Handout #1

Recommended changes to 10 CFR Part 26 for Direct Final Rulemaking to address revisions to the HHS Mandatory Guidelines for Federal Drug Testing Programs (published 11/25/08)

(Please refer to the attached table for additional information)

- Consistent with Section 1.5 of the HHS Guidelines, add the following terms and definitions to the rule:
    - Cancelled test
    - Carryover
    - Certifying scientist
    - Chain of custody (COC)
    - Federal Drug Testing Custody and Control Form (Federal CCF)
    - Rejected for testing.

- Consistent with Section 1.5 of the HHS Guidelines, revise the definitions of the following terms in the rule:
    - HHS-certified laboratory
    - Invalid result.

- Consistent with Sections 3.1 and 3.4 of the HHS Guidelines, revise the rule to lower the cutoff levels for cocaine, amphetamine, and methamphetamine, add testing for MDMSA (Ecstasy), and add initial testing for 6-acetylmorphine (6-AM).

- Consistent with Sections 3.5 of the HHS Guidelines, revise the rule to require limit of quantitation (LOQ) testing rather than limit of detection (LOD) testing for adulterant testing.

- Consistent with Sections 4.4(a)(3) and 8.9 of the HHS Guidelines, revise the rule to include additional information to provide to an observer in instances when a same gender collector is not available to observe the specimen provision during an observed collection.

- Consistent with Section 8.12 of the HHS Guidelines, add requirement to direct the collector to discard any urine specimen(s) collected if a refusal to test is determined during the collection process.

- Consistent with Section 10.2 of the HHS Guidelines, revise the rule to allow blind performance test sample lots to remain in service until the expiration date stipulated by the manufacturer.

- Consistent with Section 11.2 of the HHS Guidelines, revise the rule to state that the Responsible Person and certifying scientist at HHS Certified laboratories must meet the requirements in the HHS Guidelines.

- Consistent with Section 11.15(a)(1) of the HHS Guidelines, revise the rule to require a positive calibrator "at the cutoff" to be included as a QC specimen in each analytical run of specimen confirmatory drug testing.

- Consistent with Section 13.4(b) of the HHS Guidelines and U.S. DOT requirements in 49 CFR 40.197(b)(1), consider revising the rule to require mandatory action for dilute/negative drug test results with low creatinine concentrations (equal to or greater than 2 mg/dL and less than or equal to 5 mg/dL):
    - Require LOD testing, or
    - Require a second specimen collection under direction observation, or
    - Maintain existing Section 26.163(a)(2) optional LOD testing.

- Consistent with Section 13.4(f) of the HHS Guidelines, revise the rule to require the MRO to investigate and consider time and temperature as potential non-medical reasons for an invalid test result for pH between 9.0-9.5.

- Consistent with Section 14.1(b) of the HHS Guidelines, revise the rule to require the MRO to document a donor's verbal request for split specimen testing or single specimen retesting.

- Consistent with Section 14.1(c) of the HHS Guidelines, revise the rules to require:
  (1) an immediate recollection in cases where a split specimen cannot be tested;
  (2) that no notice to the donor be given for recollection until immediately before the collection; and

  * That the provisions in Section 26.75(e)(1) are followed until a determination can be made based on the second specimen collected.

Table 1. HHS Guidelines Revisions (2008) - Description of Potential Changes to Part 26 for Direct Final Rulemaking

ID	HHS Guidelines Section	Description of HHS Guidelines Revision	Description of (Potential) Change to Part 26	Reasoning for (Potential) Change to Part 26
1	1.5	Revised the definition of "cancelled test" to improve its clarity.	Include "cancelled test" in Section 26.5, using a definition consistent with that in the HHS Guidelines.	Using the term "cancelled test" will improve consistency with Part 26 and the HHS Guidelines. Sections 26.129(b)(2) and 26.159(b)(2) list the exclusive grounds requiring the MRO to "cancel the testing of a donor's urine specimen" which align with the applicable "rejected for testing" criteria in Section 15.1 of the HHS Guidelines.
2	1.5	Added the term "carryover."	Include "carryover" in Section 26.5, using a definition similar to that in the HHS Guidelines.	Sections 26.137(e) and 26.167(a) require HHS-certified laboratories and licensee testing facilities to implement and document procedures to ensure that "carryover" does not contaminate the testing of a donor's specimen. However, Part 26 does not define the term "carryover."
3	1.5	Revised the definition of "certifying scientist."	Include "certifying scientist" in Section 26.5, using a definition similar to that in the HHS Guidelines. Revise Section 26.155(b)(3) to allow the certifying scientist to certify all test results, consistent with the definition.	This revision would conform Part 26 with the HHS Guidelines.
4	1.5	Terms “chain of custody (COC)" and "Federal Drug Testing Custody and Control Form (Federal CCF)."	Include "chain of custody (COC)" and "Federal Drug Testing Custody and Control Form (Federal CCF) in Section 26.5, using definitions similar to those in the HHS Guidelines. The term "chain-of-custody" is used throughout Part 26 but a definition is not included in Section 26.5. Section 26.153(g) refers to "non-Federal custody-and-control form" but does not define the term "Federal custody-and-control form".	Adding these definitions will improve consistency with HHS Guidelines. Section 26.153(g) requires licensees and other entities to provide a memorandum for the record to the HHS-certified laboratory to document use of a non-Federal custody-and-control form. Under the HHS Guidelines, laboratories may reject any specimen that is submitted for testing with a non-Federal custody-and-control form.
5	1.5	Revised the definition of "invalid result" to refer to the criteria in Section 3.8 of the HHS Guidelines.	Revise the definition of "invalid result" in Section 26.5 to improve consistency with the HHS Guidelines and to include a reference to Section 26.161(f) which contains the criteria on invalid test results.	This revision would conform Part 26 with the HHS Guidelines.
6	1.5	Revised the definition of "laboratory" to state that the laboratory is a permanent location.	Revise the definition of "HHS-certified laboratory" in Section 26.5 to include the latest amendments to the HHS Guidelines (73 FR 71858).	This revision will clarify that HHS-certified laboratories must be certified in accordance with the current HHS Guidelines.

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ID	HHS Guidelines Section	Description of HHS Guidelines Revision	Description of (Potential) Change to Part 26	Reasoning for (Potential) Change to Part 26
7	1.5	Revised the definition of "rejected for testing".	Include "rejected for testing" in Section 26.5, using a definition similar to that in the HHS Guidelines.	Using the term "rejected for testing" will improve consistency with Part 26 and the HHS Guidelines. Sections 26.129(b)(2) and 26.159(b)(2) list the exclusive grounds requiring the MRO to "cancel the testing of a donor's urine specimen" which align with the applicable "rejected for testing" criteria in Section 15.1 of the HHS Guidelines.
8	3.1, 3.4	Lowered the cutoff levels for cocaine and amphetamine), added testing for MDMA (Ecstasy), and added initial testing for 6-acetylmorphine (6-AM)	Revise Section 26.31(d)(1) to include MDMA in the substances that must be tested. Revise Section 26.133 for drug testing at licensee testing facilities (change cutoff levels for cocaine and amphetamine; add 6AM testing, add MDMA testing) Revise Section 26.163 for drug testing at HHS-certified laboratories (change cutoff levels for cocaine, amphetamine, methamphetamine; add 6AM testing on initial testing, change when confirmatory testing is conducted for 6AM (no longer based on morphine), add MDMA testing) Revise Section 26.185(g)(4) and (j)(1) to clarify that 6-AM is likely but not conclusive evidence of heroin use, as it may also indicate morphine use.	This revision would conform Part 26 with the HHS Guidelines.
9	3.5	Revised to use the limit of quantification (rather than limit of detection) as the decision point for adulterant testing.	Revise Section 26.161 to require the use of LOQ testing rather than LOD testing to identify and quantify the presence of adulterants. A definition for LOQ is already included in Section 26.5.	This revision would conform Part 26 with the HHS Guidelines.
10	4.4(a)(3), 8.9	Added procedures on how to conduct an observed collection.	Revise Section 26.115(f) to include additional information to provide to an observer in instances when a same gender collector is not available to observe the specimen provision during an observed collection (based on Section 4.4(a)(3) of the HHS Guidelines).	This revision will increase consistency with the HHS Guidelines, and will provide licensees clearer direction regarding the training of collection observers.

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11	8.12	Added instruction for collector to discard any urine collected when a refusal to test occurs during the collection process.	Add requirements in new subparagraphs (Sections 26.107(d) and 26.111(d)(ii)) to require the collector to discard any urine specimen(s) provided by a donor if a refusal to test action is determined by the collector during the specimen collection process. Revise Section 26.115(g) to require the collector to discard the initial specimen collected if the donor refuses to provide a second specimen under direct observation. Move current Section 26.111(e) to Section 26.111(d)(i). Consult with stakeholders to determine how to address specimens of less than 15 mL that the collector believes might be adulterated (26.111(c)). Consider the need for the revision in a future rulemaking.	The revisions to Part 26 will clarify the collector's actions in the case of a refusal to test, and will ensure that collected specimens are not tested (an unnecessary action). These revisions will conform Part 26 specimen collection procedures with those in the HHS Guidelines.
12	10.2	HHS Guidelines specify that the blind performance test sample supplier is to provide information regarding the shelf life of the blind sample.	Revise Section 26.168(h)(1) to conform with the HHS Guidelines which requires sample suppliers to specify the shelf life of blind samples but does not specify the period of time. Section 26.168(h)(1) limits the shelf life of a blind performance test sample lots to no more than 6 months.	Industry feedback has indicated that some blind performance test sample lots last as long as 2 years. The NRC staff recognizes that advancements in the manufacturing of blind performance samples can extend the period of time for which they are viable, and that manufacturers are in good position to determine an accurate shelf life for the samples. This revision would conform Part 26 with the HHS Guidelines.
13	11.2	Added that the Responsible Person (RP) qualify as a certifying scientist.	Reduce the list of requirements in Section 26.155 by combining current requirements in Section 26.155(a) through (d) into a single requirement that the Responsible Person must meet the requirements in the HHS Guidelines. Revise Section 26.155(e) to require training specific to Part 26. Retain personnel file requirements in current Section 26.155(f).	The requirements in 26.155(a) through (d) are intended to be identical to the requirements in the HHS Guidelines. The revision to 26.155(e) clarifies that training requirements should include training specific to Part 26. The requirement in 26.155(e) is specific to Part 26 and should be retained.
14	11.15(a)(1)	Revised so that each confirmatory drug test batch must include "A calibrator with its drug concentration at the cutoff" to allow multi-point calibration while still requiring a cutoff calibrator.	Revise Section 26.167(e)(3)(ii) to require a positive calibrator "at the cutoff" to be included as a QC specimen in each analytical run of specimen confirmatory drug testing.	This revision will conform Part 26 with a change in the HHS Guidelines.

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15	13.4(b)	Section 13.4(b) requires another specimen be collected from a donor if the initial result is negative and dilute. [existing Guidelines provision]	Section 26.163(a)(2) provides licensees and other entities with the option to conduct limit of detection (LOD) testing if a specimen is dilute and the response to the immunoassay drug test is equal to or greater than 50 percent of the cutoff. The HHS Guidelines require a second specimen be collected from a donor with a negative/dilute initial specimen test result. U.S. DOT 49 CFR 40.197(b)(1) requires a second specimen collection (under direction observation) for a dilute/negative specimen with creatinine concentration greater than or equal to 2 mg/dL and less than or equal to 5 mg/dL. U.S. DOT 49 CFR 40.197(b)(1) provides optional second specimen collection (not under direct observation) for dilute/negative results with a creatinine concentration greater than 5 mg/dL. Potential Part 26 regulatory options for consideration: - require LOD testing for negative/dilute specimens of greater than or equal to 2 mg/dL and less than or equal to 5 mg/dL creatinine concentration. - require a second specimen collection under direction observation for negative/dilute specimens with creatinine concentration of greater than or equal to 2 mg/dL and less than or equal to 5 mg/dL. - maintain existing 26.163(a)(2) optional LOD testing.	Section 26.163(a)(2) provides licensees and other entities with an optional approach to further evaluate a donor's specimen based on a negative/dilute specimen test result. However, U.S. DOT policy requires an additional specimen collection for donor specimens with low creatinine levels (greater than or equal to 2 mg/dL and less than or equal to 5 mg/dL). Many licensees already conduct LOD testing on all dilute specimens per 26.163(a)(2) and a requirement to conduct LOD testing for low creatinine dilute negative specimens would not be a change in current testing policy.
16	13.4(f)	Added guidance for the MRO to interpret invalid test results based on a pH from 9.0 to 9.5.	Add a paragraph to Section 26.185(f) to require the MRO to consider a non-medical explanation (i.e., time and temperature issues) as a potential cause of an invalid urine pH of 9.0 to 9.5.	The current rule does not include a requirement for the MRO to consider how time and temperature could cause a urine specimen pH result of 9.0 to 9.5. This change is needed for consistency with the HHS Guidelinesand improves the review of invalid test results. Recent research supports that high temperature for an extended time may increase urine
17	14.1(b)	Revised to allow the MRO to request split specimen testing based on a verbal request from the donor, but the MRO must document the donor's verbal request.	Revise Section 26.165(b)(2) to state that the MRO must document the donor's verbal request for split specimen testing or single specimen retesting.	The change will conform Part 26 with the HHS Guidelines. Documentation of a donor's verbal request ensures that a record exists to demonstrate that the request was received within 3 business days permitted by rule.

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18	14.1(c)	Requires the MRO to cancel the initial test result and direct the immediate collection of a second specimen under direct observation if Bottle B of a split specimen cannot be tested.	Section 26.165(f)(2) requires the MRO to cancel the initial test result if the Bottle B of a split specimen or an aliquot of a single specimen cannot be tested. A second specimen must then be collected under direction observation as soon as reasonably practical. Revise 26.165(f)(2) to require an immediate second collection under direct observation given that the initial test result was a confirmed positive. Also stipulate that the donor should not be given notice until immediately before proceeding for the specimen collection. Include a provision to ensure that the individual's access is terminated until a determination is made on the results of the second specimen collected under	These changes will conform Part 26 with HHS Guidelines.