(40)

DRAFT 12/7/05

DOCKET NUMBER
PROPOSED RULE PR 26
(70FR 50442)

Comments for NRC 10 CFR Part 26
RIN 3150-AF12
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DOCKETED
USNRC

December 20, 2005 (9:58am)

OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

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December 19, 2005

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001
Attention: Rulemaking and Adjudications Staff
Transmitted via e-mail to SECY@nrc.gov

Dear Secretary:

Please find attached my comments for the NRC's proposed rule, 10 CFR Part 26, RIN 3150-AF12.

I am a consultant in the field of forensic toxicology, specifically to SAMHSA in the area of laboratory certification. I have served on SAMHSA's Drug Testing Advisory Board from 2001 until September 2005 and was involved in helping to draft the current HHS Guidelines (69 FR 19643) and the proposed HHS Guidelines (69 FR 19672). I offer my comments as a comparison of NRC's proposed rules versus HHS Guidelines.

If you have any question, please do not hesitate to contact me.

Sincerely,
Sue Brown, Ph.D.

Template = SECY-067

SECY-02

Note: Reference to HHS Guidelines is to HHS Guidelines April 13, 2004 (69 FR 19643)

Section 26.5 Definitions

Aliquot. Preamble states definition has been changed to 'be consistent with the same definition in the HHS Guidelines.' The definition is not worded exactly the same.
HHS Guidelines: "A fractional part of a specimen used for testing. It is taken as a sample representing the whole specimen."
NRC: "Aliquot means a portion of a specimen that is used for testing. It is taken as a sample representing the whole specimen."

Collector. Similar to HHS Guidelines.

Note: NRC 26.85(a) states a collector must be trained and knowledgeable of Part 26; thus, do not need it in definition. 26.85(a)(1) states collector must have training in "all steps necessary to complete a collection correctly..."; this would imply making an initial examination of the specimen; thus, do not need it in definition.

Confirmatory drug or alcohol test. Similar to HHS Guidelines. However, the second sentence is a re-wording of part of the HHS definition and is not correct. The purpose of a confirmatory test does not 'ensure the reliability and accuracy of an initial test result'; it ensures reliability and accuracy because it uses a different technique and chemical principle from that of the initial test. This different technique is more specific and sensitive than the initial test. Suggest delete second sentence or reword definition as in HHS Guidelines.

Confirmed test result. In context of NRC, this means a laboratory result reviewed by MRO and found to be not a reportable negative. In the HHS context, a confirmed test result would imply a non-negative test result from the laboratory sent to the MRO. Obviously, the two agencies have different emphasis. This NRC definition is clear about what this means. An HHS laboratory-based person reading this NRC Part 26 would need to understand the context difference to avoid confusion.

Control. Similar to HHS Guidelines. NRC uses word 'predefined limits'; HHS uses word 'desired limits'.

Cutoff level. This is not a definition in HHS Guidelines. There are cutoff levels for drugs/drug metabolites, adulterated specimens, and alcohol. For substituted, the specimen meets established criteria.

HHS-certified laboratory. Address has changed: 1 Choke Cherry Road, Room 2-1033, Rockville, Maryland 20857

Initial validity test. Similar to HHS Guidelines; HHS does not use phrase "and may require confirmatory validity testing".

Limit of detection (LOD). Similar to HHS Guidelines, but not exact wording. Suggest use same wording as HHS. The word 'detect' is part of NRC's definition. HHS uses the phrase 'shown to be present under defined conditions'; this more accurately describes the use of this concept in the laboratory.

Limit of quantitation (LOQ). Similar to HHS Guidelines, but not exact wording. Suggest use same wording as HHS; this more accurately describes the use of this concept in the laboratory.

Note: the difference between LOD and LOQ is one of quantitation. At LOD, the analyte is present, i.e., meets all the criteria for acceptance except quantitation (thus, 'reliably' present). At LOQ, the analyte is present and is able to be quantified; it meets all the criteria for acceptance, including quantitation (thus, 'reliably' present and quantified). The laboratory determines both of these values for the analytical procedure by analyzing decreasing concentrations of analyte. Using the word 'accurately' would imply an absolute; 'reliably' does not have that connotation and reflects actual practice (do not know 'absolutely' if the LOQ value is true and correct).

Non-negative test result.

Issue 1: Definition does not include 'invalid', as in HHS Guidelines.

Issue 2: The last sentence states 'a non-negative result may be obtained from any initial or confirmatory drug, validity, or alcohol test.' This may lead to confusion with the phrase 'non-negative initial test result' that will be used in the rule text to indicate a non-negative test result from a laboratory sent to an MRO (see Preamble Section 26.5 Definitions). Note: the phrase 'non-negative initial test result' is not defined in rule text; suggest adding definition for clarity.

Issue 3: the term 'non-negative' as a descriptor for validity screening or initial validity test is not correct. A validity test does not yield a negative or non-negative test result (i.e., zero, or some number above a cutoff value). Validity test results are based on decision points, not cutoff values. The correct descriptor term should be "presumptive adulterated, substituted, or invalid." (See also comment for 26.131(a))

Validity screening test. The definition is not in agreement with wording in HHS Guidelines. For the proposed NRC rule, are defining this term for the licensee testing facility (as stated in Preamble), which could use a 'non-instrumented testing device to determine the need for initial validity testing of a urine specimen.' HHS Guidelines allow for a 'screening validity test' for specific gravity and pH with an instrumented test. In addition, HHS' National Certification Laboratory Certification Program have always allowed the use of 'dipstick' tests as a screening test to determine the need for initial testing or additional testing of the specimen. The NRC's proposed definition is similar to the HHS' proposed Guidelines (69 FR 19672) for POCT devices for validity tests, which can be non-instrumented (but some are instrumented) and must meet criteria as set forth in those proposed Guidelines (i.e., FDA-cleared, on SAMHSA-approved list). The 'dipstick' type of tests currently allowed to be performed in HHS-certified laboratories do not fall into this POCT category. The NRC licensee testing facility may choose to employ these 'instrumented' screening tests or 'dipstick' tests for validity testing.

Suggest revise definition to be in agreement with HHS: "...means the use of a test, instrumented or non-instrumented, to determine the need for initial validity testing of a urine specimen."

Note: for HHS: screening tests are defined as those that are used to determine if an initial test is to be performed. The screening tests do not, by definition, meet the requirements of the initial test. The screening tests are allowed, as they can be more cost-effective than the initial test. If the screening test indicates the need for the initial test, then the testing facility must perform the

initial test. Of particular importance in the HHS's program is that the decision to perform a second initial
test and/or confirmatory test is based upon the initial test, not the screening test. See also comments for 26.137(b).

The Preamble would need to be revised if this definition is revised, as the Preamble discusses this term with the 'non-instrumented' wording.

Sample and Specimen: The NRC does not have a definition for these terms; HHS Guidelines do define these terms. Suggest adding definitions for these terms.

Section 26.31 Drug and alcohol testing.

26.31(d)(1) General requirements for drug and alcohol testing. Substances tested

Issue 1: list has 'marijuana metabolite' and 'cocaine metabolite', in the singular. The Preamble has "drug metabolites"; need to change Preamble to singular.

Issue 2: The list has 'adulterants'; this is one of the validity tests. The other validity tests are creatinine, pH, and specific gravity. HHS Guidelines require laboratories to perform the following on each specimen: determine the creatinine concentration, the specific gravity on specimens with the creatinine concentration less than 20 mg/dL, the pH, and perform one or more validity tests for oxidizing adulterants (see section 2.4(g) of HHS Guidelines). Suggest delete word 'adulterants' and incorporate HHS wording that specifically details which validity tests to perform; these are not listed in section. Or, split into two sub-paragraphs, one describing drug testing and one describing validity testing.

Issue 3: Creatinine can be called a 'substance', but pH and specific gravity cannot be defined as a substance. pH is the related to the hydrogen ion concentration in the urine; specific gravity is a measure of the dissolved solids in the urine. Suggest revise heading of (1) to "Testing performed".

26.31(d)(1)(C): suggest change 'substance' to 'tests'

26.31(d)(1)(i)(D).

Issue 1: The phrase "would be eligible to hold" appears to be too vague. In the context of the HHS' Guidelines, a person who is eligible to be an RP has identified themselves as such to HHS,

submitted documentation supporting their candidacy, completed training in the testing procedures at the HHS-certified laboratory for which they are employed and is awaiting approval pending an on-site interview. A candidate RP must be associated with an HHS-certified laboratory. In a less strict interpretation of this phrase, a person would be eligible who meets all the requirements of an RP, but has not been approved by HHS and is not associated with an HHS-certified laboratory; this precludes an independent body from evaluating the person's qualifications. A former RP would have met all the qualifications as set forth by HHS, and could fulfill the requirements of this section. Suggestion: replace "would be eligible to hold" with "has been".

Issue 2: "...validated in accordance with established forensic toxicological standards..."; suggest change to "...validated in accordance with HHS' requirements for a new assay in an HHS-certified laboratory." This would ensure the assay has been validated as stringently as other assays at the HHS-certified laboratory. The validation records for these assays are evaluated by the HHS inspectors at each on-site inspection, ensuring the laboratory has in place "scientifically sound and legally defensible" assays. The phrase "with established forensic toxicological standard" may be too vague to ensure that HHS' requirements are met.

26.31(d)(3). Heading is 'Drug testing.' Paragraph also discusses validity testing, which is not a drug.
Suggest revise heading to "Drug and validity testing"

26.31(d)(3)(i). Use of the terms "non-negative initial validity or drug test results" may be confused with the phrase "non-negative initial test result" as explained in the Preamble (under Section 26.5 Definitions). See also comment for "non-negative test result" definition.

26.31(d)(3)(i). In Preamble: second paragraph describes 'dilution' under a (2); wording is confusing, as dilution can be detected by validity testing. The intent of the sentence appears to be that the liquid added is not detected by validity testing, which is correct. Suggest revise: "(2) dilution, which means adding a liquid to the urine specimen to decrease the concentration of a drug or metabolite below the cutoff concentration;" deleting the reference to 'adulterated' and what a validity test may detect makes the sentence less confusing. The sentence 'adulterated' and 'substitution' phrases do not have wording about being detected by validity testing. The suggested revision would make all 3 statements read as a definition.

Section 26.85 Collector qualifications and responsibilities

26.85(b) Alcohol collector qualifications. Does not require collector to be a certified BAT, as in DOT Guidelines. There are no requirements for documentation of training or continued competency requirement; suggest add.

26.85(c) Alternative collectors. Allows for "medical professional, technologist, technician" to serve as a collector (either urine or breath) without meeting the collector qualification requirements. Comment: disagree

26.89 Preparing to collect specimens for testing.

26.89(b)(2): The proposed rule would allow the collection to occur if the donor cannot produce acceptable identification. This is in disagreement with HHS Guidelines: "If the donor's identity cannot be established, the collector shall not proceed with the collection" (HHS Guidelines section 2.2(f)(2)). Establishing positive identification is critical at the collection site to ensure the specimen obtained is from the correct donor; suggest revise to match HHS wording.

26.109 Urine specimen quantity.

26.109(b)(1). Volume of water stated in parenthesis agrees with HHS Guidelines; does not agree with DOT's guidance (not to exceed a maximum of 40 ounces over a period of 3 hours).

26.109(b)(1) – (4): If the quantity of urine is less than 30 mL, then the collector must discard this specimen and collect another. This instruction is not emphasized. Suggest make this (1): "The collector shall discard the specimen and a second specimen shall be collected" and delete the second sentence of (1); renumber (1) – (4) to (2) – (5).

26.113 Splitting the urine specimen

26.113(b)(2). In the second sentence: insert "a minimum of" before 15 mL to read "Bottle A must contain a minimum of 30 mL of urine and Bottle B must contain a minimum of 15 mL."

26.113(b)(2). Suggest revise fourth sentence. It could be interpreted that if there is less than 15 mL

for Bottle B, the collector would not send Bottle B. Bottle B is to be sent, even if empty. Suggested revision: "If there is less than 15 mL of urine available for Bottle B, all remaining urine must be poured into Bottle B. Bottle A and Bottle B must be sent to the HHS-certified laboratory."

26.115 Collecting a urine specimen under direct observation

This section is more detailed than HHS Guidelines.

26.117 Preparing urine specimens for storage and shipping

26.117(j): Directs collector to store specimen(s) that have not been shipped within 24 hours, and "any specimen that is suspected of having been substituted, adulterated, or tampered with in any way" to "be maintained cooled to not more than 6°C until they are shipped...." Also, this paragraph requires "the time between specimen shipment and receipt of the specimen at the licensee testing facility or HHS-certified laboratory should not exceed 2 business days."

Comment: These requirements are not in HHS Guidelines.

Subpart F – Licensee Testing Facilities

Comment: Require these facilities to be an Initial Instrumented Testing Facility (IITF), as described under HHS' Proposed Guidelines (69 FR 19672).

26.126(c): lists what must be included in Licensee testing facility personnel files. In Preamble, it is noted that the requirement for "color blindness would no longer be necessary because current testing technologies provide means other than color for reading test results." This statement is in conflict with the definition for "validity screening tests," which are defined as "a non-instrumented testing device to determine the need for initial validity testing of a urine specimen." These non-instrumented testing devices are read visually by the testing personnel. Thus, a test for color blindness is required for these types of visually-read devices. Recommend adding test for color blindness in 26.125(c) and amending Preamble.

26.129 Assuring specimen security, chain of custody, and preservation.

26.129(b): In Preamble, third paragraph, second sentence (first column, pg. 50545): "For example, if the collector's signature is missing on the custody-and-control form, licensee testing facility personnel would work with collection site personnel to attempt to identify the collector and obtain

the collector's signature on the form if possible." In attempting to resolve any discrepancies on the specimen custody-and-control form, the licensee testing facility personnel should attempt to obtain a "Memorandum for the Record" from the collector. This type of documentation is forensically accepted as a means to correct discrepancies found on custody-and-control forms. It is not forensically appropriate for the collector to sign the original custody-and-control form after the date

of the collection; if the collector did sign the original, then the date could not be the original date, thus causing another discrepancy on the form. Recommend to revise sentence to: "For example, if the collector's signature is missing on the custody-and-control form, licensee testing facility personnel would work with collection site personnel to attempt to identify the collector and obtain a memorandum for the record for the missing collector's signature."

26.129(c): Second sentence: "Testing facility personnel shall use aliquots of the specimen and licensee testing facility chain-of-custody forms, or other appropriate methods of tracking aliquot custody and control, when conducting validity screening and initial validity and drug tests." The Preamble states "The stakeholders requested that the proposed rule permit licensee testing facilities to use methods other than a custody-and-control form to maintain the chain of custody for aliquots of a specimen that are tested at the licensee testing facility. The proposed change would be incorporated because methods other than a custody-and-control form, such as use of bar coding, have been shown to be equally effective at tracking the chain of custody for an aliquot at licensee testing facilities." HHS has always required written documentation on a chain-of-custody form for the tracking of specimens and aliquots in its certified laboratories. While bar coding is done in these laboratories and is effective at tracking specimens, the bar code list generated by a device or instrument is always associated with a custody and control form showing the documentation of personnel who handled the specimens or aliquots. This written documentation ensures the security of the specimens and/or aliquots during the testing process. Recommend: delete the wording in the proposed text "...or other appropriate methods of tracking aliquot custody and control..." and revise Preamble.

26.129(f): The language appears to imply that Bottle B of a non-negative split specimen remains at the licensee testing facility "until test results from the HHS-certified laboratory are known to be negative for Bottle A; until the MRO informs the licensee testing facility that Bottle B must be

forwarded to an HHS-certified laboratory for testing; or, until the specimen is moved to long-term frozen storage...."

Comment: Disagree with this language. For all non-negative specimens, both Bottle A and Bottle B should be shipped to the HHS-certified laboratory. Bottle A and B would be maintained at the HHS-certified laboratory under chain-of-custody. It appears to be cumbersome for the licensee testing facility to maintain proper chain-of-custody for Bottle A and a separate custody-and-control for Bottle B, and, ensure Bottle B is moved from refrigerator to frozen storage, or discarded. The number of times Bottle B could potentially be moved increases to the probability that an error could occur with the chain-of-custody documentation. (See also comment for 26.135(a))

26.129(f): In Preamble (First column, pg. 50546): "The proposed rule would eliminate as unnecessary the last sentence of the current paragraph, which requires licensee testing facilities to ensure that emergency power equipment is available to maintain the specimens cooled in the event of a power failure." This Preamble description appears to be adequate for "cooled" specimens, i.e., maintained at not more than 6° C, but may not be adequate for long-term, frozen storage of specimens. Recommend licensee testing facilities ensure that emergency power equipment is available to maintain specimens in long-term, frozen storage.

26.129(g): When shipping specimen bottle to the HHS-certified laboratory, the licensee testing facility "shall ensure that the original custody-and-control form is packaged with its associated urine specimen bottle." Since the licensee testing facility ships only Bottle A, then the remaining Bottle B does not have an original chain-of-custody form associated with it at the licensee testing facility. This in not in agreement with procedures at an HHS-certified laboratory: The original custody-and-control form remains at the HHS-certified laboratory. If Bottle B is to be sent to another laboratory, then a copy of the original custody-and-control form is sent with Bottle B. Recommendation is same as stated in 26.129(f): require licensee testing facility to send both Bottle A and Bottle B, and the original custody-and-control form. (See also comment for 26.135(a))

26.131 Cutoff levels for validity screening and initial validity tests.

Recommend change "cutoff levels" to "decision points". Validity tests are based on decision points, not cutoff levels.

26.131(a): The use of the term "non-negative" as a descriptor for validity screening or initial validity test results is not correct. See comment for 26.5, "Non-Negative Result". Recommend revise to "The licensee testing facility shall forward any specimen that yields a presumptive adulterated, substituted, or invalid validity screening or initial validity test result to the HHS-certified laboratory for further testing."

26.131(a): The proposed rule allows the licensee testing facility to perform "either a validity screening test or an initial validity test, or both, on one or more aliquots of a urine specimen." The licensee testing facility could perform only the validity screening test. These validity screening tests usually do not have the same sensitivity as the initial validity test, and would therefore not meet the cutoffs listed in 26.131(b). These validity screening tests can be used to identify a specimen that needs further testing, either at the licensee testing facility with an initial validity test, or at an HHS-certified laboratory. At a minimum, these validity screening tests should meet the cutoff criteria of an 'invalid' specimen (see comments for 26.131(b)).

26.131(b)(1): Will NRC allow licensee testing facilities to report a specimen as negative and dilute? To be able to report a dilute, the licensee testing facility must perform an initial creatinine test with a calibrator at 2.0 mg/dL; perform a specific gravity test, using a 3-place refractometer; and, must forward any specimen with a creatinine less than 5.0 mg/dL to an HHS-certified laboratory. Section 26.137(d) would also need to be revised to require this creatinine and specific gravity test. For licensee testing facilities that only perform a validity screening test for creatinine, then all specimens with a creatinine less than 20 mg/dL must be forwarded to an HHS-certified laboratory.

26.131(b)(2): The criteria for the specimen pH listed would identify presumptive adulterated specimens due to pH too low or pH too high. HHS Guidelines have an 'invalid' criteria for pH: the pH is greater than or equal to 3 and less than 4.5, or greater than or equal to 9 and less than 11. The NRC's proposed rule would not identify presumptive invalid specimens due to pH. Recommend revise (2)(i) and (ii) to: (i) pH less than 4.5, or (ii) greater than or equal to 9. These decision points would identify both presumptive invalid and adulterated specimens.

26.131(b)(2): a 'colorimetric pH test' must have a dynamic range of 2 to 12 to be used for identifying presumptive adulterated specimens due to pH, as described in (b)(2)(i) and (ii).

Colorimetric pH tests that do not have a dynamic range of 2 to 12 are used to identify presumptive invalid specimens due to pH; these types of colorimetric pH tests would fall under the validity screening test category. If the NRC revises (2)(i) and (ii) to list pH values that would identify presumptive invalid specimens due to pH, then the wording "a colorimetric pH test" can remain. If the NRC does not revise (2)(i) or
(ii), then recommend revise wording in (2) to "Using either a colorimetric pH test with a dynamic range of 2 to 12 or pH meter, ..."

26.131(b)(3): The criteria for the nitrite listed would identify presumptive adulterated specimens due to nitrite, but not invalid specimens due to nitrite. HHS Guidelines have criteria for an 'invalid' specimen due to nitrite if the concentration is greater than or equal to 200 mcg/mL but less than 500 mcg/mL. Recommend revising to "Nitrite concentration is equal to or greater than 200 micrograms (mcg) per milliliter (mL)...."

The cutoff of 200 would identify presumptive invalid and presumptive adulterated specimens and would be required to be sent to an HHS-certified laboratory. Note: 26.131(b)(5) uses a 200 nitrite-equivalent cutoff for the general oxidant colorimetric test to identify the presence of halogen, which is in agreement with the 200 mcg/mL cutoff.

26.131(b)(3): Revise last part of sentence to read "...or a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite-equivalents)." This revision will emphasize the general oxidant test must be calibrated with a 200 mcg/mL nitrite solution in order to identify specimens with nitrite equal to or greater than 200. This same general oxidant test can also be used to identify the presence of chromium (VI), as described in 26.131(b)(4); however, to identify chromium (VI), the assay must be calibrated with a 50 mcg/mL chromium (VI) equivalents solution.

26.131(b)(4): Revise to read "The possible presence of chromium (VI) is determined using..." Neither the general oxidant colorimetric test nor the chromium (VI) colorimetric test is the confirmatory test for the presence of chromium (VI). Use of the wording "Presence of chromium (VI) is indicated" would imply the test can identify chromium (VI). HHS Guidelines (section 2.5(h)(7)) use the wording "possible presence of" when describing how to report an invalid result.

26.131(b)(5): Revise to read "The possible presence of halogen (e.g., bleach, iodide, fluoride) is

determined using...."

Neither the general oxidant colorimetric test nor the halogen colorimetric test is the confirmatory test for the presence of halogen. Use of the wording "Presence of halogen ... is indicated" would imply the tests can identify a halogen. HHS Guidelines (section 2.5(h)(7)) use the wording "possible presence of" when describing how to report an invalid result.

26.131(b)(5): HHS Guidelines have criteria for 'invalid' due to possible presence of a halogen based on odor of the specimen. Recommend revise to match HHS Guidelines: "The possible presence of a halogen (e.g., bleach, iodide, fluoride) is indicated using either a general oxidant colorimetric test (with a cutoff equal to or greater than 200 mcg/mL nitrite equivalents or equal to or greater than 50
mcg/mL chromium (VII) equivalents) or a halogen colorimetric test (halogen concentration equal to or greater than the LOD) or relying on the odor of the specimen."

26.131(b)(6): Revise to read "The possible presence of glutaraldehyde is determined using ...."

Neither the aldehyde test nor the characteristic immunoassay response is the confirmatory test for the presence of gluteraldehyde. Use of the wording "Presence of gluteraldehyde is indicated" would imply the tests can identify gluteraldehyde.

26.131(b)(7): Revise to match HHS Guideline wording (section 2.4(h)(7)(vii)). Pyridine cannot be specifically identified using the general oxidant colorimetric test or the chromium (VII) colorimetric test. Both tests can identify other possible adulterants, such as nitrite, chromium (VII), and halogen. HHS Guideline wording is: "The possible presence of an oxidizing adulterant is determined by using a general oxidant colorimetric test (with greater than or equal to 200 mcg/mL nitrite-equivalent cutoff, a greater than or equal to 50 mcg/mL chromium (VI)-equivalent cutoff, or a halogen concentration is greater than or equal to the LOD).

26.131(b)(8): Revise to match HHS Guideline wording: "The possible presence of surfactant is determined by using a surfactant colorimetric test with a cutoff equal to or greater than 100 mcg/mL dodecylbenzene sulfonate equivalent or a foam/shake test; or".

The surfactant colorimetric test is not the confirmatory test for surfactant. Use of the wording "Presence of surfactant is indicated" would imply the tests can identify surfactant. HHS Guidelines

allow for a foam/shake test when identifying possible invalid specimens due to surfactant. HHS Guidelines (section 2.5(h)(7)) use the wording "possible presence of" when describing how to report an invalid result.

26.131(b)(9)(iii): add the word "two" before "separate" to read "...on two separate aliquots..."

HHS Guidelines require two separate aliquots to demonstrate the inability to obtain valid immunoassay drug test results and for the specimen to be considered possibly an 'invalid' specimen. Adding the word "two" clarifies the number of aliquots required.

26.135 Split specimens.

26.135(a): Recommend that the licensee testing facility forward both Bottle A and Bottle B to the HHS-certified laboratory for any specimen identified as non-negative. See also comment for 26.129(f). The security of Bottle B and the integrity of the chain-of-custody documentation for Bottle B at the licensee testing facility would appear to be cumbersome and open to possible error. HHS-certified laboratories have processes in place that allow tracking of both bottles, ensuring the security and integrity of the specimen. In addition, Bottle B would be available at the HHS-certified laboratory if a retest is requested, eliminating the need for the licensee's testing facility to ship Bottle B.

26.135(b): NRC proposes to require the donor to request testing of Bottle B in writing. HHS Guidelines do not require the donor to request testing of Bottle B in writing.

26.135(b): The proposed rule allows only the donor to request testing of Bottle B: "...neither the licensee, MRO, NRC, nor any other entity may order testing of Bottle B without the donor's written permission." HHS Guidelines allow for a Federal agency to have the split specimen tested if the donor does not choose the retesting of Bottle B. (See HHS Guideline section 2.6(e)(4)). This wording allows a Federal agency to order a retest of Bottle B "as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result."

Recommend the NRC consider adding this provision. In a legal or administrative proceeding, it may be in the best interest for the donor to not request a retest of Bottle B. However, it would be in the best interest of the NRC to request a retest of Bottle B to verify the first result.

26.135(c): Long-term, frozen storage is required to maintain Bottle B of a specimen confirmed as non-negative by the MRO. The licensee testing facility should be required to have emergency back-up power to ensure the long-term, frozen storage remains at the required temperature during a power outage. See also comment for 26.129(f).

26.137 Quality assurance and quality control.

26.137(b) Performance testing and quality control requirements for validity screening tests.

Issue 1: The proposed wording in (1), (2), and (3) suggests a point-of-collection test (POCT) may be used for specimen validity testing. POCT testing has been proposed by HHS in 69 FR 19672, but has not been published as a final rule. Therefore, the "SAMHSA list of point-of-collection testing devices" does not exist.

Issue 2: A drug POCT is a 'device' in FDA terminology and it is cleared by the FDA. A specimen validity POCT is not required to be cleared by the FDA and should not be referred to as a 'device'. The proposed requirement in 26.137(a)(1)(i) to be FDA cleared must be deleted.

Issue 3: Not all specimen validity POCTs are non-instrumented. Restricting use of only non-instrumented validity POCT would eliminate some of the instrumented tests; these 'instrumented' tests are usually read by an automatic reader, not by a human reader. In 26.137(b)(5), the 'colorimetric pH tests that have a narrow dynamic range and do not support the 2 -12 pH cutoffs' can be an instrumented test. Most HHS-certified laboratories use this type of test for their pH screening test. Allowing only 'non-instrumented' devices for performing validity screening tests would eliminate the possibility of a licensee testing facility from performing this type of testing for pH. This would be unduly restrictive. In 26.137(b)(6), the 'general oxidizing adulterant test or one or more specific oxidizing adulterant tests for validity screening' can be an instrumented test. HHS-certified laboratories use this type of instrumented test for their initial validity test. Allowing only 'non-instrumented devices' for performing validity screening tests would eliminate the possibility of a licensee testing facility from performing this type of instrumented testing for oxidizing adulterants. This would be unduly restrictive.

Issue 4: Most current POCT devices on the market include drug and specimen validity tests on the same device. Does NRC envision allowing the use of such a device for only the specimen validity tests? If so, what will the analyst "do" with the drug results? There could possibly be some liability issues, as a drug test had been performed.

Issue 5: POCT testing, as proposed by HHS, is a category of testing unto itself. This category of testing includes the drug and the specimen validity testing of the specimen; they are not separated out by drug and specimen validity, as proposed here by the NRC. The proposed HHS Guidelines for POCTs include requirements for quality assurance, device validation, annual validation, training and re-training of testers, provision for performance testing, provision for failures of the device, and reporting of results. NRC's proposal to use only the validity POCT appears to be difficult and complex in writing the regulations.

Issue 6: Current HHS Guidelines allow laboratories to use screening validity tests that are not POCT-type of tests. **Recommend the NRC revise this section** to require these types of screening tests **and not to use specimen validity POCTs as a screening validity test.** In reality, licensee testing facilities will probably follow current HHS-certified laboratory practice for specimen validity testing. Examples of screening validity tests currently allowed by HHS are: pH paper, dipstick tests for pH, dipstick tests for oxidants, dipstick tests for nitrite, and instrumented colorimetric pH tests with a narrow dynamic range.

26.137(b)(1)(ii): The requirement to have the licensee or other entity ensure the "device effectively determines the validity of the specimen" appears overly burdensome.

26.137(b)(1)(ii)(A): Performance testing of the devices should be done by personnel who will be using the devices. If a licensee testing facility will be using the device, then the trained *personnel* should perform the testing for evaluation. Personnel at an HHS-certified laboratory will not be using these types of devices, and would presumably not have personnel trained in the testing procedures.

26.137(b)(1)(ii)(B): A validity POCT for nitrite should be able to identify samples that have a nitrite concentration at or above 200 mcg/dL. This is the cutoff for an invalid result. Validating a device using samples with a concentration in the ranges of 650 – 800 mcg/mL will not test the device at the 200 cutoff.

26.137(b)(1)(ii)(B): A validity POCT for creatinine will be unable to distinguish creatinine concentrations in the ranges listed (5 -20 and 1 – 5). At best, a validity POCT for creatinine will

have a cutoff of 20 mg/dL, and should be able to distinguish between a sample with a creatinine of 15 mg/dL from a sample with a creatinine of 25 mg/dL.

26.137(b)(1)(iii): The requirement to have the licensee or other entity ensure the device "continues to effectively determine the validity of the specimen" appears overly burdensome.

26.137(b)(1)(iv): This requirement appears to be overly burdensome for the licensee or other entity.

26.137(b)(2): Each licensee testing facility personnel who is to perform the validity screening test should test the quality control samples. The non-instrumented test has a visually read endpoint, which must be interpreted by the tester. Each tester must be able to interpret the quality control samples correctly before performing the test on donor specimens.

26.137(b)(4): Validity screening tests for creatinine cannot measure to 1 decimal point. At best, a dipstick method for creatinine has a cutoff of 20 mg/dL. Recommend delete this requirement.

26.137(b)(6): The requirement for the test "to detect at least the activity equivalent of 500 mcg/dL of nitrite" should be changed to "200 mcg/dL of nitrite". The 200 cutoff value will detect possible 'invalid' specimens. The 500 cutoff is for adulterated specimens.

26.137(b): There are no requirements to allow the performance of a screening specific gravity test using a three-place refractometer. This would allow reporting of dilute specimens by the licensee testing facility. Recommend adding.

26.137(c) Non-negative validity screening test results.
26.137(c): The proposed wording here uses "may be adulterated, substituted, dilute, or invalid." Elsewhere the proposed rule uses the term 'non-negative'. See also comment for 'non-negative' under section 26.5.

26.137(c): The validity screening tests can only identify possible adulterated (due to pH or an oxidizing adulterant) or substituted (due to creatinine less than 20 mg/dL) specimens; suggest use only these two terms.

26.137(b) and 26.137(c): Recommend the following revision:

26.137(b) *Quality Control requirements for performing validity screening tests.*

(1) The creatinine validity screening test must use a 20 mg/dL cutoff concentration

(2) The pH validity screening test must be able to determine the pH is less than 4.5 or greater than or equal to 9.

(3) The oxidant validity screening test must detect 200 mcg/mL nitrite.

(4) At the beginning of any 8-hour period during which the licensee testing facility will perform a validity screening test, each licensee testing facility personnel who performs validity screening tests shall test the required quality control samples for each validity screening test.

(5) The creatinine validity screening tests must have, at a minimum, the following controls:

(i) One control between 3 – 15 mg/dL; and

(ii) One control between 25 – 30 mg/dL.

(6) The pH validity screening tests must have, at a minimum, the following controls:

(i) One control below the lower decision point in use;

(ii) One control between the decision points in use; and

(iii) One control above the upper decision point in use.

(7) The licensee testing facility may use either a general oxidizing adulterant test or one or more specific oxidizing adulterant tests for oxidizing adulterant validity screening test. At a minimum, the oxidizing adulterant validity screening test must have the following controls:

(i) One control that is negative for the oxidizing adulterant; and

(ii) One control that contains the oxidizing adulterant at a concentration above the cutoff concentration.

(8) Any licensee testing facility personnel that performs a visually-read validity screening test must undergo testing for color blindness.

(9) Any visually-read validity screening test must have the required quality control samples analyzed by each licensee testing facility personnel that perform the test, during each 8-hour period.

26.137(c) *Validity screening test results.* If the results of a validity screening test indicate that the specimen may be adulterated or substituted, the licensee testing facility may either perform initial validity testing or shall forward the specimen to the HHS-certified laboratory for further testing.

26.137(d) Quality control requirements for performing initial validity tests.

26.137(d)(1): Revise second sentence to match HHS Guideline requirements: a calibrator at 2 mg/dL, a control in the range of 1.0 mg/dL to 1.5 mg/dL, a control in the range of 3 mg/dL to 20 mg/dL, and a control in the range of 21 mg/dL to 25 mg/dL.

26.137(d): There are no requirements for performing an initial specific gravity test. Suggest add requirement to match HHS Guidelines.

26.137(e) Quality control requirements for initial drug tests.

26.137(e)(1): Suggest delete second and third sentence, as per recommendation to not use POCT-type of tests for validity testing.

26.137(e)(6): Matches HHS Guidelines except requirement for "a sufficient number of calibrators" is not included (HHS section 2.5(b)(4)). Suggest add to match HHS.

26.137(e)(6)(ii): wording similar to HHS Guidelines, but use of the word "a" implies that the control may have only one drug or drug metabolite. There must be a positive control for all drugs and drug metabolites and this positive control must be analyzed with each analytical run. This will ensure all drug or drug metabolite assays have a positive control. Recommend delete word "a".

26.137(e)(6)(iii): wording similar to HHS Guidelines, but the use of the word "a" implies that the control may have only one drug or drug metabolite. There must be a below cutoff control for all drugs and drug metabolites and this control must be analyzed with each analytical run. This will ensure that all drug and drug metabolite assays have a below cutoff control. Recommend delete word "a".

26.137(e)(7): This section contains wording about a quality control sample that must be part of each analytical run – the one percent blind performance test sample. Suggest move second sentence to (e)(6) for clarity and make it (e)(6)(iv).

26.137, Preamble:

Pg. 50550, center column, last sentence: section 26.137(d)(7) does not exist.

Pg. 50550, last column, last sentence and pg. 50551, first column, sentence 1 - 3: The example given is not correct as practiced in HHS-certified laboratories. An analytical run of 50 specimens includes one blind test sample and 4 other quality control samples, as defined in NRC's proposed sections 26.137(e)(6) and 26.137(e)(7). The analytical run, in this example, would have 45 donor specimens to meet the 10% requirement of all specimens in an analytical run must be quality control samples. The blind test sample may be either a blank (certified negative urine), or a sample with drug or drug metabolite, usually targeted at 50% or greater above the cutoff. The blind test sample usually has one drug or drug metabolite. Sentence 3 is unclear, as it appears to imply that the 'fortified' quality control samples, as defined in 26.137(e)(6)(ii) and (iii), may have a varied concentration.

Recommend revise this example as follows: "For example, if an analytical run tested 45 donor specimens, the licensee testing facility would include 5 additional samples, all of which are quality control samples. The total number of samples in the analytical run would then be 50. At least one of the 5 quality control samples must be a control that appears as a donor sample to the initial testing technician. This blind test sample could be either a certified drug negative sample or a sample with drug or drug metabolite above the cutoff. The other 4 quality control samples must meet the requirements of 26.137(e)(6)(i) – (iii): there must be one each of a certified negative control, a 25% above the cutoff positive control, and a 75% of the cutoff control. The last quality control sample could be any of the required quality control samples."

26.137: General Comment:

There are no proposed rules for licensee's testing facilities to test performance testing (PT) samples. This should be a crucial piece of the testing facilities quality assurance program. These PT samples are different from the blind samples the licensee submits.

Subpart G – Laboratories Certified by the Department of Health and Human Services

26.155 Laboratory personnel.

26.155(a)(4), Preamble: NRC is proposing deleting requirement that laboratory procedures be maintained in a laboratory "manual". HHS Guidelines use the term "manual". To be consistent, suggest not delete this term.

26.155(a)(4), Text: Add term "manual", as per HHS Guidelines.

26.155(b), Preamble: pg. 50554, last column: The second sentence reads "...to individual who validates test results at the HHS-certified laboratory...."; the word "validates" should be changed to "certifies", as test results are certified, not validated in an HHS-certified laboratory.

26.159 Assuring specimen security, chain of custody, and preservation.

26.159(f): HHS-certified laboratories send a copy of the original custody-and-control form for a retest specimen. Suggest revise wording in first sentence.

26.161 Cutoff levels for validity testing

26.161(b)(2), and 2(i) – (ix): The wording here is similar as that found for licensee testing facility. (See section 26.131 comments for recommendations) However, it is redundant and unnecessary, as the same information is conveyed in 26.131(c) – (f), which is similar to HHS Guidelines. Recommend delete 26.161(b)(2), and (2)(i) – (ix).

26.161(b)(2): add 'invalid' to list.

26.161(c)(3): insert hyphen: "chromium (VI)-equivalents"

26.161(c)(4): insert hyphen: "nitrite-equivalents"; "chromium (VI)-equivalents".

26.161(c)(6): insert hyphen: "nitrite-equivalents"; "chromium (VI)-equivalents".

26.161(c)(7): insert hyphen: "sulfonate-equivalents"

26.161(f)(3): wording similar to SVT, but not exactly the same: "...or equal to or greater than 200 mcg/mL nitrite equivalents using a general oxidant colorimetric test...." This proposed wording does not convey the intended meaning as written by HHS, which is that the general oxidant test must be positive "with an equivalent of 200 mcg/mL of nitrite". The general oxidant test may be calibrated with a 200 mcg/mL nitrite calibrator or with a 50 mcg/mL chromium (VI) calibrator. If the test is calibrated with the 50 chromium (VI) calibrator, then the test will produce a positive result for

specimens with nitrite concentrations much less than 200 mcg/mL; this is not the intended cutoff for nitrite. Suggest revise wording to "...or equal to or greater than the equivalent of 200 mcg/mL nitrite using a general oxidant colorimetric test...." to match HHS Guideline wording.

26.161(f)(7): add hyphen: "nitrite-equivalents" and "chromium (VI)-equivalents"

26.161(f)(8): add hyphen: "sulfonate-equivalent"

26.161(g): HHS Guidelines direct the laboratory to contact the MRO for a specimen with an invalid result to decide "if testing by another certified laboratory would be useful in being able to report a positive or adulterated result" (see HHS section 2.4(h)(12)). With the implementation of 69 FR 19643, HHS-certified laboratories are allowed to report an 'invalid' result using the same initial test on two separate aliquots. This has led to the majority of HHS-certified laboratories eliminating their confirmatory tests for adulterants, and reporting more invalid results. Recommend NRC delete this proposed rule, as it would impose a burden to the reporting laboratory to contact the licensee's or other entity's MRO for every invalid result.

26.161, Preamble:

Pg. 50557, center column, 26.161(d) and (e) paragraph: In discussing the proposed cutoff values for a substituted specimen, the specific gravity values are listed to 3 decimal places; the values should be listed to 4 decimal places, as a 4-place refractometer test is required to be able to report a

substituted specimen. Recommend revise to "...and the specific gravity is less than or equal to 1.0010 or equal to or greater than 1.0200."

Pg. 50557, center column, 26.161(d) and (e) paragraph: In discussing the proposed cutoff values for a dilute specimen, the creatinine and specific gravity values are incorrect. Recommend revise to "...a specimen is dilute if the creatinine concentration is equal to or greater than 2 mg/dL but less than 20 mg/dL and the specific gravity is greater than 1.0010 but less than 1.0030."

26.163 Cutoff levels for drugs and drug metabolites

26.163(a)(2): In first sentence, delete the word "confirmatory". A dilute result may be reported by

testing a single aliquot (see 26.161(e)).

26.163(a)(2): Revise wording requiring the use of limit of detection (LOD). HHS Guidelines do not use this term, but rather use "confirm the presence of the drug or metabolite." Recommend revise to "...the MRO may direct the laboratory to test the specimen for the presence of drugs and/or drug metabolites using the laboratory's confirmatory assay."

26.163(a)(2), Preamble and
26.163(a)(2), Text:

Issue 1: As stated, there are "legitimate reasons that a donor may provide a urine specimen that is dilute." A donor attempting to subvert the testing process is one reason, but not the only one. There are well documented cases of healthy persons capable of providing a urine specimen that would meet the dilute criteria. The main reason for these dilute specimens in normal, healthy persons is the attention of the health-conscious individual to drinking lots of fluids during the course of a day. The number of dilute specimens seen at HHS-certified laboratories appears to have increased since the laboratories began testing for creatinine and specific gravity. In a large category five HHS-certified laboratory, there may be up to 10% of specimens identified as dilute. The proposed NRC rule to require the laboratory to re-screen a dilute specimen and "inform" the licensee's or other entity's MRO would be overly burdensome. Recommend to eliminate this requirement.

Issue 2: The proposed requirement "to conduct initial drug testing of dilute specimens using FDA-approved analytical kits that have the lowest concentration levels available for the initial testing technologies" would be overly burdensome to the laboratories. The laboratory would need to have more than one FDA-approved analytical kit for a drug or metabolite to fulfill this requirement. For example, the initial drug test cutoff level for marijuana metabolite is 50 ng/mL. The initial drug test kit manufacturers market a kit for use at this cutoff. However, the kit manufacturers also market a kit with a cutoff of 20 ng/mL. To fulfill the proposed rule requirement, the laboratory would need to re-screen the dilute specimen with the 20 ng/mL cutoff kit, using different controls. There are currently also other kits with lower cutoffs for opiate metabolites and amphetamines. Use of these different kits effectively lowers the initial test cutoff levels for these drugs and treats the donor differently.

If the NRC does not eliminate this proposed rule, then recommend the laboratory not be

required to re-screen the identified dilute specimen, but be allowed to compare the initial drug test immunoassay response for the specimen to the initial drug test immunoassay response for the cutoff calibrator with the initial drug test kit used for testing. If the specimen's response is within 50 percent of the response of the cutoff calibrator, then the laboratory would report this to the licensee's or other entity's MRO on the final report. The additional burden for the laboratory would be how to capture the initial test immunoassay response number and report it on the report form; this could be solved with the laboratory's information system.

26.165 Testing split specimens and retesting single specimens

26.165(a)(1) – (2): describes how to test split specimens

26.165(a)(3): describes how to discard Bottle B, if Bottle A is negative. However, does not describe how to discard Bottle A. This paragraph does not discuss testing of split specimens and thus, appears out of place in this section.

26.165(a)(4): describes how donor may request a retest for a split specimen collection. The wording is lengthy and confusing. The wording should be similar to that of section 26.165(b)(1). The first sentence describes how a laboratory is to report a result; this should be in 'reporting results' section. The MRO must first determine if the laboratory result is a reportable drug positive, adulterated or substituted before informing the donor they have a right to request a retest. Recommend combine
this paragraph with 26.165(b)(1) for clarity and model it after section 2.6(e) in HHS Guidelines, which uses wording for both split specimen and single specimen for retests.

26.165(a)(4): The proposed rule allows only the donor to request testing of Bottle B: "...neither the licensee, MRO, NRC, nor any other entity may order testing of Bottle B without the donor's written permission." HHS Guidelines allow for a Federal agency to have the split specimen tested if the donor does not choose the retesting of Bottle B and there is pending legal action. See Section 2.6(e)(4) of HHS Guidelines. This wording allows a Federal agency to order a retest of Bottle B as "part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result." Recommend NRC consider adding this provision. In a legal or administrative proceeding, it may be in the best interest for the donor to not request a retest of Bottle B. However, it would be in the best interest of the NRC to request a retest of Bottle B to verify the first result.

26.165(a)(5): The HHS-certified laboratory may not have Bottle B. If the specimen was tested at a licensee testing facility, then the licensee testing facility may send only Bottle A to the HHS-certified laboratory for testing if identified as non-negative. The time frame of one business day may be too restrictive in this case.

26.165(a)(5): HHS-certified laboratories obtain request for sending a specimen to a second laboratory for retest from an MRO, not from the donor. Suggest revise wording.

26.165(a)(6): It is unclear why NRC is proposing allowing the MRO to provide the donor with the quantitative value of the retest. This requirement is not in HHS Guidelines.

26.165(b): recommend combine with 26.165(a)(4) and make heading "Donor request to MRO for a retest" and model after section 2.6(e) in HHS Guidelines.

26.165(b)(2): The first sentence agrees with HHS Guidelines: a donor may not request a retest on an invalid result. However, the second sentence is confusing, as it appears to allow a retest. In section 26.185(f)(3), the NRC proposes to direct the MRO to request a second collection under direct observation. Thus, a retest is not necessary. The NRC's proposed action by the MRO for an invalid agrees with HHS Guidelines. Recommend delete 26.165(b)(2). Note: wording in Preamble suggests a retest is not allowed for an invalid result (pg. 50560, center column).

26.165(c)(1): In first sentence, delete word "standard"; there is no "standard confirmatory drug test" in an HHS-certified laboratory.

26.165(c)(2): delete "down to the assay's LOD". The wording will then agree with HHS Guidelines; no mention of LOD is in HHS Guidelines. See also comment in section 26.163(a)(2).

26.165(d): Change "appropriate" to "required" to match HHS Guidelines.

26.165(e): Wording agrees with HHS Guidelines, except for sentence two: this sentence is confusing and redundant; if the second laboratory does not find creatinine and specific gravity

values that meet the substituted criteria, then the second laboratory reports a "failed to reconfirm" result to the MRO, not a "non-confirmed"; also, the wording "...exceed the original test cutoff parameters" is redundant – have stated this specifically in first sentence. Recommend delete the second sentence.

26.165(f)(2): The proposed rule would direct MRO to cancel test if donor request a retest and testing by the second laboratory cannot be done due to insufficient specimen, lost in transit, split not available. HHS Guidelines require a recollect under direct observation (section 2.6(e)(3)).

26.165(f)(2): another reason that Bottle B could not be retested is insufficient volume in Bottle B, or no volume at all.

26.165(f), Preamble: pg. 50561, first column: When performing a retest, the second laboratory "reconfirms" the result of the first laboratory, not "confirms". Suggest NRC change wording to "reconfirm" to be consistent with HHS language.

26.167 Quality assurance and quality control

Overall comment for section: replace the hyphens in the control ranges to the word "to"; example: a control in the range of 3 to 4 mg/dL. The HHS Guidelines use the word "to" for clarity.

26.167(c)(1)(iv): the lower control should be 1.0 to 1.5 mg/dL, not 1. The decimal place is important at this lower end of the linear range.

26.167(c)(3)(i) – (v): recommend renumber to (i) – (vi) and make (ii) "pH screening tests must have, at a minimum, the following controls: ..." This will match organization of HHS Guidelines and remove last sentence of (c)(3)(i) for clarity.

26.167(c)(3)(iii): recommend rearrange sentence: "An initial pH meter test, if a pH screening test is not used, must have the following calibrators and controls:" This will match HHS wording.

26.167(c)(3)(iv): recommend rearrange sentence: "An initial or confirmatory pH meter test, if a pH screening test is used, must have the following calibrators and controls when the screening result

indicates that the pH is below the upper decision point in use." This will match HHS wording.

26.167(c)(3)(v): recommend rearrange sentence: "An initial or confirmatory pH meter test, if a pH screening test is used, must have the following calibrators and controls when the screening result indicates that the pH is above the upper decision point in use." This will match HHS wording.

26.167(c)(4)(i): recommend reference appropriate section that states the cutoff concentrations. These would be sections 26.161(c)(3), (4), and (6). This matches HHS language.

26.167(c)(4)(ii): In second sentence revise to "Each confirmatory analytical run..." to match HHS wording and for clarity.

26.167(d)(2) – (3): wording should be similar to and arranged the same as that in 26.137(e)

26.167(e)(1): recommend delete; this does not describe a quality control sample.

26.167(f)(3): The criteria for the concentration of the positive samples would not result in a positive result by initial testing and does not match the concentration stated in 26.137(f)(5)(i)(A). Suggest revise to match, or delete sentence, as it is stated in subsequent section. Note: wording is "...spiked with concentrations between 60 – 80 percent of the initial cutoff values for the panel of drugs...." in the proposed text.

26.167(f)(3): HHS does not require blind samples to meet the criteria for dilute. Suggest delete.

26.167(f)(5): the list does not contain "diluted", as required in 26.167(f)(3)

26.167(f)(5)(i) – (ii): Listing the specific concentrations is confusing and may be restrictive. The criteria for the samples are listed in 26.17(f)(5). Recommend delete.

26.167(f)(5)(i)(A): To ensure a drug positive on the initial drug test, the drug or drug metabolite concentration should be between 1.5 and 2 times the initial drug test cutoff concentration. The proposed 20 percent above the designated cutoff for the initial drug test may produce in a negative

result.

26.167(f)(5)(i)(C): It is unclear why a "routine sample" would need to be below the cutoff "for special purposes." A routine sample submitted to the laboratory would be tested first by the initial test; having a drug concentration below the cutoff would produce a negative result. Recommend revise wording to clarify or delete the requirement.

26.167(f)(5)(i)(D): HHS Guidelines require a negative sample to contain no drug.

26.167(f)(5)(i)(E): change "fortified with" to "contain"

26.167(f)(5)(ii)(D) and (E): Recommend combine these to ensure sample meets requirement of substituted or dilute, as required in 26.167(f)(3).

26.167(g)(3): change "certifying scientist" to "responsible person". The responsible person in an HHS-certified laboratory will be the individual overseeing any corrective action required for a false positive error.

26.169 Reporting results

26.169(a): the wording "any indications of tampering, adulteration, or substitution that may be present" is redundant. The laboratory will report the sample as adulterated, substituted, invalid, or dilute, if those categories apply. In addition, any notation on the CCF by the collector will be reported. Recommend delete this phrase.

26.169(b): the list of non-negative test results does not include 'invalid'.

26.169(d): HHS Guidelines do not require laboratories to report numerical values for a dilute specimen. Recommend delete 'dilute' in this section.

26.169(d): The first sentence has wording "when applicable". This implies laboratories may or may not provide numerical values to the MRO. HHS Guidelines require laboratories to report numerical values for substituted and adulterated specimens. Recommend delete "when applicable".

26.169(d): The sentence "If the numerical values for creatinine are below the LOD, the laboratory shall report to the MRO "creatinine none detected" (i.e., substituted) along with the numerical values" should be revised. The numerical value that is reported to the MRO is from the confirmatory creatinine test; if the value is below the LOD, then HHS requires the laboratory to report "creatinine: none detected" with a colon; if the value is below the LOD, then a numerical value cannot be provided; for a substituted result, the laboratory must report the specific gravity value. Suggest revise sentence to "For a substituted result, if the numerical value for the creatinine is below the LOD, the laboratory shall report to the MRO "creatinine: none detected" and the value of the specific gravity test."

26.169(f): The first sentence appears redundant, as it is stated in (d) for substituted, adulterated, dilute results. The intent may have been to have the laboratory provide numerical values for drug positive test results.

26.169(k)(1): HHS requires laboratories to report the total number of specimens reported, not received.

26.169(k): HHS requires laboratories to report the number of specimens rejected for testing because of a fatal flaw and the number rejected for testing because of an uncorrected flaw. These elements are not listed in the (k).

Subpart H – Determining Fitness-for-Duty Policy Violations and Determining Fitness

26.183 Medical review officer.

26.183(a): Qualifications. There is no requirement of the MRO to have specific knowledge regarding the pharmacology and toxicology of illicit drugs. HHS Guidelines require the MRO to have such knowledge (see section 2.6(a)(2) of HHS Guidelines).

26.183(c): NRC proposes to use the wording "subversion of the testing process" to describe a donor possibly tampering with the specimen provided in order to "beat" the drug test. HHS Guidelines use the word 'tamper', as does DOT. Use of the word 'subversion' appears to be harsh

and judgmental.

26.183(d)(1): in Preamble, pg. 50567, column 3: The sentence "In addition, the proposed rule would require that MROs must personally review..." does not include invalid or dilute test results.

26.185 Determining a fitness-for duty policy violation.

26.185(a): The second sentence appears out of place. It describes a qualification and should be in listed in 26.183(a).

26.185(f)(2): recommend change "...may authorize an alternative method for drug testing" to "may authorize an alternative specimen type for drug testing". This change would match the intent of this proposed rule, as stated in the Preamble. The use of "alternative method for drug testing" suggests there may be other testing methods for the urine specimen the donor has provided, which is not the case.

26.185(g)(2): the reference of section 26.31(c)(1)(ii) appears to be incorrect. There is no 26.31(c)(1)(ii) in the proposed text.

26.185(i)(1): recommend delete "with a specific substance". An adulterated specimen may be due to 'pH too low' or 'pH too high'; pH is not a specific substance.

26.185(l): The use of the word "retesting" is confusing in this paragraph. In HHS Guidelines, retesting is meant to describe the testing of an aliquot of bottle A or the testing of Bottle B, as requested by the donor, through the MRO. The first sentence of this paragraph allows the MRO to request a retest of an aliquot of Bottle A if "any question arise as to the accuracy or validity of a non-negative test result". This provision is not found in the HHS Guidelines. Recommend delete first sentence.

26.185(m): This type of provision is not in the HHS Guidelines. The use of the phrase "scientifically insufficient" appears to be contradictory to a test result from an HHS-certified laboratory. A test result provided by an HHS-certified laboratory would be scientifically sufficient and defensible; that is inherent in the HHS certification process for laboratories.

26.185(o): Review of two drug positive results from the same individual over a period of time to try to make a determination of the last drug exposure cannot be done with any accuracy due to the pharmacology of the drugs in the human body and the use of urine as a specimen type. The quantitative values from a urine drug test do not indicate how much drug a person was exposed to, or when the person was last exposed. While there may be some general guidelines for how long a particular drug remains in the body, there are no guidelines for what the quantitative value of the drug would be in all possible exposure cases. Recommend NRC reconsider including this proposed rule.

26.185(o): The only drug example given is for marijuana; is marijuana the only drug that could fall under this type of review?

26.215 Recordkeeping requirements for collection sites, licensee testing facilities, and laboratories certified by the Department of Health and Human Services.

26.215(b): HHS-certified laboratories are required to maintain records for 2 years. A written request by a Federal agency to the laboratory may be made to extend this time and the laboratory is required to maintain a copy of the documentation package that supports the chain of custody, testing, and reporting of a donor's specimen. This documentation package would not contain items listed in NRC's proposed 26.215(b)(1), (4), (7), (8), (9), (10), (13). Suggest NRC clarify that a documentation package supporting the test result of a donor's specimen is to be maintained for longer than 2 years, if requested.

Preamble VII. Issues for Public Comment, pg. 50616 – 50617:

Issue 3: Could the "qualified, independent forensic toxicologist" be a responsible person of an HHS-certified laboratory?

Issue 5: See comments in related sections for validity testing.

DRAFT 12/7/05

Issue 7: See comment under section 26.137(b). Recommend do **not** allow licensee's testing facilitates to use non-instrumented validity tests, as described in the HHS proposed rule (69 FR 19672) under POCT.

Issue 14: See comment under section 26.135(b). Recommend add wording to allow licensee or other entity to request a retest of aliquot of single specimen or retest Bottle B if donor chooses not to give permission when there is a legal or administrative proceeding to defend an original positive, adulterated, or substituted result.

From: "Brown, Sue" <suebrown@rti.org>
To: <SECY@nrc.gov>
Date: Mon, Dec 19, 2005 5:50 PM
Subject: Part 26 Comments

Attached are comments to Part 26.

Sincerely,
Sue Brown, Ph.D.
Consultant

E-mail: suebrown@rti.org

Mail Envelope Properties (43A73920.3C0 : 8 : 960)

Subject:	Part 26 Comments
Creation Date:	Mon, Dec 19, 2005 5:50 PM
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Post Office	**Route**
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Files	**Size**	**Date & Time**
MESSAGE	107	Monday, December 19, 2005 5:50 PM
NRC Part 26 Comments_sbrown.doc	154624	
Mime.822	213454	

Options

Expiration Date:	None
Priority:	Standard
Reply Requested:	No
Return Notification:	None
Concealed Subject:	No
Security:	Standard