NRC Staff-Proposed Changes for Direct Final Rulemaking 10 CFR Part 26

Proposed Amendment to Incorporate Selected Provisions of the November 25, 2008, U.S. Department of Health and Human Services' Mandatory Guidelines for Federal Workplace Drug Testing (i.e., HHS Guidelines)

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Notes:

(1) This document will be made publicly available.
(2) The initializations and acronyms used in this document can be determined from NRC document NUREG-0544, "NRC Collection of Abbreviations," located at http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/.
(3) For further information please email FFDprogram.resource@nrc.gov.

The purposes of this document are to:

1. Facilitate early and effective public involvement, discussion, and understanding of NRC staff-proposed changes to incorporate selected provisions of the HHS Guidelines into 10 CFR Part 26 (Part 26), "Fitness for Duty Programs," and

2. Inform the NRC staff of public concerns and considerations regarding the proposed incorporation of selected HHS Guidelines' provisions into Part 26.

Recommended Changes 1-7 – Section 26.5

Description of changes:

Section 26.5 contains a list of definitions for terms that appear in Part 26. The recommended changes to this section will either add terms and definitions or revise the definitions of existing terms in Part 26. These changes will improve consistency between Part 26 and the HHS Guidelines.

Enclosure 2

Rule text change 1 – Define "Cancelled Test"

Section 26.5: *Cancelled Test* means the result reported by the MRO to the licensee or other entity when a specimen has been reported to the MRO as an invalid result (and the donor has no legitimate explanation), has been rejected for testing by the licensee testing facility or HHS-certified laboratory, or when the retesting of a single specimen or the testing of Bottle B of a split specimen fails to reconfirm the original test result.

Conforming changes:

Section 26.129(b)(1)(ii): If there is reason to believe that the integrity or identity of a specimen is in question (as a result of tampering or discrepancies between the information on the specimen bottle and on the accompanying custody-and-control forms that cannot be resolved), ~~the specimen may not be tested,~~ the laboratory shall reject the specimen for testing, and the MRO shall report a cancelled test result to the licensee and other entity. ~~and the~~ The licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine.

Section 26.129(b)(2): The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen and report a cancelled test result to the licensee or other entity:

Section 26.159(b)(1)(ii): If the licensee or other entity has reason to question the integrity and identity of the specimens, the laboratory shall reject the specimens for testing, and the MRO shall report a cancelled test result for each specimen to the licensee or other entity. ~~the specimen may not be tested and the~~The licensee or other entity shall ensure that another collection occurs as soon as reasonably practical, except if a split specimen collection was performed, either the Bottle A or Bottle B seal remains intact, and the intact specimen contains at least 15 mL of urine. In this instance, if the licensee testing facility has retained the specimen in Bottle B, the licensee testing facility shall forward the intact specimen for testing to the HHS-certified laboratory and may not conduct any testing at the licensee testing facility.

Section 26.159(b)(2): The following are exclusive grounds requiring the MRO to cancel the testing of a donor's urine specimen, and report a cancelled test result to the licensee or other entity:

Section 26.165(f)(1): If the results of testing Bottle B or retesting the aliquot of a single specimen are negative, the MRO shall report a cancelled test result to the licensee or other entity, and the licensee and other entity—.

Section 26.165(f)(2): If a donor requests that Bottle B be tested or that an aliquot of a single specimen be retested, and either Bottle B or the single specimen are not available due to circumstances outside of the donor's control (including, but not limited to, circumstances in which there is an insufficient quantity of the single specimen or the specimen in Bottle B to permit retesting, either Bottle B or the original single specimen is lost in transit to the second HHS-certified laboratory, or Bottle B has been lost at the HHS-certified laboratory or licensee testing facility), the MRO shall cancel the test, report a cancelled test result to the licensee or other entity for the donor's specimen, and inform the licensee or other entity that another collection is required under direct observation as soon as reasonably practical. The licensee or other entity shall eliminate from the donor's personnel and other records any matter that could

link the donor to the original positive, adulterated, or substituted test result(s) and any temporary administrative action, and may not impose any sanctions on the donor for a cancelled test. If test results from the second specimen collected are positive, adulterated, or substituted and the MRO determines that the donor has violated the FFD policy, the licensee or other entity shall impose the appropriate sanctions specified in subpart D of this part, but may not consider the original confirmed positive, adulterated, or substituted test result in determining the appropriate sanctions.

Basis for change:

This change to Section 26.5 will add the term "cancelled test" to improve consistency with Section 1.5 of the HHS Guidelines. While Sections 26.129(b)(2) and 26.159(b)(2) describe the exclusive grounds requiring the Medical Review Officer (MRO) to "cancel the testing of a donor's urine specimen," neither provision uses the term "cancelled test," nor is the term defined in Part 26. Adding this definition and updating Sections 26.129(b)(2) and 26.159(b)(2) will clarify these requirements and improve consistency between Part 26 and the HHS Guidelines.

In addition, changes to Sections 26.129(b)(1)(ii), 26.159(b)(1)(ii), 26.159(b)(2), 26.165(f)(1) and 26.165(f)(2) include conforming changes that will clarify existing actions taken by laboratories and MROs when a specimen is rejected for testing and the MRO reports a canceled test result.

Rule text change 2 – Define "Carryover"

Section 26.5: *Carryover* means the effect that occurs when a sample's result (e.g., drug concentration) has been affected by a preceding sample during analysis.

Basis for change:

The term "carryover" is not defined in Section 26.5, but it is used in Sections 26.137(e)(7) and 26.167(a), which require licensee testing facilities and HHS-certified laboratories to ensure that "carryover" does not contaminate the testing of a donor's specimen or otherwise affect the donor's specimen results. In addition, Sections 26.91(c)(4) and (5) describe the requirements for EBTs that prevent carryover effects from previous testing. The NRC has not received any information indicating that carryover is an issue at current HHS-certified laboratories. However, adding this definition to Part 26 will improve consistency with Section 1.5 of the HHS Guidelines and clarify the intent of the existing requirements in the rule.

Rule text change 3 – Define "Certifying scientist"

Section 26.5: *Certifying scientist (CS)* means the individual responsible for verifying the chain of custody and scientific reliability of any test result reported by an HHS-certified laboratory.

Basis for change:

The position "certifying scientist" is not defined in Section 26.5, but is discussed in Section 26.155(b). Adding this definition will improve consistency between Part 26 and the HHS Guidelines by clarifying the roles and responsibilities of the position.

Rule text change 4 – Define "Federal Drug Testing Custody and Control Form"

Section 26.5: *Federal Drug Testing Custody and Control Form (Federal CCF)* means 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., licensee testing facility, HHS-certified laboratory). The form may also be used to report the test result to the Medical Review Officer.

Conforming change:

Section 26.153(g): If licensees or other entities use a form other than the current ~~Federal custody and control form~~ *Federal Drug Testing Custody and Control Form (Federal CCF)*, licensees and other entities shall provide a memorandum to the HHS-certified laboratory explaining why a non-Federal CCF ~~form~~ was used, but must ensure, at a minimum, that the form used contains all the required information on the ~~Federal custody and control form~~ *Federal CCF*.

Basis for change:

This change to Section 26.5 will add a definition for "Federal Drug Testing Custody and Control Form" to be consistent with the term used in Section 1.5 of the HHS Guidelines. Revising the term in Section 26.153(g) will clarify the original intent of the provision. This new definition does not preclude the use of electronic versions of the Federal CCF.

Rule text change 5 – Revise the definition of "Invalid result"

Section 26.5: *Invalid result* means the result reported by an HHS-certified laboratory in accordance with the criteria established in § 26.161(f) when a positive, negative, adulterated, or substituted result cannot be established for a specific drug or specimen validity test ~~for a specimen that contains an unidentified adulterant, contains an unidentified interfering substance, has an abnormal physical characteristic,~~ For example, the specimen may contain~~s~~ inconsistent physiological constituents~~, or has an endogenous substance at an abnormal concentration~~ that prevents the laboratory from completing testing or obtaining a valid drug test result.

Basis for change:

This change to Section 26.5 will revise the definition of "invalid test result" used in Part 26 to be consistent with the term used in Section 1.5 of the HHS Guidelines. This revision also will include a reference to the invalid test result criteria in Section 26.161(f) to improve the clarity of the definition.

Rule text change 6 – Revise the definition of "HHS-certified laboratory"

Section 26.5: *HHS-certified laboratory* means a laboratory that is certified by HHS pursuant to ~~perform urine drug testing under~~ the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (the HHS Guidelines), and is listed monthly in the **Federal Register** by HHS ~~on April 11, 1988 (53 FR 11970), and as amended, June 9, 1994 (59 FR 29908), November 13, 1998 (63 FR 63483), and April 13, 2004 (69 FR 19643).~~

Basis for change:

This change to Section 26.5 will revise the definition of "HHS-certified laboratory" to accurately represent the public notification of laboratories that have HHS certification pursuant to Subpart I of the HHS Guidelines.

Rule text change 7 – Define "Rejected for testing"

Section 26.5: *Rejected for testing* means the result reported by a licensee testing facility or HHS-certified laboratory when no tests are performed for a specimen as described in Sections 26.129(b) and 26.159(b).

Basis for change:

This change to Section 26.5 will add a definition for the term "rejected for testing" that is similar to the definition in Section 1.5 of the HHS Guidelines. The term "rejected for testing" appears in Section 26.169(h)(8) as a test result that HHS-certified laboratories must include in the annual statistical summary report of urinalysis results provided to licensees and other entities. Including a definition will clarify the term. In addition, including the term and definition will align with other proposed changes in Sections 26.129(b)(1)(ii) and 26.159(b)(1)(ii) that include cancelled test results and laboratory actions to reject specimens for testing [see rule text change 1 – Define "Cancelled Test"].

Recommended Change 8(a) – 8(e) – Sections 26.31(d)(1), 26.133, 26.163(a)(1) and (b)(1), 26,169(h)(3), 26.185(g)(4) and (j)(1), 26.405(d)

Description of changes:

These changes will revise Part 26 by adding testing for MDMA/MDA/MDEA to the testing panel; updating the substances and cutoff levels for initial and confirmatory testing; eliminating 6-AM as definitive proof of heroin use, stating that it is a primary indicator of heroin use, requiring a clinical examination to evaluate the source of the 6-AM; and updating the HHS-certified laboratory annual statistical summary reporting requirements to include the expanded testing panel. These changes will ensure that Part 26 is consistent with Section 3.4 of the HHS Guidelines.

Rule change 8(a) – Specify substances tested

Description of change:

Sections 26.31(d)(1) and 26.405(d) identify the substances for which licensees and other entities are required to test. This change will add testing for MDMA/MDA/MDEA (designer drugs commonly referred to as *Ecstasy*) to the testing panel to be consistent with Section 3.4 of the HHS Guidelines.

Rule text change:

Section 26.31(d)(1): Substances tested. At a minimum, licensees and other entities shall test for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine, methylenedioxymethampthemine (MDMA), methylenedioxyamphethamine (MDA), methylenedioxyethylamphetamine (MDEA), phencyclidine, adulterants, and alcohol.

Section 26.405(d): At a minimum, licensees and other entities shall test specimens for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine, MDMA, MDA, and MDEA), phencyclidine, adulterants, and alcohol at the cutoff levels specified in this part, or comparable cutoff levels if specimens other than urine are collected for drug testing. Urine specimens collected for drug testing must be subject to validity testing.

Rule change 8(b) – Specify initial test cutoff levels

Description of change:

This change will update the substances and cutoff levels for initial testing listed in Sections 26.133 and 26.163(a)(1) to conform with changes to the HHS Guidelines in Section 3.4 as follows:

(1) Lower the initial test cutoff level for cocaine metabolites from 300 ng/mL to 150 ng/mL.
(2) Lower the initial test cutoff level for amphetamines (AMP) from 1000 ng/mL to 500 ng/mL.
(3) Clarify that for amphetamines testing, methamphetamine (MAMP) is the target analyte for AMP/MAMP testing.

(4) Clarify that the initial test cutoff level for opiate metabolites is for codeine/morphine and that morphine is the target analyte.
(5) Include initial testing for 6-Acetylmorphine at a cutoff level of 10 ng/mL.
(6) Include initial testing for MDMA at a cutoff level of 500 ng/mL.
(7) Add footnotes to the cutoff level tables consistent with Section 3.4 of the HHS Guidelines.

Rule text change:

Section 26.133:

INITIAL TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drug or metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolite	~~300~~ 150
Opiate metabolites:	~~2000~~
Codeine/Morphine [1]	2000
6-acetylmorphine (6-AM)	10
Phencyclidine (PCP)	25
Amphetamines [2]	~~1000~~
AMP/MAMP [3]	500
MDMA [4]	500

[1] Morphine is the target analyte for codeine/morphine testing.
[2] 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.
[3] Methamphetamine (MAPM) is the target analyte for amphetamine (AMP)/MAMP testing.
[4] Methylenedioxymethamphetamine.

Section 26.163(a)(1):

INITIAL TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drug or metabolites	Cutoff level [nanograms (ng)/mL]
Marijuana metabolites	50
Cocaine metabolites	~~300~~ 150
Opiate metabolies:	~~2000~~
Codeine/Morphine [1]	2000
6-acetylmorphine (6-AM)	10
Phencyclidine (PCP)	25
Amphetamines [2]	~~1000~~
AMP/MAMP [3]	500
MDMA [4]	500

[1] Morphine is the target analyte for codeine/morphine testing.
[2] 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.
[3] Methamphetamine is the target analyte for amphetamine (AMP)/methamphetamine (MAMP) testing.
[4] Methylenedioxymethamphetamine.

Conforming Changes:

Sections 26.133 and 26.163(a)(1) specify the cutoff levels for initial and confirmatory testing of specimens "to determine whether they are *negative* for the indicated drugs and drug metabolites." These changes will revise the provisions to clarify that the specified cutoff levels shall be used to determine the specimen is negative *or positive* for the indicated drug or drug metabolite being testing.

26.133 Cutoff levels for drugs and drug metabolites. Subject to the provisions of §26.31(d)(3)(iii), licensees and other entities may specify more stringent cutoff levels for drugs and drug metabolites than those in the table below and, in such cases, may report initial test results for only the more stringent cutoff levels. Otherwise, the following cutoff levels must be used for initial testing of urine specimens to determine whether they are negative or positive for the indicated drugs and drug metabolites:

26.163 Cutoff levels for drugs and drug metabolites.
(a) Initial drug testing. (1) HHS-certified laboratories shall apply the following cutoff levels for initial testing of specimens to determine whether they are negative or positive for the indicated drugs and drug metabolites, except if validity testing indicates that the specimen is dilute or the licensee or other entity has established more stringent cutoff levels:

Rule text change 8(c) – Specify confirmatory test cutoff levels

Description of change:

Section 26.163(b)(1) specifies the cutoff levels for confirmatory testing of specimens that are identified as positive on an initial drug test. These changes will conform Part 26 with Section 3.4 of the HHS Guidelines as follows:

(1) Lower the confirmatory test cutoff level for cocaine metabolite from 150 ng/mL to 100 ng/mL.
(2) Lower the confirmatory test cutoff levels for amphetamine and methamphetamine from 500 ng/mL to 250 ng/mL.
(3) Update the table footnote regarding reporting of methamphetamine positive results to lower the concentration that amphetamine also must be present in the specimen from 200 ng/mL to 100 ng/mL.
(4) Eliminate the requirement that confirmatory testing of 6-AM only proceed when confirmatory testing shows a morphine concentration exceeding 2000 ng/mL. If initial testing for 6-AM is positive, confirmatory testing for 6-AM is to proceed independent of the morphine concentration.
(5) Include confirmatory testing for MDMA, MDA, and MDEA at a confirmatory test cutoff level of 250 ng/mL.
(6) Add footnotes to the cutoff level table consistent with Section 3.4 of the HHS Guidelines.

Rule text change:

Section 26.163(b)(1):

CONFIRMATORY TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES

Drug or metabolites	Cutoff level (ng/mL)
Marijuana metabolite [1]	15
Cocaine metabolite [2]	~~150~~ 100
Opiates:	
Morphine	2000
Codeine	2000
6-acetylmorphine [3]	10
Phencyclidine (PCP)	25
Amphetamines	
Amphetamine	~~500~~ 250
Methamphetamine [34]	~~500~~ 250
MDMA	250
MDA [4]	250
MDEA [5]	250

[1] As delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).

[2] As benzoylecgonine.
[3] ~~Test for 6-AM when the confirmatory test shows a morphine concentration exceeding 2,000 ng/mL~~.To be reported positive for methamphetamine, a ~~S~~specimen must also contain amphetamine at a concentration equal to or greater than ~~200~~100 ng/mL.
[4] Methylenedioxyamphetamine.
[5] Methylenedioxyethylamphetamine.

Rule text change 8(d) – Identify 6-AM as definitive proof of heroin use

Description of change:

Currently, Sections 26.185(g)(4) and (j)(1) refer to a confirmatory test result for 6-AM as definitive proof of heroin use and that a clinical evaluation for signs of abuse is not required. These provisions are consistent with the U.S. DOT regulation 49 CFR Part 40, "Procedures for Transportation Workplace Drug and Alcohol Testing Programs," October 1, 2010. However, NRC staff are aware of rare circumstances where individuals taking very high doses of morphine may test positive for 6-AM without any evidence of heroin use. During the investigation of these rare circumstances, it was shown that the manufacturing process for morphine could result in the production of 6-AM as a by-product. As a result, NRC is proposing to eliminate the references in Sections 26.185(g)(4) and (j)(i) that a positive confirmatory test result for 6-AM is definitive proof of heroin use.

Rule text change:

Section 26.185(g)(4): If the drugs detected in a dilute specimen are any opium, opiate, or opium derivative (e.g., morphine, ~~/~~codeine) or if the drugs or drug metabolites detected indicate the use of prescription or over-the-counter medications, before determining that the donor has violated the FFD policy under paragraph (a) of this section, the MRO or his/her designee, who shall also be a licensed physician with knowledge of the clinical signs of drug abuse, shall conduct the clinical examination for abuse of these substances that is required in paragraph (j) of this section. An evaluation for clinical evidence of abuse is not required if the laboratory confirms the presence of 6-AM ~~(i.e., the presence of this metabolite is proof of heroin use) in the dilute specimen~~.

Section 26.185(j)(1): If the MRO determines that there is no legitimate medical explanation for a positive confirmatory test result for opiates and before the MRO determines that the test result is a violation of the FFD policy, the MRO or his/her designee, who shall also be a licensed physician with knowledge of the clinical signs of drug abuse, shall determine that there is clinical evidence, in addition to the positive confirmatory test result, that the donor has illegally used opium, an opiate, or an opium derivative (e.g., morphine, ~~/~~codeine). This requirement does not apply if the laboratory confirms the presence of 6-AM ~~(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. The MRO may not determine that the consumption of food products is a legitimate medical explanation for the presence of morphine or codeine at or above this concentration.

Rule text change 8(e) – Specify Annual Statistical Summary of Urinalysis Testing from the HHS-Certified Laboratory

Description of change:

This change will update the HHS-certified laboratory annual statistical summary reporting requirements to include the expanded testing panel in Sections 26.31(d)(1) and 26.405.

Rule text change:

Section 26.169(h)(3): Number of specimens reported as positive on confirmatory tests by drug or drug metabolite for which testing is conducted, including, but not limited to—

(i) Marijuana metabolite (as THCA);

(ii) Cocaine metabolite (as benzoylecgonine);

(iii) Opiates (total);
- (A) Codeine;
- (B) Morphine; and
- (C) 6-AM;

(iv) Phencyclidine;

(v) Amphetamines (total);
- (A) Amphetamine; ~~and~~
- (B) Methamphetamine;
- (C) MDMA;
- (D) MDA; and
- (E) MDEA

Basis for changes 8(a) – 8(e):

These changes will enhance consistency between Part 26 and Section 3.4 of the HHS Guidelines. The bases for the specific changes are as follows:

(1) Requiring the testing of additional substances will enable the identification of a greater range of drugs that could impair employee performance. MDMA and its derivatives, MDEA and MDA in particular, will be added to the list because of their increasing prevalence in society and adverse effect on persons in the workplace.

(2) Lowering the cutoff levels for cocaine metabolites and amphetamines will increase the timeframe in which the drugs might be identified, at levels equal to or higher than the established cutoff levels, in users after use. Increasing the window of detection for illicit drug use provides higher assurance that persons will be unable to subvert the testing process through temporarily abstinence from the drug. As a result, the lower cutoffs are expected to increase the number of urine specimens that are identified as containing cocaine metabolites and amphetamines – this proposition was indicated by drug testing performed by DOT, a review by HHS, and as assessment by Quest laboratory. The proposed changes will improve the deterrent and detection effect of the Part 26 testing program and remove more illicit drug users from authorization to NRC-licensed facilities subject to 10 CFR Part 26. In addition, the changes to Sections 26.133 and 26.163(a) create consistency with the definition provided for "cutoff" in Section 26.5, which states that

the cutoff is the concentration or decision criteria established for designating and reporting a test result as positive. The HHS Guidelines also state that initial and confirmatory cutoff concentrations are used to test and report urine specimens as "negative or positive" for a drug (73 FR71861).

(3) The most recent amendment to the HHS Guidelines (73 FR 75122, November 25, 2008) and the U.S. DOT regulation 49 CFR Part 40 (75 FR 49850, August 16, 2010) reported that research has shown that 6-AM is present in specimens even when the morphine concentration is below 2000 ng/mL and therefore conducting confirmatory testing for 6-AM only on specimens with a confirmatory test result of morphine exceeding 2000 ng/mL is no longer valid.

(4) Eliminating statements in the Commission's regulations regarding 6-AM as definitive proof of heroin use is consistent with toxicological information reviewed by NRC demonstrating that only in rare circumstances that individuals receiving high doses of morphine for pain management may test positive for 6-AM at the 10 ng/mL cutoff level.

Recommended Change 9(a) – 9(b) - Sections 26.161(c)(3), (c)(4), (c)(5), and (c)(6), 26.161(f)(5) and (f)(7)

Description of changes:

These changes will revise Part 26 by replacing "limit of detection" (LOD) with "limit of quantitation" (LOQ) as the decision point for adulterant testing and for validity test results indicating an invalid specimen based on the possible presence of halogen or an oxidizing adulterant. These changes will ensure that Part 26 is consistent with Sections 3.5 and 3.8 of the HHS Guidelines.

Recommended Change 9(a) – Replace Limit of Detection (LOD) with Limit of Quantitation (LOQ) for adulterant testing

Description of change:

Section 26.161(c) addresses the method of testing used to identify an adulterated specimen. The recommended changes will replace LOD with LOQ in this section as the decision point for adulterant testing. The changes will also revise the definition for LOQ in Part 26. These changes will align Part 26 with the HHS Guidelines requirements on adulterant testing in Section 3.5.

Rule text change:

Section 26.5: *Limit of quantitation (LOQ)* means the lowest concentration of an analyte at which the concentration of the analyte can be accurately established ~~determined under defined conditions~~.

Section 26.161(c)(3): The presence of chromium (VI) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 50 mcg/mL chromium (VI)-equivalents) 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 ~~LOD~~ LOQ of the confirmatory test on the second aliquot;

Section 26.161(c)(4): The presence of halogen (e.g., bleach, iodine, fluoride) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents or a cutoff equal to or greater than 50 mcg/mL chromium (VI) -equivalents) or a halogen colorimetric test (halogen concentration equal to or greater than the ~~LOD~~ 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 ~~LOD~~ LOQ of the confirmatory test on the second aliquot;

Section 26.161(c)(5): The presence of glutaraldehyde is verified using either an aldehyde test (aldehyde present) or the specimen yields the characteristic immunoassay response on one or more drug immunoassay tests for the initial test on the first aliquot and gas chromatography/ mass spectrometry (GC/MS) for the confirmatory test with the glutaraldehyde concentration equal to or greater than the ~~LOD~~ LOQ of the analysis on the second aliquot;

Section 26.161(c)(6): The presence of pyridine (pyridinium chlorochromate) is verified using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents or a cutoff equal to or greater than 50 mcg/mL chromium (VI) -equivalents) 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 GC/MS for the confirmatory test with the pyridine concentration equal to or greater than the ~~LOD~~ LOQ of the analysis on the second aliquot;

Recommended Change 9(b) – Replace LOD with LOQ for validity test results indicating an invalid specimen based on the possible presence of halogen or an oxidizing adulterant.

Description of change:

Section 26.161(f) addresses the method of testing used to identify invalid specimens. This change will replace LOD with LOQ as the decision point for determinations of validity test results indicating an invalid specimen based on the possible presence of halogen or an oxidizing adulterant. This change will align Part 26 with the HHS Guidelines requirements in Section 3.8.

Rule text change:

Section 26.161(f)(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 ~~LOD~~ LOQ for both the initial test and the confirmatory test on two separate aliquots or relying on the odor of the specimen as the initial test;

Section 26.161(f)(7): The possible presence of an oxidizing adulterant is determined by using the same general oxidant colorimetric test (with cutoffs equal to or greater than 200 mcg/mL nitrite equivalents, equal to or greater than 50 mcg/mL chromium (VI)-equivalents, or a halogen concentration equal to or greater than the ~~LOD~~ LOQ) for both the initial test and the confirmatory test on two separate aliquots;

Basis for changes 9(a) – 9(b):

The recommended changes will replace the LOD with the LOQ as the decision point for determinations of adulterant testing and validity test results that indicate the possible presence of halogen or an oxidizing adulterant to improve consistency with the requirements for adulterant and validity testing in Sections 3.5 and 3.8 in the HHS Guidelines.

Recommended Change 10 – Sections 26.85(c), 26.109(b), 26.111(a) and (c), 26.115(f)

Description of changes:

These changes will revise Part 26 by clarifying specimen collection procedures regarding alternative collectors, urine specimen quantity and acceptability, and collecting a urine specimen under direct observation.

Rule Change 10(a) – Clarify collection procedures for an observed collection completed by a trained observer

Description of change:

Section 26.115(f) describes the procedures for a direct observed specimen collection conducted by an individual other than the collector. The instructions apply to instances when a same gender collector is not available to observe the specimen provision and a same gender observer must be used to observe the donor provision of a specimen. The recommended changes will supplement the existing instructions for observers with more detailed information on the process changes and will improve the consistency of the Part 26 instructions with Sections 4.4(a) and 8.9 of the HHS Guidelines.

Rule text change:

Section 26.115(f): (1) If someone other than the collector is to observe the collection, the collector shall select an observer who has received training on the following subjects:

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

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

(2) ~~t~~The collector shall instruct the observer to follow the procedures in this paragraph. At the point in a routine collection where the donor enters the restroom with the collection container, ~~T~~the individual who observes the collection shall follow these procedures:

(i) The observer shall enter the restroom with the donor;

(ii) ~~(1)~~ The observer shall instruct the donor to adjust his or her clothing to ensure that the area of the donor's body between the waist and knees is exposed;

(iii) ~~(2)~~ The observer shall watch the donor urinate into the collection container. Specifically, the observer shall directly watch the urine go from the donor's body into the collection container (the use of mirrors or video cameras is not permitted);

(iv) After the donor has completed urinating in the collection container, the donor and observer shall leave the restroom and the donor shall hand the collection container directly to the collector. 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;

(v) ~~(3)~~ If the observer is not the collector, the observer may not ~~take~~ touch or handle the collection container ~~from the donor~~, but shall ~~observe the specimen as the donor takes it to the collector.~~ maintain visual contact of the collection container until the donor hands the container to the collector; and

(vi) ~~(4)~~ If the observer is not the collector, the collector shall check the box for an observed collection, record the observer's name, and write the reason for the observed collection on the custody-and-control form.

Rule change 10(b) – Clarify procedures regarding urine specimen quantity

Description of change:

This change will add a new Section 26.85(c)(6) to allow FFD program personnel to directly observe a person hydrating in order to provide a sufficient quantity of urine. The revisions to Section 26.109(b) also will clarify that the collector may continue processing other specimen collections as long as the person hydrating is under direct observation of another collector or FFD program personnel. These changes will enhance the effectiveness of the FFD program by ensuring that specimen collections are conducted efficiently.

Rule text change:

Section 26.85(c): (6) Any FFD Program person may be assigned to directly observe a person hydrating in order to provide a sufficient quantity of urine per § 26.109(b). This person shall be instructed on how to perform this duty to provide assurance that the donor cannot subvert the testing process (e.g., leave the collection site) but need not meet the qualification requirements in paragraphs (c)(1)-(4) of this section.

Section 26.109(b): If the quantity of urine in the first specimen provided by the donor is less than 30 mL, the collector shall take the following steps:

(1) The collector shall encourage the donor to drink a reasonable amount of liquid (normally, 8 ounces of water every 30 minutes, but not to exceed a maximum of 40 ounces over 3 hours) until the donor provides a specimen containing at least 30 mL. The collector shall provide the donor with a separate collection container for each successive specimen.

(A) The collector may continue processing other specimen collections as long as the person hydrating to provide a urine specimen is under direct observation of another collector or an FFD Program person per § 26.85(c)(6) and the collection area and processing methodology affords equivalent collection assurances as required by Subpart E of this part.

Rule change 10(c) – Clarify the term "altered" with regard to urine specimen acceptability

Description of change:

This change will clarify that the term "altered" used in Section 26.111 with regard to urine specimen acceptability can include "adulterated or diluted." Specifically, the phrase "(e.g., adulterated or diluted)" will be added to these provisions following the term "altered." This

change also will clarify that any FFD program personnel, in addition to a collector, may inform a donor that he or she may volunteer to submit a second specimen under direct observation.

Rule text change:

Section 26.111(a): Immediately after the donor provides the urine specimen to the collector, including specimens of less than 30 mL but greater than 15 mL, the collector shall measure the temperature of the specimen. The temperature measuring device used must accurately reflect the temperature of the specimen and not contaminate the specimen. The time from urination to temperature measurement may not exceed 4 minutes. If the temperature of a urine specimen is outside the range of 90 °F to 100 °F (32 °C to 38 °C), that is a reason to believe the donor may have altered (e.g., adulterated or diluted) or substituted the specimen.

Section 26.111(c) …In addition, the collector shall inform the donor that he or she may volunteer to submit a second specimen under direct observation to counter the reason to believe the donor may have altered (e.g., adulterated or diluted) or substituted the specimen.

Basis for changes 10(a) – (c):

The recommended changes will clarify certain Part 26 instructions regarding alternative collectors, urine specimen quantity and acceptability, and collecting a urine specimen under direct observation. The revisions will provide licensees with clearer direction regarding observer training and collection procedures for these collection situations.

Recommended Change 11 – Section 26.107(d), 26.111(e), 26.115(g)

Description of change – Clarify collector actions following refusal to test

The recommended changes will add sections to Part 26 and revise existing sections that describe collector actions to take when a refusal to test is determined during the specimen collection process. Specifically, the changes will ensure that the collector discards any urine specimens provided by the donor if a refusal to test occurs, including cases in which the donor refuses to provide a second specimen under direct observation.

Rule text change:

Section 26.107(d): If a refusal to test is determined by the collector at any point during the specimen collection process, the collector shall (1) inform the donor that a refusal to test has been determined, (2) terminate the collection process; (3) document the refusal occurrence on the CCF; (3) discard any urine specimen(s) provided by the donor; and (4) immediately contact the designated FFD program manager.

Section 26.111(e): As much of the suspect specimen as possible must be preserved, except when the collector determines that a refusal to test has occurred during the specimen collection process, in which case the collector shall discard any urine specimen(s) collected.

Section 26.115(g): If a donor declines to allow a directly observed collection that is required or permitted under this section, the donor's refusal to provide a specimen constitutes an act to subvert the testing process. The collector shall:
(1) inform the donor that a refusal to test has been determined;
(2) terminate the collection process;
(3) document the refusal occurrence on the CCF;
(4) discard any urine specimen(s) collected; and
(5) immediately contact the designated FFD Program manager.

Basis for change:

These changes will improve conformity of the urine specimen collection procedures in Part 26 with those in Section 8.12 of the HHS Guidelines and Section 40.191(d) of the DOT drug and alcohol testing requirements. The revisions will clarify the appropriate actions that a specimen collector is to take when a refusal to test is determined during the specimen collection process and will provide direction on when to discard specimen(s) that may have been provided by the donor.

Recommended Change 12 – Section 26.168(h)(1)

Description of change – Revise blind performance test sample in service requirement

Section 26.168(h)(1) requires blind performance test samples providers to place a sample lot in service for no more than 6 months. The recommended change eliminates the 6-month in service requirement. Section 26.168(h)(2) continues to require the sample supplier to provide an expiration date on each sample. This change is consistent with Section 10.2 of the HHS Guidelines, which require the supplier to provide information regarding the shelf life of the blind performance test sample.

Rule text change:

Section 26.168(h)(1): Ensure that all blind performance test sample lots are placed in service by the supplier only after confirmation by an HHS-certified laboratory~~, and for no more than 6 months~~;

Basis for change:

This change will conform Part 26 with Section 10.2 of the HHS Guidelines, which does not specify a timeline and instead requires the supplier to provide a "shelf life" for each sample. The 6-month in service limitation on each blind performance test sample lot was too restrictive given that some the suppliers indicate that sample lots can be stable for much longer than 6 months (e.g., 2 years).

Recommended Change 13 (a) – (d) – Section 26.155(a), (b), (c), (d), and (e)

Description of changes:

Section 26.155 identifies the qualifications and responsibilities of HHS-certified laboratory personnel, including the responsible person (RP), certifying scientist, and other personnel. The changes will delete requirements in Part 26 that are already detailed in the HHS Guidelines and insert references to the applicable sections in the HHS Guidelines. The HHS certifies laboratories through its National Laboratory Certification Program. This certification provides assurance that persons responsible for the conduct of drug testing at laboratories are appropriately trained and qualified and meet acceptable academic or technical requirements.

Rule text change 13(a) – Revise Responsible Person qualifications and responsibility requirements.

Description of change:

Section 26.155(a) outlines the qualifications and responsibilities of a Responsible Person (RP) managing an HHS-certified laboratory. The recommended changes to this section will consolidate the subsections under 26.155(a) into one subsection that references the applicable requirements in the HHS Guidelines.

Rule text change:

Section 26.155 (a): Day-to-day management of the HHS-certified laboratory. HHS-certified laboratories shall have a responsible person (RP) to assume professional, organizational, educational, and administrative responsibility for the laboratory's drug testing facilities. The RP shall meet the requirements in Sections 11.2, and 11.3 of the Department of Health and Human Services Mandatory Guidelines for Federal Workplace Drug Testing Programs (the HHS Guidelines), as amended. This individual shall ensure that copies of all procedures and records of the dates on which they are in effect are maintained. (Specific contents of the procedures are described in § 26.157.)

~~(1) This individual shall have documented scientific qualifications in analytical forensic toxicology. Minimum qualifications are as follows:~~

~~(i) Certification by the appropriate State as a laboratory director in forensic or clinical laboratory toxicology; or~~

~~(ii) A PhD in one of the natural sciences with an adequate undergraduate and graduate education in biology, chemistry, and pharmacology or toxicology; or~~

~~(iii) Training and experience comparable to a Ph.D. in one of the natural sciences, such as a medical or scientific degree with additional training and laboratory/research experience in biology, chemistry, and pharmacology or toxicology; and~~

~~(iv) In addition to the requirements in paragraphs (a)(1)(i) through (a)(1)(iii) of this section, the responsible person shall also have the following minimum qualifications:~~

~~(A) Appropriate experience in analytical forensic toxicology including experience with the analysis of biological material for drugs of abuse; and~~

~~(B) Appropriate training and/or experience in forensic applications of analytical toxicology (e.g., publications, court testimony, research concerning analytical toxicology of drugs of abuse, or other factors that qualify the individual as an expert witness in forensic toxicology).~~

~~(2) This individual shall be engaged in and responsible for the day-to-day management of the testing laboratory, even if another individual has overall responsibility for an entire multi-specialty laboratory.~~

~~(3) This individual shall be responsible for ensuring that there are enough personnel with adequate training and experience to supervise and conduct the work of the drug testing laboratory. He or she shall ensure the continued competency of laboratory personnel by documenting their in-service training, reviewing their work performance, and verifying their skills.~~

~~(4) This individual shall be responsible for ensuring that the laboratory has a manual of standard operating procedures that are complete, up-to-date, available for personnel performing tests, and followed by those personnel. The procedures must be reviewed, signed, and dated by this responsible person whenever the procedures are first placed into use or changed or when a new individual assumes responsibility for management of the laboratory. This individual shall ensure that copies of all procedures and records of the dates on which they are in effect are maintained. (Specific contents of the procedures are described in Sec. 26.157.)~~

~~(5) This individual shall be responsible for maintaining a quality assurance program to assure the proper performance and reporting of all test results; maintaining acceptable analytical performance for all controls and standards; maintaining quality control testing; and assuring and documenting the validity, reliability, accuracy, precision, and performance characteristics of each test and test system.~~

~~(6) This individual shall be responsible for taking all remedial actions that may be necessary to maintain satisfactory operation and performance of the laboratory in response to quality control systems not being within performance specifications, including errors in result reporting or in the analysis of performance testing results. This individual shall ensure that test results are not reported until all corrective actions have been taken and he or she can assure that the test results provided are accurate and reliable.~~

Rule text change 13(b) – Revise Certifying Scientist qualifications and responsibility requirements

Description of change:

Section 26.155(b) outlines the qualifications and responsibilities of a certifying scientist at an HHS-certified laboratory. The recommended changes will consolidate the specific education, training, and experience requirements specified in Sections 26.155(b)(1) through (b)(3) into one subsection that references the applicable requirements in the HHS Guidelines.

Rule text change:

Section 26.155(b) *Certifying scientist.*
~~(1)~~ HHS-certified laboratories shall have one or more certifying scientists who review all pertinent data and quality control results to certify the laboratory's test results. The certifying scientist shall meet the requirements in Section 11.5 of the HHS Guidelines, as amended.

~~(2) A certifying scientist shall be an individual with at least a bachelor's degree in the chemical or biological sciences, medical technology, or an equivalent field who reviews all pertinent data and quality control results. The individual shall have training and experience in the theory and practice of all methods and procedures used in the laboratory, including a thorough understanding of chain-of-custody procedures, quality control practices, and analytical procedures relevant to the results that the individual certifies. Relevant training and experience must also include the review, interpretation, and reporting of test results; maintenance of chain of custody; and proper remedial action to be taken in response to aberrant test or quality control results, or a determination that test systems are out of control limits.~~

~~(3) A laboratory may designate certifying scientists who only certify results that are reported negative and certifying scientists who certify results that are reported both negative and adulterated, substituted, dilute, or invalid.~~

Rule change 13(c) – Delete provisions for day-to-day operations and supervision of analysts

Description of change:

Section 26.155(c) outlines the requirements for day-to-day operations and supervision of analysts. The recommended changes will delete this subsection for consistency with the current HHS Guidelines.

Rule text change:

~~Section 26.155(c) Day-to-day operations and supervision of analysts. HHS- certified laboratories shall assign one or more individuals who are responsible for day-to-day operations and supervision of the technical analysts. The designated individual(s) shall have at least a bachelor's degree in the chemical or biological sciences, medical technology, or an equivalent field. The individual(s) shall also have training and experience in the theory and practice of the procedures used in the laboratory, resulting in his or her thorough understanding of quality control practices and procedures; review, interpretation, and reporting of test results; maintenance of the chain of custody; and proper remedial actions to be taken in response to aberrant test or quality control results, or the finding that test systems are out of control limits.~~

Rule change 13(d) – Revise requirements for other personnel

Section 26.155(d) outlines the requirements for "other personnel." The recommended changes will revise this subsection (now subsection (c) due to rule change 13(c) above) to reference the HHS Guidelines, which include more specific requirements.

26.155~~(d)~~(c): Other technicians and non-technical staff shall have the training and skills ~~for their assigned task~~ detailed in Section 11.6 of the HHS Guidelines, as amended.

Conforming changes:

Sections 26.155(e) and (f) will be renumbered to accommodate the revisions specified above.

Section 26.155~~(e)~~(d): Training. HHS-certified laboratories shall make available continuing education programs to meet the needs of laboratory personnel.

Section 26.155~~(f)~~(e): Files. At a minimum, each laboratory personnel file must include a résumé, any professional certification(s) or license(s), a job description, and documentation to show that the individual has been properly trained to perform his or her job.

Basis for changes 13(a) – 13(d):

Section 26.155 currently restates the qualifications and responsibilities for HHS-certified laboratory personnel that are specified in the HHS Guidelines. It is unnecessary to restate the HHS Guideline requirements in Part 26. These changes will reduce regulatory burden and improve clarity and consistency with the HHS Guidelines by replacing the Part 26 requirements with a reference to the HHS Guidelines.

Recommended Change 14 – Sections 26.137(e), 26.167(d) and (e)

Description of change – Revise requirements for quality control samples for initial and confirmatory testing

Sections 26.137(e) and 26.167(d) and (e) list the quality control samples that are required for specimens subjected to initial and confirmatory drug testing. The recommended changes will update the terminology and provisions in Part 26 to align with HHS Guidelines in Sections 11.12 and 11.14. In addition, these changes will revise the Part 26 definitions for "calibrator" and "control" to conform with the definitions in Section 1.5 of the HHS Guidelines for these terms. Finally, Section 26.167(e)(3)(iii) will be updated to specify that a calibrator with its drug concentration at the cutoff must be included as a QA sample during confirmatory testing. This change is consistent with a revision to the HHS Guidelines in Section 11.15(a)(1).

Rule text change:

Section 26.137(e)(6): A minimum of 10 percent of ~~all~~ the total specimens and quality control samples in each analytical run of specimens to be initially tested for drugs by the licensee testing facility must be quality control samples (i.e., calibrators or controls), which the licensee testing facility shall use for internal quality control purposes. (These samples are not forwarded to the HHS-certified laboratory for further testing, other than for performance testing of the samples.) Licensee testing facilities shall ensure that quality control samples that are positive for each drug and metabolite for which the FFD program conducts testing are included in at least one analytical run each calendar quarter. The quality control samples for each analytical run must include—
(i) ~~Sample(s)~~ At least one control certified by an HHS certified laboratory to contain no drug~~s~~ or drug metabolite~~s~~ (i.e., negative urine sample~~s~~);
(ii) At least one positive control with the drug~~(s)~~ or drug metabolite~~(s)~~ targeted at 25 percent above the cutoff;
(iii) At least one positive control with the drug~~(s)~~ or drug metabolite~~(s)~~ targeted at 75 ~~25~~ percent ~~below~~ of the cutoff;
(iv) A sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff (after acceptable values are obtained for the known calibrators, those values will be used to calculate sample data); and
(v) At least one positive control, certified to be positive by an HHS certified laboratory, which appears to be a donor specimen to the licensee testing facility technicians.

Section 26.167(d)(3): Quality control samples for each analytical run of specimens for initial testing must include—
(i) ~~Sample(s)~~ At least one control certified to contain no drug~~s~~ or drug metabolite~~s~~ (i.e., negative urine sample~~s~~);
(ii) At least one positive control with ~~a~~ the drug~~(s)~~ or drug metabolite~~(s)~~ targeted at 25 percent above the cutoff;
(iii) At least one positive control with ~~a~~ the drug~~(s)~~ or drug metabolite~~(s)~~ targeted at 75 ~~25~~ percent ~~below~~ of the cutoff;
(iv) A sufficient number of calibrators to ensure and document the linearity of the assay method over time in the concentration area of the cutoff (after acceptable values are obtained for the known calibrators, those values will be used to calculate sample data); and
(v) At least one control that appears to be a donor specimen to the laboratory analysts.

(4) A minimum of 10 percent of the total specimens in each analytical run must be quality control samples (i.e., calibrators or controls), as defined by paragraphs (d)(3)(i) through (iv) of this section.

Section 26.167(e): Quality control requirements for performing confirmatory drug tests. (1) Confirmatory tests for drugs and drug metabolites must be performed using gas chromatography/mass spectrometry (GC/MS) or other confirmatory test methodologies that HHS-certified laboratories are permitted to use in Federal workplace drug testing programs for this purpose.
(2) ~~At least~~ A minimum of 10 percent of the samples in each analytical run of specimens must be quality control samples (i.e., calibrators ~~and~~ or controls).
(3) Each analytical run of specimens that are subjected to confirmatory testing must include—
(i) ~~Sample(s)~~ At least one control certified to contain no drug or drug metabolite ~~(i.e., negative urine samples)~~;
(ii) ~~Positive~~ A calibrator~~(s) and control(s) with a drug(s) or drug metabolite(s)~~ with its drug concentration at the cutoff;
(iii) At least one positive control with ~~a~~ the drug~~(s)~~ or drug metabolite~~(s)~~ targeted at 25 percent above the cutoff; and
(iv) At least one ~~calibrator or~~ control ~~that is~~ targeted at or below 40 percent of the cutoff.

Conforming changes:

Section 26.5: *Calibrator* means a solution of known concentration in the appropriate matrix that ~~which~~ 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 ~~cutoff concentration and/or a~~ calibration curve over a concentration range ~~of interest~~.

Section 26.5: *Control* means a sample used to ~~monitor the status of an analysis to maintain its performance~~ evaluate whether an analytical procedure or test is operating within predefined tolerance limits.

Basis for change:

The recommended changes will update the terminology and provisions in Part 26 to align with HHS Guidelines in Sections 11.12 and 11.14. In addition, these changes will revise the Part 26 definitions for "calibrator" and "control" to conform with definitions in Section 1.5 of the HHS Guidelines. Finally, Section 26.167(e)(3)(iii) will be updated to specify that a calibrator with its drug concentration at the cutoff must be included as a QA sample during confirmatory testing. This change is consistent with a revision to the HHS Guidelines in Section 11.15(a)(1).

Recommended Change 15 – Section 26.163(a)

Description of change – Special analyses, require LOD testing for low creatinine level dilute specimens

Section 26.163(a)(2) provides licensees and other entities with the option to conduct special analyses on a donor specimen with a negative/dilute test result. Specifically, the section allows for the option of "limit of detection" (LOD) testing on dilute specimens (i.e., specimens with a creatinine concentration greater than or equal to 2 mg/dL but less than 20 mg/dL) if the immunoassay response for initial testing is equal to or greater than 50% of the cutoff calibrator in a drug class.

The NRC is proposing to include mandatory LOD testing of dilute specimens with creatinine concentrations equal to or greater than 2 mg/dL but less than or equal to 5 mg/dL to enhance consistency between the NRC and the U.S. DOT testing of dilute specimens and to enhance the detection of illicit drugs when specimens do not present normal physiological characteristics. HHS Guidelines do not address LOD testing for this situation.

Rule text change:

Section 26.163(a)(2): At the licensee's or other entity's discretion, as documented in the FFD program policies and procedures, the licensee or other entity may require the HHS-certified laboratory to conduct special analyses of dilute specimens as follows:

(i) If initial validity testing indicates that a specimen is dilute, the HHS-certified laboratory shall compare the responses of the dilute specimen to the cutoff calibrator in each of the drug classes;

(ii) If any response is equal to or greater than 50 percent of the cutoff, the HHS-certified laboratory shall conduct confirmatory testing of the specimen down to the LOD for those drugs and/or drug metabolites; and

(iii) The laboratory shall report the numerical values obtained from this special analysis to the MRO.

Section 26.163(a)(3): If initial validity testing indicates that a specimen is dilute, with a creatinine concentration greater than or equal to 2 mg/dL but less than less than 5 mg/dL, the HHS-certified laboratory shall compare the responses of the dilute specimen to the cutoff calibrator in each of the drug classes;

(i) If any response is equal to or greater than 50 percent of the cutoff, the HHS-certified laboratory shall conduct confirmatory testing of the specimen down to the LOD for those drugs and/or drug metabolites; and

(ii) The laboratory shall report the numerical values obtained from this special analysis to the MRO.

Basis for change:

The DOT drug testing policy in 49 CFR 40.197(b)(1) requires action (i.e., a second specimen collection under direct observation) for donors with dilute negative test results with creatinine concentrations equal to or greater than 2 mg/dL but less than or equal to 5 mg/dL. Because NRC provides licensees and other entities with an option to conduct LOD testing (§ 26.163(a)(2)) for dilute specimens, if a licensee or other entity does not conduct the special analyses, no additional action is taken for donor specimens with very low creatinine concentrations. This action to require LOD testing of dilute specimens with creatinine

concentrations equal to or greater than 2 mg/dL but less than or equal to 5 mg/dL enhances consistency between the NRC and the DOT testing requirements for dilute specimens. It also increases the detection of illicit drugs when specimens do not present normal physiological characteristics.

Recommended Change 16 – Section 26.185(f) (and conforming changes)

Description of change – Require additional MRO review for invalid specimens with pH 9.0 to 9.5

Section 26.185(f) documents the appropriate process for reviewing invalid specimens. The recommended change will permit the MRO to solicit information regarding the time and temperature conditions of the specimen's collection, receipt, transportation, and storage. The change will permit the MRO to consider evidence that elapsed time and high temperature may have affected the test results for a specimen with pH between 9.0 and 9.5, in the case that no acceptable medical explanation is provided.

Rule text change:

Section 26.131(b)(2): The pH of the specimen is either less than 4.5 or equal to or greater than 9, using either a colorimetric pH test with a dynamic range of 2 to 12 or pH meter that is capable of measuring pH to one decimal place (for initial validity tests), or colorimetric pH tests, dipsticks, and pH paper (for pH validity screening tests) that have a narrow dynamic range. If the pH is greater than 9.0, the licensee test facility shall document on the CCF the pH value, time the pH was measured, the ambient temperature of the room in which the pH was measured, and the ambient temperature of the storage location for the specimen prior to shipment to the HHS-certified laboratory.

Section 26.185(f): *Review of invalid specimens.*

(1) If the HHS-certified laboratory reports an invalid result, the MRO shall consult with the laboratory to determine whether additional testing by another HHS-certified laboratory may be useful in determining and reporting a positive or adulterated test result. If the MRO and the laboratory agree that further testing would be useful, the HHS-certified laboratory shall forward the specimen to a second laboratory for additional testing.

(2) If the MRO and the laboratory agree that further testing would not be useful and there is no technical explanation for the result, the MRO shall contact the donor and determine whether there is an acceptable medical explanation for the invalid result. If there is an acceptable medical explanation, the MRO shall report to the licensee or other entity that the test result is not an FFD policy violation, but that a negative test result was not obtained. If the medical reason for the invalid result is, in the opinion of the MRO, a temporary condition, the licensee or other entity shall collect a second urine specimen from the donor as soon as reasonably practical and rely on the MRO's review of the test results from the second collection. The second specimen collected for the purposes of this paragraph may not be collected under direct observation. If the medical reason for the invalid result would similarly affect the testing of another urine specimen, the MRO may authorize an alternative method for drug testing. Licensees and other entities may not impose sanctions for an invalid test result due to a medical condition.

(3) If the MRO and the laboratory agree that further testing would not be useful and there is no legitimate technical or medical explanation, and the invalid result is based on pH in the range of 9.0 to 9.5, the MRO shall consider whether there is evidence of elapsed

time and/or high temperature that could account for the pH value. If an acceptable explanation exists for the invalid test result due to pH, based on objective and sufficient information, that elapsed time and/or high temperature caused the high pH and donor action did not result in the invalid pH result, the MRO shall report a cancelled test result to the licensee or other entity, cancel the test result, and direct the licensee or other entity to collect a second urine specimen from the donor as soon as reasonably practicable. The second specimen collected may not be collected under direct observation.

(i) In determining whether objective and sufficient information exists, the MRO shall:
- (A) Contact, as needed, the collection site, transportation company, licensee testing facility, and/or HHS-certified laboratory to the discuss time and temperature timeline associated with the particular specimen;
- (B) Consider whether other specimens subject to same day collection, transportation, storage, and temperature characteristics were adversely affected;

(ii) The MRO shall also exercise professional judgment in applying the following objective principles:
- (A) If the elapse time between collection and the time in which the HHS-certified laboratory conducted its initial validity test for pH between 9.0 and 9.5 is greater than 48 hours, the MRO should consider cancelling the test.
- (B) If the elapsed time was between 24 and 48 hours, and the urine was transferred or stored at a temperature greater than 98 degrees Fahrenheit, the MRO should consider cancelling the test.
- (C) If the elapse time was less than 24 hours and the pH was between 9.0 and 9.5, the MRO shall implement 26.185(f)(4).

~~(3)~~(4) If the MRO and the laboratory agree that further testing would not be useful and there is no legitimate technical or medical explanation for the invalid test result, the MRO shall require that a second collection take place as soon as practical under direct observation. The licensee or other entity shall rely on the MRO's review of the test results from the directly observed collection

Basis for change:

This change will conform Part 26 with Section 13.4(f) of the HHS Guidelines. Recent research indicates that a specimen exposed to high temperatures and/or an extended period of time (between specimen collection and pH testing) may result in a pH in the range of 9.0 to 9.5. Therefore, for invalid specimen results based on pH from 9.0 to 9.5, the MRO is to evaluate alternative, non-medical explanations that may have caused the specimen result. Examples of non-medical explanations are, but not limited to: an extended period of time (over 24 hours) between specimen collection and pH testing; high temperature exposure during specimen handling, transport and/or storage; and a combination of an extended period of time and high temperature. The recommended change will enable the MRO to consider time and temperature as an alternative, non-medical explanation for this type of invalid result.

Recommended Change 17 – Section 26.165(b)(2)

Description of change – Require documentation for donor request for specimen retesting or Bottle B testing

Section 26.165(b)(2) states that, within 3 business days of receiving notification of a positive, adulterated, or substituted test result, the donor may request retesting of the single specimen or the testing of the Bottle B split specimen. The recommended change will revise Section 26.165(b) to require the MRO to document a verbal request received from the donor for single specimen retesting and Bottle B testing.

Rule text change:

Section 26.165(b)(2): The MRO shall inform the donor that he or she may, within 3 business days of notification by the MRO of the confirmed positive, adulterated, or substituted test result, request the retesting of an aliquot of the single specimen or the testing of the Bottle B split specimen. The MRO shall provide the donor with specific instructions for making this request (i.e., providing telephone numbers or other contact information). The MRO shall have the ability to receive the donor's calls at all times during the 3-day period (e.g., by use of an answering machine with a "time stamp" feature when there is no one in the MRO's office to answer the phone). The donor's request may be oral or in writing. The MRO shall document in his or her records the verbal request from the donor to retest an aliquot of a single specimen or test the Bottle B from a split specimen.

Conforming change:

Section 26.165(b)(3): The donor shall provide his or her permission for retesting an aliquot of the single specimen or the testing of bottle B. Neither the licensee, MRO, NRC, nor any other entity may order retesting of a single specimen or testing of a specimen in Bottle B without the donor's written permission, except as permitted in § 26.165(b)(2) and § 26.185(l).

Basis for change:

This change will conform Part 26 with Section 14.1(b) of the HHS Guidelines. Documenting the verbal request will provide a record that the donor initiated the request within 3 business days of notification of the result by the MRO, as required by Section 26.165(b)(2).

Recommended Change 18 – Sections 26.165(f)(2) and 26.115(a)

Description of change – Require immediate recollection of second specimen under direct observation when Bottle B or aliquot is not available for testing

Section 26.165(f)(2) states that for a MRO-confirmed positive, adulterated, or substituted test result, if the Bottle B of a split specimen or an aliquot of a single specimen is not available for testing, the MRO shall cancel the initial test result and inform the licensee or other entity that a second specimen must be collected under direct observation "as soon as reasonably practical." Section 14.1(c) of the HHS Guidelines requires the MRO to report the cancelled test to the licensee and direct the licensee to ensure the collection of another specimen under direct observation with no advanced notice for the donor. This change will revise Section 26.165(f)(2) to be consistent with the HHS Guidelines. This change also will clarify that the licensee shall continue to administratively withdraw the individual's authorization until the results of the second specimen collection are determined.

Rule text change:

Section 26.165(f)(2): If a donor requests that Bottle B be tested or that an aliquot of a single specimen be retested, and either Bottle B or the single specimen are not available due to circumstances outside of the donor's control (including, but not limited to, circumstances in which there is an insufficient quantity of the single specimen or the specimen in Bottle B to permit retesting, either Bottle B or the original single specimen is lost in transit to the second HHS-certified laboratory, or Bottle B has been lost at the HHS-certified laboratory or licensee testing facility), the MRO shall cancel the test, report a cancelled test result to the licensee or other entity, and ~~inform~~ direct the licensee or other entity ~~that another~~ to conduct an immediate collection of a second specimen ~~is required~~ under direct observation ~~as soon as reasonably practical~~. The donor shall receive no notice of the collection requirement until immediately before the notice to proceed to the collection site. The licensee or other entity shall continue to administratively withdraw the individual's authorization, as required by Section 26.165(f)(1) until the results of the second specimen collection have been received by the MRO. The licensee or other entity shall eliminate from the donor's personnel and other records any matter that could link the donor to the original positive, adulterated, or substituted test result(s) and any temporary administrative action, and may not impose any sanctions on the donor for a cancelled test. If test results from the second specimen collected are positive, adulterated, or substituted and the MRO determines that the donor has violated the FFD policy, the licensee or other entity shall impose the appropriate sanctions specified in subpart D of this part, but may not consider the original confirmed positive, adulterated, or substituted test result in determining the appropriate sanctions.

Section 26.115(a): Procedures for collecting urine specimens must provide for the donor's privacy unless directed by this subpart or the MRO or FFD program manager determines that a directly observed collection is warranted. The following circumstances constitute the exclusive grounds for performing a directly observed collection:

(1) The donor has presented, at this or a previous collection, a urine specimen that the HHS-certified laboratory reported as being substituted, adulterated, or invalid to the MRO and the MRO reported to the licensee or other entity that there is no adequate medical explanation for the result;

(2) The donor has presented, at this collection, a urine specimen that falls outside the required temperature range;

(3) The collector observes conduct clearly and unequivocally indicating an attempt to dilute, substitute, or adulterate the specimen; ~~and~~

(4) A directly observed collection is required under § 26.69~~.~~; and

(5) The donor requests a retest and either Bottle B or the single specimen is not available due to circumstances outside of the donor's control, as required under § 26.165(f)(2).

Basis for change:

This change will conform Part 26 with Section 14.1(c) of the HHS Guidelines as follows: in the case that an original specimen is unavailable when a donor requests that Bottle B be tested or that an aliquot of a single specimen be retested, a second specimen will be collected immediately, under direct observation, and without advanced notice to the donor. This helps ensure that the donor does not have an opportunity to subvert the testing process by temporarily abstaining from drug use, becoming unavailable for the test, or by diluting, adulterating, or substituting the urine specimen. Furthermore, the re-test process parallels that which would be conducted for a random test. This change also will clarify that the MRO shall report the cancelled test result to the licensee or other entity, consistent with the HHS Guidelines. Lastly, the change will clarify that the licensee shall continue to administratively withdraw the donor's authorization until the test results of the second specimen collection are determined, which is consistent with the requirements in Section 26.165(f)(1).

Recommended Change 19 – Section 26.167(d)(1)

Description of change – Provide option to use confirmatory test methodologies for initial testing at an HHS-certified laboratory

Section 26.167(d)(1) describes the quality control requirements for performing initial drug tests at an HHS-certified laboratory and requires the use an immunoassay that meets the requirements of the Food and Drug Administration for commercial distribution. The change would permit licensees and other entities with the option of requiring the HHS-certified laboratory to use a confirmatory test methodology permitted in Federal workplace drug testing programs for initial testing if so desired.

Rule text change:

Section 26.167(d)(1): Any initial drug test performed by an HHS-certified laboratory must use, at least, an immunoassay that meets the requirements of the Food and Drug Administration for commercial distribution. A licensee or other entity may request that the laboratory use any confirmatory test methodology permitted for use in Federal workplace drug testing programs for this purpose. Non-instrumented immunoassay testing devices that are pending HHS/SAMHSA review and approval may not be used for initial drug testing under this part.

Basis for change:

The current rule limits initial drug testing to immunoassay testing technology. By revising the rule to permit the use of confirmatory test methodologies (e.g., GC/MS, GC/MS/MS, LC/MS, LC/MS/MS), NRC is providing licensees and other entities with the option to use more advanced testing technologies for initial drug testing.

Identified Inconsistencies in Terminology Used in Part 26

1. Variations in the spelling of "chain of custody" and "custody and control"

The HHS Guidelines uses the term, "chain of custody," to refer to the tracking of a specimen's handling and storage. The HHS Guidelines use the term, "custody and control form," to refer to the form used to document the "chain of custody." However, Part 26 uses variations of both of these terms, and derivations of these forms interchangeably, creating confusion around the tracking process and the required documentation for drug test specimens.

Use of Chain of Custody and Term Derivations

Term	Section
chain of custody	26.5 26.117(k) 26.129(d), (h) 26.137(a) 26.155(b)(2) 26.159(g) 26.167(a)
chain-of-custody	26.89(d) 26.127(b) 26.153(d) 26.155(b)(2) 26.157(b)
chain-of-custody form	26.129(c)
chain-of-custody document	26.715(b)(2)

Use of Custody and Control and Term Derivations

Term	Section	
custody and control	26.5 26.87(f)(5) 26.129(c) 26.129(d)	
custody-and-control form	26.85(a)(1) 26.87(f)(3) 26.87(f)(5) 26.107(b) 26.113(b)(3) 26.115(d) 26.115(f)(4) 26.117(d) 26.117 (e) 26.117 (g) 26.117 (i) 26.117 (k) 26.119(b) 26.119(b)(1)(ii) 26.119(b)(2)(i) 26.119(g)	26.119(h) 25.153(g) 26.159(b) 26.159(b)(1) 26.159(b)(2)(i) 26.159(e) 26.159(f) 26.159(g) 26.159(h)(2) 26.169(f) 26.169(g) 26.183(d)(2)(ii) 26.185(d)(3)

Recommendation:
Consider revising Part 26 to consistently use terminology to describe the tracking process and the required documentation for drug test specimens. To be consistent with the HHS Guidelines, Part 26 should use the terms "chain of custody" and "custody and control form."

2. Use of "Practical," "practicable," and "possible"

Part 26 includes a variety of phrases using "practical", "practicable", or "possible" to convey a timeframe to complete a required action. The variety of terms may be confusing to regulated entities and a consistent application of terms may improve the clarity of provisions in Part 26.

2(a) Use of Practical, Practicable, and Possible

Term	Phrasing	Section
Practical	as soon as practical	26.31(c)(3) 26.95(a) 26.129(b)(1) 26.129(c) 26.185(f)(3) 26.405(c)(3)
	as soon as reasonably practical	26.93(b) 26.117(j) 26.129(b)(1)(ii) 26.129(e) 26.159(b)(1)(ii) 26.165(b)(5) 26.165(f)(2) 26.185(f)(2)
	at the earliest reasonable and practical opportunity	26.31(d)(2)(v) 26.89(a)
Practicable	as soon as practicable	26.91(e)(4)(ii)
	as soon as reasonably practicable	26.31(d)(2)(iii) 26.115(b) 26.405(b)(2)
Possible	as soon as possible	26.101(a) 26.111(c)

2(b) Sections regarding feasibility vs. capability of performing an action

Part 26 also uses the words "practical" or "practicable" as a qualifier for a set of instructions. It is unclear whether these terms were intended to direct licensees and other entities to perform an action when it is convenient or effective ("practical") or when it is simply possible ("practicable"). These sections include:

Phrasing	Section
where practicable	26.11
when reasonably practicable	26.189(d)
to the extent practicable	26.207(a)(2)
if it is impractical for the individual to comply with a treatment plan	26.69(e)(1)
if practical, a water coloring agent that meets the requirements of § 26.87(e)(1) must be placed in the toilet bowl to be used by the donor and in any other accessible source of standing water, including, but not limited to, the toilet tank.	26.87(f)(2)
If it is impractical to maintain continuous physical security of a collection site from the time a urine specimen is presented until the sealed container is transferred	26.87(f)(5)

Recommendation:

Consider revising Part 26 to use consistent terms regarding the timeframes for required actions.

Note The HHS Guidelines uses the term, "as soon as practicable," although it only appears once in the document. The DOT's Part 40 uses the terms, "as soon as possible" and also describes the timeframe for required actions as "practicable."