning;

(3) Security;

(4) Quality control/quality assurance programs;

(5) Analytical methods and procedures;

(6) Equipment and maintenance programs;

(7) Personnel training;

(8) Reporting procedures; and

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

(c) All procedures in the SOP manual must be in compliance with these Guidelines and other guidance documents.

(d) A copy of all procedures that have been replaced or revised and the dates on which they were in effect must be maintained by the HHS-certified IITF for two years to allow the IITF to retrieve the procedures that were used to test a specimen.

Section 12.2 What are the responsibilities of the responsible technician (RT)?

(a) Manage the day-to-day operations of the IITF even where another individual has overall responsibility for an entire multi-specialty facility.

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

(c) Maintain a complete, current SOP manual that is available for personnel at the IITF, and followed by those personnel. The SOP manual must be reviewed, signed, and dated by the RT whenever procedures are first placed into use or changed or when a new individual assumes responsibility for management of the IITF.

(d) Maintain a quality assurance program to assure the proper performance and reporting of all test results; verify and monitor acceptable analytical performance for all controls and standards; monitor quality control

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testing; document the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.

(e) Implement all remedial actions necessary to maintain satisfactory operation and performance of the IITF in response to quality control systems not being within performance specifications, errors in result reporting or in analysis of performance testing samples, and deficiencies identified during inspections. This individual must ensure that specimen results are not reported until all corrective actions have been taken and he or she can assure that the results provided are accurate and reliable.

Section 12.3 What qualifications must the RT have?

An RT must:

- (a) Have at least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;
- (b) Have training and experience in the analytical methods and forensic procedures used by the IITF that are relevant to the results;
- (c) Have training and experience in reviewing and reporting forensic test results, maintenance of chain of custody, recordkeeping, and understanding proper remedial action in response to problems that may arise;
- (d) Be found to fulfill RT responsibilities and qualifications upon interview by HHS-trained inspectors during each on-site inspection of the HHS-certified IITF; and
- (e) Qualify as a certifying technician.

Section 12.4 What happens when the RT is absent or leaves an HHS-certified IITF?

(a) All HHS-certified IITFs must have an RT and an alternate RT. When an RT is absent, an alternate RT must be present and able to maintain the responsibilities of the RT.

(1) When an HHS-certified IITF is without the RT and alternate RT for 14 calendar days or less (e.g., vacation, illness, business trip), the HHS-certified IITF may continue testing Federal agency specimens under the direction of a certifying technician.

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

(b) When an RT permanently leaves an HHS-certified IITF:

(1) The HHS-certified IITF may maintain its certification and continue testing Federal agency specimens under the direction of an alternate RT for a period of up to 180 days while seeking to hire and receive the Secretary's approval of the new permanent RT.

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

(c) To nominate an individual as RT or alternate RT, the IITF must submit to the Secretary the candidate's current resume or curriculum vitae, copies of diplomas and any licensures, a training plan (not to exceed 90 days) to transition into the RT position, an itemized defense of the candidate's qualifications compared to the minimum RT qualifications described in the Guidelines, and arrange to have official academic transcript(s) submitted by the candidate's institution(s) of higher learning. The candidate must be found acceptable during an on-site inspection of the IITF.

(d) The HHS-certified IITF must fulfill other inspection and PT criteria as required prior to conducting Federal agency testing under a new RT.

Section 12.5 What qualifications must an individual have to certify a result reported by an HHS-certified IITF?

The certifying technician must have:

- (a) Training and experience in the analytical methods and forensic procedures used by the IITF that are relevant to the results that the individual certifies; and
- (b) Training and experience in reviewing and reporting forensic test results, maintenance of chain of custody, and understanding proper remedial action in response to problems that may arise.

Section 12.6 What qualifications and training must other IITF personnel have?

- (a) All IITF staff (e.g., technicians, administrative staff) must have the appropriate training and skills for the tasks assigned.
- (b) Each individual working in an HHS-certified IITF must be properly trained (i.e., receive training in each area of work that the individual will be performing, including training in forensic procedures related to their job duties) before he or she is permitted to work independently in any area of the facility with Federal agency specimens and the training must be documented.

Section 12.7 What security measures must an HHS-certified IITF maintain?

- (a) An HHS-certified IITF must control access to the facility and ensure that no unauthorized individual can gain access to specimens, aliquots, or records.
- (b) Authorized visitors must be escorted at all times except for individuals authorized to conduct inspections on behalf of Federal, state, or other accrediting agencies or emergency personnel (e.g., firefighters and medical rescue teams).
- (c) An HHS-certified IITF must maintain a record that documents the dates, time of entry and exit, and purpose of entry of authorized escorted visitors accessing secured areas, and their authorized escorts.

Section 12.8 What are the internal IITF chain of custody requirements for a specimen or an aliquot?

- (a) An HHS-certified IITF must use chain of custody procedures to maintain control and accountability of specimens from receipt through completion of testing, reporting of results, during storage, and continuing until final disposition of the specimens.
- (b) An HHS-certified IITF must use chain of custody procedures to document the handling and transfer of aliquots throughout the testing process and until final disposal.
- (c) The date and purpose must be documented on an appropriate chain of custody document each time a specimen or aliquot is handled or transferred, and every individual in the chain must be identified.
- (d) Chain of custody must be maintained and documented by using either paper copy or electronic procedures.
- (e) Each individual that handles a specimen or aliquot must sign and complete the appropriate entries on the chain of custody document when the specimen or aliquot is received.

Section 12.9 What are the requirements for an initial drug test?

- (a) An initial drug test must be an immunoassay test.
- (b) An IITF must validate an initial drug test before using it to test specimens;
- (c) Initial drug test kits must be approved, cleared, or otherwise recognized by FDA as accurate and reliable for the testing of a specimen for identifying drugs of abuse or their metabolites.
- (d) An IITF may conduct a second initial drug test using a method with different specificity, to rule out cross-

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reacting compounds. This second initial drug test must satisfy the batch quality control requirements specified in Section 12.11.

Section 12.10 What must an HHS-certified IITF do to validate an initial drug test?

- (a) An HHS-certified IITF must demonstrate and document for each initial drug test:
 - (1) The ability to differentiate positive and negative specimens;
 - (2) The performance of the test around the cutoff concentration, using samples at several concentrations between 0 and 150 percent of the cutoff concentration;
 - (3) The effective concentration range of the test; and
 - (4) The effect of carryover that may occur between aliquots.
- (b) Each new lot of a drug test reagent must be verified prior to being placed into service.

Section 12.11 What are the batch quality control (QC) requirements when conducting an initial drug test?

- (a) Each batch of specimens must contain the following QC samples:
 - (1) At least one control certified to contain no drug or drug metabolite;
 - (2) At least one positive control with the drug or drug metabolite targeted at 25 percent above the cutoff;
 - (3) At least one control with the drug or drug metabolite targeted at 75 percent of the cutoff; and
 - (4) At least one control that appears as a donor specimen to the IITF analysts.
- (b) A minimum of 10 percent of the total specimens and QC samples in each batch must be QC samples (i.e., calibrators or controls).

Section 12.12 What are the analytical and quality control requirements for conducting specimen validity tests?

- (a) Each specimen validity test result must be based on a single test on one aliquot;
- (b) Each specimen validity test must satisfy the QC requirements in Section 12.14; and
- (c) Controls must be analyzed concurrently with specimens.

Section 12.13 What must an HHS-certified IITF do to validate a specimen validity test?

An HHS-certified IITF must demonstrate and document for each specimen validity test the appropriate performance characteristics of the test; and must re-verify the test periodically, or at least annually.

Section 12.14 What are the requirements for conducting each specimen validity test?

- (a) The requirements for measuring creatinine concentration are as follows:
 - (1) The creatinine concentration must be measured to one decimal place on the test;
 - (2) The creatinine test must have a calibrator at 2 mg/dL; and
 - (3) The creatinine test must have a control in the range of 1.0 mg/dL to 1.5 mg/dL, a control in the range of 3 mg/dL to 20 mg/dL, and a control in the range of 21 mg/dL to 25 mg/dL.
- (b) The requirements for measuring specific gravity are as follows:
 - (1) For specimens with creatinine test results less than 20 mg/dL and greater than 5.0 mg/dL, an IITF must perform a screening test using a refractometer to identify specific gravity values that are acceptable (equal to or greater than 1.003) or dilute (equal to or greater than 1.002 and less than 1.003). Specimens must be forwarded to an HHS-certified laboratory when the creatinine test result is equal to or less than 5.0 mg/dL or when the screening specific gravity test result is less than 1.002.
 - (2) The screening specific gravity test must have the following QC samples:
 - (i) A calibrator or control at 1.000; and
 - (ii) One control targeted at 1.002; and
 - (iii) One control in the range of 1.004 to 1.018.
- (c) The requirements for measuring pH are as follows:
 - (1) The IITF may perform the pH test using a pH meter, colorimetric pH test, dipsticks, or pH paper. Specimens must be forwarded to an HHS-certified laboratory when the pH is less than 4.5 or equal to or

greater than 9.0.

(2) The pH test must have, at a minimum, the following QC samples:

(i) One control below 4.5;

(ii) One control between 4.5 and 9.0;

(iii) One control above 9.0; and

(iv) One or more calibrators as appropriate for the test. For a pH meter: Calibrators at 4, 7, and 10.

(d) The requirements for measuring the nitrite concentration are that the nitrite test must have a calibrator at 200 mcg/mL nitrite, a control without nitrite (i.e., certified negative urine), one control in the range of 200 mcg/mL to 250 mcg/mL, and one control in the range of 500 mcg/mL to 625 mcg/mL. Specimens with a nitrite concentration equal to or greater than 200 mcg/mL must be forwarded to an HHS-certified laboratory; and,

(e) Requirements for performing oxidizing adulterant tests are that the test must include an appropriate calibrator at the cutoff specified in Sections 11.19(d)(3), (4), or (6) for the compound of interest, a control without the compound of interest (i.e., a certified negative control), and at least one control with one of the compounds of interest at a measurable concentration. Specimens with an oxidizing adulterant result equal to or greater than the cutoff must be forwarded to an HHS-certified laboratory.

Section 12.15 What are the requirements for an HHS-certified IITF to report a test result?

(a) An HHS-certified IITF must report a test result directly to the agency's MRO within an average of 3 working days after receipt of the specimen using the Federal CCF and/or electronic report. Before any test result is reported, it must be certified by a certifying technician.

(b) A primary (Bottle A) specimen is reported negative when each drug test is negative and each specimen validity test result indicates that the specimen is a valid urine specimen.

(c) A primary (Bottle A) urine specimen is reported dilute when the creatinine concentration is greater than 5 mg/dL but less than 20 mg/dL and the specific gravity is equal to or greater than 1.002 but less than 1.003.

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

(e) An HHS-certified IITF may transmit a result to the MRO by various electronic means (e.g., teleprinter, facsimile, or computer) in a manner designed to ensure confidentiality of the information. A result may not be reported verbally by telephone. An IITF must ensure the security of the data transmission and limit access to any data transmission, storage, and retrieval system.

(f) For all test results, an HHS-certified IITF may fax, courier, mail, or electronically transmit a legible image or copy of the completed Federal CCF, and/or forward a computer-generated electronic report. The computer-generated report must contain sufficient information to ensure that the test result is properly associated with the custody and control form that the MRO received from the collector.

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Section 12.16 How does an HHS-certified IITF handle a specimen that tested positive, adulterated, substituted, or invalid at the IITF?

(a) The remaining specimen is resealed using a tamper-evident label/seal;

(b) The individual resealing the remaining specimen initials and dates the tamper-evident label/seal; and

(c) The resealed specimen and split specimen and the Federal CCF are sealed in a leak-proof plastic bag, and are sent to an HHS-certified laboratory under chain of custody within one day after completing the drug and specimen validity tests.

Section 12.17 How long must an HHS-certified IITF retain a specimen?

A specimen that is negative, negative/dilute, or rejected for testing is discarded.

Section 12.18 How long must an HHS-certified IITF retain records?

- (a) An HHS-certified IITF must retain all records generated to support test results for at least 2 years.
- (b) A Federal agency may request an HHS-certified IITF to maintain a copy of the documentation package (as described in Section 12.20(b)) that supports the chain of custody, testing, and reporting of a donor's specimen that is under legal challenge by a donor. The Federal agency's request to the IITF must be in writing and must specify the period of time to maintain the documentation package.
- (c) The IITF may retain records other than those included in the documentation package beyond the normal 2 year period of time to ensure that it can fully support the reported test result.

Section 12.19 What statistical summary report must an HHS-certified IITF provide?

- (a) An HHS-certified IITF must provide to each Federal agency for which testing is conducted a semiannual statistical summary report that contains the following information:
 - (1) Reporting period (inclusive dates);
 - (2) IITF name and address;
 - (3) Federal agency name;
 - (4) Total number of specimens tested;
 - (5) Number of specimens collected by reason for test;
 - (6) Number of specimens reported negative and the number reported negative/dilute;
 - (7) Number of specimens rejected for testing because of a fatal flaw and the number rejected for testing because of an uncorrected flaw;
 - (8) Number of specimens forwarded to an HHS-certified laboratory for additional drug testing and/or specimen validity testing.
- (b) The report must be submitted by mail, fax, or e-mail within 14 working days after the end of the semiannual period.
- (c) The HHS-certified IITF must make available copies of an agency's test results when requested by the Secretary or by the Federal agency for which the IITF is performing drug-testing services.
- (d) The HHS-certified IITF must make available a qualified individual to testify in a proceeding against a Federal employee when that proceeding is based on a test result reported by the HHS-certified IITF.

Section 12.20 What IITF information is available to a Federal employee?

- (a) A Federal employee who is the subject of a drug test may, upon written request through the MRO and the Federal agency, have access to any records relating to his or her drug test, any records relating to the results of any relevant certification, review, or revocation of certification proceedings, and access to a documentation package.
- (b) A standard documentation package provided by an HHS-certified IITF must contain the following items:
 - (1) A cover sheet that provides a brief description of the drug testing procedures and specimen validity tests performed on the donor's specimen;
 - (2) A table of contents page that lists by page number all documents and materials in the package;
 - (3) A copy of the Federal CCF with any attachments, copies of all internal chain of custody records for the specimen, memoranda (if any) generated by the IITF, and a copy of the electronic report (if any) generated by the IITF;
 - (4) A brief description of the IITF's drug and specimen validity test procedures, instrumentation, batch QC requirements;
 - (5) Copies of all test data for the donor's specimen with all calibrators and controls identified and copies of all internal chain of custody documents related to the tests; and
 - (6) Copies of the resume or curriculum vitae for the responsible technician and for the certifying technician that certified the test result.

Section 12.21 What type of relationship is prohibited between an HHS-certified IITF and an MRO?

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

a specific MRO.

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

Section 12.22 What type of relationship can exist between an HHS-certified IITF and an HHS-certified laboratory?

An HHS-certified IITF can freely enter into any relationship with an HHS-certified laboratory.

Subpart M--Medical Review Officer (MRO)

Section 13.1 Who may serve as an MRO?

(a) A licensed physician who has: (1) Either 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 13.2; and

(4) Satisfactorily passed an examination administered by a nationally recognized entity that certifies MROs or subspecialty board for physicians performing a review of Federal employee drug test results, which has been approved by the Secretary.

(b) Nationally recognized entities that certify MROs or subspecialty boards for physicians performing a review of Federal employee drug test results that seek approval by the Secretary must submit their qualifications and a sample examination. Based on an annual objective review of the qualifications and content of the examination, the Secretary shall annually publish a list in the Federal Register of those entities and boards that have been approved.

Section 13.2 What are the training requirements before a physician can serve as an MRO?

A physician must receive training that includes a thorough review of:

(a) The collection procedures used to collect Federal agency specimens;

(b) How to interpret test results reported by laboratories;

(c) Chain of custody, reporting, and recordkeeping requirements for Federal agency specimens;

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(d) The HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs; and

(e) Procedures for interpretation, review, and reporting of results specified by any Federal agency for which the individual may serve as MRO.

Section 13.3 What are the responsibilities of an MRO?

(a) The MRO must review all positive, adulterated, substituted, rejected for testing, and invalid test results. Staff under the direct, personal supervision of the MRO may review and report negative and 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

(b) The MRO must discuss potential invalid results with the laboratory as addressed in Section 11.19(g), to determine whether testing at another certified laboratory may be warranted.

(c) After receiving a report from an HHS-certified laboratory or 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;

- (4) Report the verified result to the Federal agency;
- (5) Maintain the records (for a minimum of 2 years) and the confidentiality of the information;
- (6) Review all positive, adulterated, substituted, and invalid test results before the result is transmitted to the agency's designated representative; and
- (d) The MRO must conduct a medical evaluation when a collector reports that the donor was unable to provide a urine specimen, as addressed in Section 13.5.

Section 13.4 What must an MRO do when reviewing a test result?

- (a) When an HHS-certified laboratory or HHS-certified IITF reports a negative result on the primary (Bottle A) specimen, the MRO reports a negative result to the agency.
- (b) When an HHS-certified laboratory or HHS-certified IITF reports a negative/dilute result on the primary (Bottle A) urine specimen, the MRO reports a negative/dilute result to the agency and directs the agency to immediately collect another specimen from the donor.
- (c) When an HHS-certified laboratory reports a positive result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is any legitimate medical explanation for the positive result.
 - (1) If the donor provides a legitimate medical explanation for the positive result, the MRO reports the test result as negative to the agency. If a laboratory also reports that the specimen is dilute, the MRO reports a negative/dilute result to the agency and directs the agency to immediately collect another specimen from the donor.
 - (2) If the donor is unable to provide a legitimate medical explanation, the MRO reports a positive result to the agency. If a laboratory also reports that the specimen is dilute, the MRO may choose not to report the dilute result.
- (d) When an HHS-certified laboratory reports a positive result for opiates on the primary (Bottle A) urine specimen, the MRO must determine that there is clinical evidence in addition to the urine test result of illegal use of any opium, opiate, or opium derivative (e.g., morphine/codeine) listed in Schedule I or II of the Controlled Substances Act. However, this requirement does not apply if the laboratory confirms the presence of 6-acetylmorphine (i.e., the presence of this metabolite is proof of heroin use) or the morphine or codeine concentration is equal to or greater than 15,000 ng/mL and the donor does not present a legitimate medical explanation for the presence of morphine or codeine at or above this concentration. Consumption of food products must not be considered a legitimate medical explanation for the donor having morphine or codeine at or above this concentration.
- (e) When an HHS-certified laboratory reports an adulterated or substituted result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if the donor has a legitimate medical explanation for the adulterated or substituted result.
 - (1) If the donor provides a medical explanation that is legitimate, 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 specimen was adulterated or substituted.
- (f) When an HHS-certified laboratory reports an invalid result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is a legitimate medical explanation for the invalid result. In the case of an invalid result based on pH of 9.0 to 9.5, when an employee has no other medical explanation for the pH in this range, the MRO must consider whether there is evidence of elapsed time and high temperature that could account for the pH value. The MRO may contact the collection site, IITF, and/or laboratory to discuss time and temperature issues (e.g., time elapsed from collection to receipt at the testing facility, likely temperature conditions between the time of the collection and transportation to the testing facility, specimen storage conditions).
 - (i) If the donor provides a medical explanation that appears to be legitimate (e.g., a valid prescription medication) or if the MRO determines that time and temperature account for the pH in the 9.0-9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and informs the Federal agency that a recollection is not required because there is an acceptable explanation for the invalid result.
 - (ii) If the donor is unable to provide an acceptable medical explanation or if the MRO determines that time and temperature fail to account for the pH in the 9.0-9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and directs the Federal agency to immediately collect another specimen from the donor using a direct observed collection.

(g) When an HHS-certified laboratory or HHS-certified IITF reports a rejected for testing result on the primary (Bottle A) urine specimen, the MRO reports a test cancelled result to the agency and directs the agency to immediately collect another specimen from the donor.

Section 13.5 What action does the MRO take when the collector reports that the donor did not provide a sufficient amount of urine for a drug test?

(a) For purposes of this section, a medical condition includes an ascertainable physiological condition (e.g., a urinary system dysfunction) or a medically documented pre-existing psychological disorder, but does not include unsupported assertions of "situational anxiety" or dehydration. Permanent or long-term medical conditions are those physiological, anatomic, or psychological abnormalities documented as being present prior to the attempted collection, and considered not amenable to correction or cure for an extended period of time, if ever. Examples would include destruction (any cause) of the glomerular filtration system leading to renal failure; unrepaired traumatic disruption of the urinary tract; or a severe psychiatric disorder focused on

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genitor-urinary matters. Acute or temporary medical conditions, such as cystitis, urethritis or prostatitis, though they might interfere with collection for a limited period of time, cannot receive the same exceptional consideration as the permanent or long-term conditions discussed in the previous sentence.

(b) When the collector reports that the donor did not provide a sufficient amount of urine, 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) As the MRO, if another physician will perform the evaluation, you must provide the other physician with the following information and instructions:

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

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

(iii) That the referral physician must agree to follow the requirements of paragraphs (c) through (e) of this section.

(c) As the referral physician conducting this evaluation, you must recommend that the MRO make one of the following determinations:

(1) A medical condition as defined in paragraph (a) of this section has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. As the MRO, if you accept this recommendation, you must report a test cancelled result to the Federal agency.

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

(d) As the referral physician making the evaluation, after completing your evaluation, you must provide a written statement of your recommendations and the basis for them to the MRO. You must not include in this statement detailed information on the employee's medical condition beyond what is necessary to explain your conclusion.

(e) If, as the referral physician making this evaluation, you determine that the employee's medical condition is a serious and permanent or long-term disability (as defined in paragraph a of this section) that is highly likely to prevent the employee from providing a sufficient amount of urine for a very long or indefinite period of time, you must set forth your determination and the reasons for it in your written statement to the MRO. As the MRO, upon receiving such a report, you must follow the requirements of Section 13.6, where applicable.

(f) As the MRO, you must seriously consider and assess the referral physician's recommendations in making your determination about whether the employee has a medical condition that has, or with a high degree of probability could have, precluded the employee from providing a sufficient amount of urine. You must report your determination to the Federal agency in writing as soon as you make it.

(g) When a Federal agency receives a report from the MRO indicating that a test is cancelled as provided in paragraph (c)(1) of this section, the agency takes no further action with respect to the donor. The donor remains in the random testing pool.

Section 13.6 What happens when an individual is unable to provide a sufficient amount of urine for a Federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test because of a permanent or long-term medical condition?

(a) This section concerns a situation in which the donor has a medical condition that precludes him or her from providing a sufficient specimen for a Federal agency applicant/pre-employment test, a follow-up test, or a return-to-duty test; and the condition involves a permanent or long-term disability (as defined in paragraph (a) of Section 13.5). 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 13.5.

(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 13.5 and any further medical examination. This report must state the basis for the determination that a permanent or long-term medical condition exists, making provision of a sufficient urine specimen impossible, and for the determination that no signs and symptoms of drug use exist.

(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 13.5 and any further medical examination. This report must state that a permanent or long-term medical condition (as defined in Section 13.5(a) exists, making provision of a sufficient urine specimen impossible, and state the reason for the determination that signs and symptoms of drug use exist. Because this is a cancelled test, it does not serve the purposes of a negative test (e.g., the Federal agency is not authorized to allow the donor to begin or resume performing official functions, because a negative test is needed for that purpose).

Section 13.7 Who may request a test of a split specimen?

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

(b) The donor has 72 hours (from the time the MRO notified the donor that his or her specimen was reported positive, adulterated, or substituted) to request a test of the split (Bottle B) specimen. The MRO must inform the donor that he or she has the opportunity to request a test of the split (Bottle 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 (Bottle A) specimen.

Section 13.8 How does an MRO report a primary (Bottle A) specimen test result to an agency?

(a) The MRO must report all verified results to an agency by faxing a completed MRO copy of the Federal CCF, transmitting a scanned image of the completed MRO copy of the Federal CCF, or faxing a separate report using a letter/memorandum format.

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

(c) The MRO must send a paper copy of either the completed MRO copy of the Federal CCF or the separate letter/

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memorandum report for all positive, adulterated, and substituted results.

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

Section 13.9 What type of relationship is prohibited between an MRO and an HHS-certified laboratory or an HHS-certified IITF?

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

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

Subpart N--Split Specimen Tests

Section 14.1 When may a split specimen be tested?

(a) A donor has the opportunity to request through the MRO that the split (Bottle B) specimen be tested at a different (i.e., second) HHS-certified laboratory when the primary (Bottle 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 his or her records the verbal request from the donor to have the split (Bottle B) specimen tested.

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

(d) If a donor chooses not to have the split (Bottle B) specimen tested by a second laboratory, a Federal agency may have a split (Bottle 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 (Bottle B) specimen when the primary (Bottle A) specimen was reported positive?

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

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

(c) If the second laboratory fails to reconfirm the presence of the drug or drug metabolite that was reported by the first laboratory, the second laboratory must conduct specimen validity tests in an attempt to determine the reason for being unable to reconfirm the presence of the drug or drug metabolite. The second laboratory should conduct the same specimen validity tests as it would conduct on a primary (Bottle A) specimen and reports those results to the MRO.

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

(a) A laboratory must use one of the following criteria to reconfirm an adulterated result when testing a split (Bottle B) specimen:

(1) pH must be measured using the laboratory's confirmatory pH test with the appropriate cutoff (i.e., either less than 3 or equal to or greater than 11);

(2) Nitrite must be measured using the laboratory's confirmatory nitrite test with a cutoff concentration of equal to or greater than 500 mcg/mL;

(3) Surfactant must be measured using the laboratory's confirmatory surfactant test with a cutoff concentration of equal to or greater than 100 mcg/mL dodecylbenzene sulfonate-equivalent cutoff; or

(4) For adulterants without a specified cutoff (e.g., glutaraldehyde, chromium (VI), pyridine, halogens (such as, bleach, iodine), peroxidase, peroxide, other oxidizing agents), the laboratory must use its confirmatory specimen validity test at an established limit of quantitation (LOQ) to reconfirm the presence of the adulterant.

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

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

(a) A laboratory must use the following criteria to reconfirm a substituted result when testing a split (Bottle B) specimen:

(1) The creatinine must be measured using the laboratory's confirmatory creatinine test with a cutoff concentration of less than 2 mg/dL; and

(2) The specific gravity must be measured using the laboratory's confirmatory specific gravity test with the specified cutoffs of less than or equal to 1.0010 or equal to or greater than 1.0200.

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

Section 14.5 Who receives the split specimen result?

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

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

The MRO takes the following actions when the second laboratory reports the result for the split urine specimen as:

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

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

(c) Failed to reconfirm a single or all drug positive results and substituted. If the donor provides a legitimate medical explanation for the substituted result, the MRO reports a failed to reconfirm (specify drug(s)) and cancels both tests. If there is no legitimate medical explanation, the MRO reports a failed to

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reconfirm (specify drug(s)) and a refusal to test (substituted) to the agency. The MRO gives the donor 72 hours to request Laboratory A to review the creatinine and specific gravity results for the primary (Bottle A) specimen. If the original creatinine and specific gravity results confirm that the specimen was substituted, the MRO reports a refusal to test (substituted) to the agency. If the original creatinine and specific gravity results from Laboratory A fail to confirm that the specimen was substituted, the MRO cancels both tests and directs the agency to immediately collect another specimen using a direct observed collection procedure. The MRO shall notify the HHS office responsible for coordination of the drug-free workplace program about the failed to reconfirm and cancelled test.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(a) The MRO must report all verified results to an agency by faxing a completed MRO copy of the Federal CCF, transmitting a scanned image of the completed MRO copy of the Federal CCF, or faxing a separate report using a letter/memorandum format.

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

(c) The MRO must send a paper 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 the numerical values of the drug test results to the agency.

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

A split (Bottle B) specimen is retained for the same period of time that a primary (Bottle A) specimen is retained and under the same storage conditions. This applies even for those cases when the split (Bottle B) specimen is tested by a second laboratory and the second laboratory does not confirm the original result reported by the first laboratory on the primary (Bottle A) specimen.

Subpart O--Criteria for Rejecting a Specimen for Testing

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

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

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

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

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

(d) There is an insufficient amount of specimen for analysis in the primary (Bottle A) specimen unless the split (Bottle B) specimen can be re-designated as the primary (Bottle A) specimen.

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

The following discrepancies are considered to be correctable:

(a) If a collector failed to sign the Federal CCF, the HHS-certified laboratory or IITF must attempt to recover the collector's signature before reporting the test result. If the collector can provide a memorandum for record recovering the signature, the laboratory or IITF may report the test result for the specimen. If after 5 business days the laboratory or IITF cannot recover the collector's signature, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the Federal CCF.

(b) If a specimen is submitted using a non-Federal form or an expired Federal CCF, the laboratory or IITF must test the specimen and also attempt to obtain a memorandum for record explaining why a non-Federal form or an expired Federal CCF was used and ensure that the form used contains all the required information. If after 5 business days the laboratory or IITF cannot obtain a memorandum for record from the collector, the laboratory or IITF must report a rejected for testing result and indicate the reason for the rejected for testing result on the report to the MRO.

Section 15.3 What discrepancies are not sufficient to require an HHS-certified laboratory or an HHS-certified IITF to reject a 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 laboratory or IITF are considered insignificant and should not cause a laboratory or IITF to reject a specimen or cause an MRO to cancel a test:

- (1) An incorrect laboratory name and address appears at the top of the form;
- (2) Incomplete/incorrect/unreadable employer name or address;
- (3) MRO name is missing;
- (4) Incomplete/incorrect MRO address;
- (5) A transposition of numbers in the donor's SSN;
- (6) A phone number is missing/incorrect;
- (7) A fax number is missing/incorrect;
- (8) A "reason for test" box is not marked;
- (9) A "drug tests to be performed" box is not marked;
- (10) A "specimen collection" box is not marked;
- (11) The "observed" box is not marked (if applicable);
- (12) The collection site address is missing;
- (13) The collector's printed name is missing but the collector's signature is properly recorded;
- (14) The time of collection is not indicated;
- (15) The date of collection is not indicated;
- (16) Incorrect name of delivery service;
- (17) The collector has changed or corrected information by crossing out the original information on either the Federal CCF or specimen label/seal without dating and initialing the change; or
- (18) The donor's name inadvertently appears on the laboratory copy of the Federal CCF or on the tamper-evident labels used to seal the specimens.
- (19) The collector failed to check the specimen temperature box and the "Remarks" line did not have a comment regarding the temperature being out of range. If after 5 business days the collector cannot provide a memorandum for record to attest to the fact that he or she did measure the specimen temperature, the laboratory or IITF may report the test result for the specimen but indicates that the collector could not provide a memorandum to recover the omission.

(b) The following omissions and discrepancies on the Federal CCF that are made at the laboratory or IITF are considered insignificant and should not cause an MRO to cancel a test:

- (1) The testing laboratory or IITF fails to indicate the correct name and address in the results section when a different laboratory or IITF name and address is printed at the top of the Federal CCF;
- (2) The accessioner fails to print his or her name;
- (3) The certifying scientist or certifying technician fails to print his or her name;
- (4) The certifying scientist or certifying technician accidentally initials the Federal CCF rather than signing for a specimen reported as rejected for testing;
- (5) The accessioner fails to mark one of the "primary (Bottle A) specimen bottle seal intact" boxes, but the laboratory or IITF reported a "rejected for testing" result with an appropriate comment on the "Remarks" line.

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

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

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

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

(2) The certifying scientist failed to sign the paper copy (Copy 1) of the Federal CCF for a specimen being

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reported drug positive, adulterated, substituted, or invalid result; or

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

(b) If error (a)(1) occurs, the MRO must contact the collector to obtain a statement to verify that the donor refused to sign the MRO copy. If after 5 business days the collector cannot provide such a statement, the MRO must cancel the test.

(c) If error (a)(2) occurs, the MRO must obtain a statement from the certifying scientist that he or she inadvertently forgot to sign the Federal CCF, but did, in fact, properly conduct the certification review. If after 5 business days the MRO cannot get a statement from the certifying scientist, the MRO must cancel the test.

(d) If error (a)(3) occurs, the MRO must contact the HHS-certified laboratory or HHS-certified IITF. If after 5 business days the laboratory or IITF does not retransmit a corrected electronic report, the MRO must cancel the test.

Subpart P--Laboratory or IITF Suspension/Revocation Procedures

Section 16.1 When may an HHS-certified laboratory or IITF be suspended?

These procedures apply when:

(a) The Secretary has notified an HHS-certified laboratory or IITF in writing that its certification to perform drug testing under these Guidelines has been suspended or that the Secretary proposes to revoke such certification.

(b) The HHS-certified laboratory or IITF has, within 30 days of the date of such notification or within 3 days of the date of such notification when seeking an expedited review of a suspension, requested in writing an opportunity for an informal review of the suspension or proposed revocation.

Section 16.2 What definitions are used for this subpart?

Appellant. Means the HHS-certified laboratory or IITF which has been notified of its suspension or proposed revocation of its certification to perform drug and/or specimen validity testing and has requested an informal review thereof.

Respondent. Means the person or persons designated by the Secretary in implementing these Guidelines.

Reviewing Official. Means the person or persons designated by the Secretary who will review the suspension or proposed revocation. The reviewing official may be assisted by one or more of his or her employees or consultants in assessing and weighing the scientific and technical evidence and other information submitted by the appellant and respondent on the reasons for the suspension and proposed revocation.

Section 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 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 phone number of the appellant's representative. In its first written submission to the reviewing official, the respondent shall specify the name, address, and phone number of the respondent's representative.

Section 16.5 When must a request for informal review be submitted?

(a) Within 30 days of the date of the notice of the suspension or proposed revocation, the appellant must submit a written request to the reviewing official seeking review, unless some other time period is agreed to by the parties. A copy must also be sent to the respondent. The request for review must include a copy of the notice of suspension or proposed revocation, a brief statement of why the decision to suspend or propose revocation is wrong, and the appellant's request for an oral presentation, if desired.

(b) Within 5 days after receiving the request for review, the reviewing official will send an acknowledgment and advise the appellant of the next steps. The reviewing official will also send a copy of the acknowledgment to the respondent.

Section 16.6 What is an abeyance agreement?

Upon mutual agreement of the parties to hold these procedures in abeyance, the reviewing official will stay these procedures for a reasonable time while the laboratory or IITF attempts to regain compliance with the Guidelines or the parties otherwise attempt to settle the dispute. As part of an abeyance agreement, the parties can agree to extend the time period for requesting review of the suspension or proposed revocation. If abeyance begins after a request for review has been filed, the appellant shall notify the reviewing official at the end of the abeyance period advising whether the dispute has been resolved. If the dispute has been resolved, the request for review will be dismissed. If the dispute has not been resolved, the review procedures will begin at the point at which they were interrupted by the abeyance agreement with such modifications to the procedures as the reviewing official deems appropriate.

Section 16.7 What procedure is used to prepare the review file and written argument?

The appellant and the respondent each participate in developing the file for the reviewing official and in submitting written arguments. The procedures for development of the review file and submission of written argument are:

(a) Appellant's Documents and Brief. Within 15 days after receiving the acknowledgment of the request for review, the appellant shall submit to the reviewing official the following (with a copy to the respondent):

(1) A review file containing the documents supporting appellant's argument, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not to exceed 20 double-spaced pages, explaining why respondent's decision to suspend or propose revocation of appellant's certification is wrong (appellant's brief).

(b) Respondent's Documents and Brief. Within 15 days after receiving a copy of the acknowledgment of the request for review, the respondent shall submit to the reviewing official the following (with a copy to the appellant):

(1) A review file containing documents supporting respondent's decision to suspend or revoke appellant's certification to perform drug and/or specimen validity testing, tabbed and organized chronologically, and accompanied by an index identifying each document. Only essential documents should be submitted to the reviewing official.

(2) A written statement, not exceeding 20 double-spaced pages in length, explaining the basis for suspension or proposed revocation (respondent's brief).

(c) Reply Briefs. Within 5 days after receiving the opposing party's

submission, or 20 days after receiving acknowledgment of the request for review, whichever is later, each party may submit a short reply not to exceed 10 double-spaced pages.

(d) Cooperative Efforts. Whenever feasible, the parties should attempt to develop a joint review file.

(e) Excessive Documentation. The reviewing official may take any appropriate step to reduce excessive documentation, including the return of or refusal to consider documentation found to be irrelevant, redundant, or unnecessary.

Section 16.8 When is there an opportunity for oral presentation?

(a) Electing Oral Presentation. If an opportunity for an oral presentation is desired, the appellant shall request it at the time it submits its written request for review to the reviewing official. The reviewing official will grant the request if the official determines that the decision-making process will be substantially aided by oral presentations and arguments. The reviewing official may also provide for an oral presentation at the official's own initiative or at the request of the respondent.

(b) Presiding Official. The reviewing official or designee will be the presiding official responsible for conducting the oral presentation.

(c) Preliminary Conference. The presiding official may hold a prehearing conference (usually a telephone conference call) to consider any of the following: simplifying and clarifying issues; stipulations and admissions; limitations on evidence and witnesses that will be presented at the hearing; time allotted for each witness and the hearing altogether; scheduling the hearing; and any other matter that will assist in the review process. Normally, this conference will be conducted informally and off the record; however, the presiding official may, at his or her discretion, produce a written document summarizing the conference or transcribe the conference, either of which will be made a part of the record.

(d) Time and Place of Oral Presentation. The presiding official will attempt to schedule the oral presentation within 30 days of the date appellant's request for review is received or within 10 days of submission of the last reply brief, whichever is later. The oral presentation will be held at a time and place determined by the presiding official following consultation with the parties.

(e) Conduct of the Oral Presentation.

(1) General. The presiding official is responsible for conducting the oral presentation. The presiding official may be assisted by one or more of his or her employees or consultants in conducting the oral presentation and reviewing the evidence. While the oral presentation will be kept as informal as possible, the presiding official may take all necessary steps to ensure an orderly proceeding.

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

(3) Admission of Evidence. The Federal Rules of Evidence do not apply and the presiding official will generally admit all testimonial evidence unless it is clearly irrelevant, immaterial, or unduly repetitious. Each party may make an opening and closing statement, may present witnesses as agreed upon in the prehearing conference or otherwise, and may question the opposing party's witnesses. Since the parties have ample opportunity to prepare the review file, a party may introduce additional documentation during the oral presentation only with the permission of the presiding official. The presiding official may question witnesses directly and take such other steps necessary to ensure an effective and efficient consideration of the evidence, including setting time limitations on direct and cross-examinations.

(4) Motions. The presiding official may rule on motions including, for example, motions to exclude or strike redundant or immaterial evidence, motions to dismiss the case for insufficient evidence, or motions for summary judgment. Except for those made during the hearing, all motions and opposition to motions, including argument, must be in writing and be no more than 10 double-spaced pages in length. The presiding official will set a reasonable time for the party opposing the motion to reply.

(5) Transcripts. The presiding official shall have the oral presentation transcribed and the transcript shall be made a part of the record. Either party may request a copy of the transcript and the requesting party shall be responsible for paying for its copy of the transcript.

(f) Obstruction of Justice or Making of False Statements. Obstruction of justice or the making of false statements by a witness or any other person may be the basis for a criminal prosecution under

18 U.S.C. 1505 or 1001.

(g) Post-hearing Procedures. At his or her discretion, the presiding official may require or permit the parties to submit post-hearing briefs or proposed findings and conclusions. Each party may submit comments on any major prejudicial errors in the transcript.

Section 16.9 Are there expedited procedures for review of immediate suspension?

(a) Applicability. When the Secretary notifies a laboratory or IITF in writing that its certification to perform drug and specimen validity testing has been immediately suspended, the appellant may request an expedited review of the suspension and any proposed revocation. The appellant must submit this request in writing to the reviewing official within 3 days of the date the laboratory or IITF received notice of the suspension. The request for review must include a copy of the suspension and any proposed revocation, a brief statement of why the decision to suspend and propose revocation is wrong, and the appellant's request for an oral presentation, if desired. A copy of the request for review must also be sent to the respondent.

(b) Reviewing Official's Response. As soon as practicable after the request for review is received, the reviewing official will send an acknowledgment with a copy to the respondent.

(c) Review File and Briefs. Within 7 days of the date the request for review is received, but no later than 2 days before an oral presentation, each party shall submit to the reviewing official the following:

(1) A review file containing essential documents relevant to the review, tabbed, indexed, and organized chronologically; and

(2) A written statement, not to exceed 20 double-spaced pages, explaining the party's position concerning the suspension and any proposed revocation. No reply brief is permitted.

(d) Oral Presentation. If an oral presentation is requested by the appellant or otherwise granted by the reviewing official, the presiding official will attempt to schedule the oral presentation within 7-10 days of the date of appellant's request for review at a time and place determined by the presiding official following consultation with the parties. The presiding official may hold a prehearing conference in accordance with Section 16.8(c) and will conduct the oral presentation in accordance with the procedures of Sections 16.8(e), (f), and (g).

(e) Written Decision. The reviewing official shall issue a written decision upholding or denying the suspension or

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proposed revocation and will attempt to issue the decision within 7-10 days of the date of the oral presentation or within 3 days of the date on which the transcript is received or the date of the last submission by either party, whichever is later. All other provisions set forth in Section 16.14 will apply.

(f) Transmission of Written Communications. Because of the importance of timeliness for these expedited procedures, all written communications between the parties and between either party and the reviewing official shall be by facsimile, secured electronic transmissions, or overnight mail.

Section 16.10 Are any types of communications prohibited?

Except for routine administrative and procedural matters, a party shall not communicate with the reviewing or presiding official without notice to the other party.

Section 16.11 How are communications transmitted by the reviewing official?

(a) Because of the importance of a timely review, the reviewing official should normally transmit written communications to either party by facsimile, secured electronic transmissions, or overnight mail in which case the date of transmission or day following mailing will be considered the date of receipt. In the case of communications sent by regular mail, the date of receipt will be considered 3 days after the date of mailing.

(b) In counting days, include Saturdays, Sundays, and Federal holidays. However, if a due date falls on a Saturday, Sunday, or Federal holiday, then the due date is the next Federal working day.

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

In addition to any other authority specified in these procedures, the reviewing official and the presiding official, with respect to those authorities involving the oral presentation, shall have the authority to issue orders; examine witnesses; take all steps necessary for the conduct of an orderly hearing; rule on requests and motions; grant extensions of time for good reasons; dismiss for failure to meet deadlines or other requirements; order the parties to submit relevant information or witnesses; remand a case for further action by the respondent; waive or modify these procedures in a specific case, usually with notice to the parties; reconsider a decision of the reviewing official where a party promptly alleges a clear error of fact or law; and to take any other action necessary to resolve disputes in accordance with the objectives of these procedures.

Section 16.13 What administrative records are maintained?

The administrative record of review consists of the review file; other submissions by the parties; transcripts or other records of any meetings, conference calls, or oral presentation; evidence submitted at the oral presentation; and orders and other documents issued by the reviewing and presiding officials.

Section 16.14 What are the requirements for a written decision?

(a) Issuance of Decision. The reviewing official shall issue a written decision upholding or denying the suspension or proposed revocation. The decision will set forth the reasons for the decision and describe the basis therefore in the record. Furthermore, the reviewing official may remand the matter to the respondent for such further action as the reviewing official deems appropriate.

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

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

Section 16.15 Is there a review of the final administrative action?

Before any legal action is filed in court challenging the suspension or proposed revocation, respondent shall exhaust administrative remedies provided under this subpart, unless otherwise provided by Federal law. The reviewing official's decision, under Section 16.9(e) or 16.14(a), constitutes final agency action and is ripe for judicial review as of the date of the decision.

[FR Doc. E8-26726 Filed 11-24-08; 8:45 am]

BILLING CODE 4162-20-P