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OFFICE OF SECRETARY
RULEMAKINGS AND
ADJUDICATIONS STAFF

To 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:

I would like to thank the Nuclear Regulatory Commission (NRC) for the opportunity to comment on the Federal Register publication of 10 CFR Part 26 Fitness for Duty Program; Proposed Rule (RIN 3150-AF12). I am a forensic toxicologist with over 20 years of post-mortem, clinical, and workplace drug testing. My comments and recommendation reflect the knowledge and experience of my past and present involvement in the field of forensic workplace drug testing. I hope that you will accept the concerns and criticism of the specific passages in the proposed rule that I have identified.

Sincerely
Charles LoDico

Preamble:

Pg.50445
"ng/dl Nanograms per deciliter" in workplace drug testing the units used is ng/mL nanograms per milliliter.

Pg.50446
THC-COOH is the abbreviation for delta-9-tetrahydrocannabinol-9-carboxylic acid

Pg.50446
"One proposed change to 10 CFR Part 26 that was included from the proposed HHS Guidelines is permission for licensees to use non-instrumented validity testing devices to determine 50447 Federal Register / Vol. 70, No. 165 / Friday, August 26, 2005 / Proposed Rules whether a urine specimen must be subject to further testing at an HHS certified laboratory." Recommend not to reference any section of the proposed HHS guidelines.

Template = SECY-067

SECY-02

Pg 50448

“One example of such a change is that ‘Bottle B’, the second portion of a split urine specimen, would now only be tested with the donor’s written permission.” **Recommend that NRC require that the donor contact the MRO within 72 hours of notification by MRO of positive adulterated or substituted specimen.**

Pg. 50452

“However, in consideration of the increased costs and burden that are associated with instrumented initial validity testing, proposed Subpart F would permit licensee testing facilities to use non-instrumented validity testing devices to conduct ‘‘validity screening tests’’ of urine specimens, which may be a less expensive alternative than the instrumented initial validity tests required in the current HHS Guidelines.” **Please provide a definition for instrumented initial validity testing and non-instrumented validity testing devices**

Pg. 50452

“HHS also published a proposed revision to the Guidelines (69 FR 19673; April 13, 2004) that would permit the use of validity screening devices for the detection of substitution and the presence of adulterants in urine specimens. These devices include non-instrumented devices with visually-read endpoints as well as semi-automated or automated instrumented testing devices with machine-read end points. Specimen validity tests conducted with these devices use colorimetric assays, which is the same scientific principle as the initial tests conducted at HHS certified laboratories.” **NRC should not construct a rule based on proposed HHS guidelines**

Pg. 50453

“Non-instrumented specimen validity devices for urine testing have been shown to detect adulterants in urine specimens and creatinine concentrations on tests that were conducted on specimens that were spiked with drug analytes. However, the results from the preliminary studies are variable. Therefore, the proposed HHS Guidelines include extensive performance testing requirements for these devices, which proposed Subpart F would also incorporate.” **NRC should not construct a rule based on proposed HHS guidelines**

Pg. 50453

The proposed rule would extend this requirement to the review of non-negative validity test results, consistent with the addition of requirements to conduct validity testing throughout the proposed rule, as discussed in Section VI with respect to proposed § 26.31(d)(3)(i). **If a non-negative validity test result is the same as adulterated or substituted specimen; it would be best if the result is be identified specifically as such.**

Pg. 50474

The terms, ‘‘validity screening test,’’ ‘‘initial validity test,’’ ‘‘confirmatory validity test.’’ **It appears that validity screening test and initial validity test is the same, this is very**

confusing, NRC should have a definition for only an initial validity test and confirmatory validity test.

Pg. 50480

Proposed § 26.25(c)(1)–(c)(6) would list the necessary characteristics of an alternative Federal or State program that, under the proposed rule, licensees and other entities could rely upon to satisfy the requirements of this part for an individual who is subject both to Part 26 and an alternative program. Proposed § 26.25(c)(1) and (3) would permit licensees and other entities to rely on the alternative program to meet the proposed rule's drug testing requirements if the alternative program tests for the drugs and drug metabolites that are specified in the proposed rule at or below the cutoff levels established in the proposed rule and an HHS certified laboratory conducts the program's specimen validity and drug testing. **NRC should not construct a rule based on proposed HHS guidelines.**

Pg. 50535

If the ambient temperature is low or the specimen is small, it may be necessary to measure the specimen temperature sooner than 4 minutes after the collector receives the specimen from the donor. **This kind of language in a rule is difficult to monitor and subject to legal challenge. Recommend to be silent and remove from the rule.**

Pg. 50626

Confirmatory drug or alcohol test means a second analytical procedure to identify the presence of alcohol or a specific drug or drug metabolite in a specimen. The purpose of a confirmatory test is to ensure the reliability and accuracy of an initial test result. **Include in the definition “ is independent of the initial test and which uses a different technique and chemical principle from that of the initial test”.**

Pg 50626

Dilute specimen means a urine specimen with creatinine and specific gravity concentrations that are lower than expected for human urine. **The NRC has not established the cutoff for specific gravity used to determine dilute and substituted.**

Pg 50626

Room 815, 5600 Fishers Lane, Rockwall 2 Bldg., Rockville, Maryland 20857. **Wrong address ,the right address is 1 Choke Cherry Rd. Room 2-1035, Rockville MD 20857**

Pg. 50626

Non-negative test result means a report by the licensee testing facility or the HHS-certified laboratory that a urine specimen meets the criteria for substitution established in this part. **NRC has not established the analytical reporting cutoff to determine when a specimen has met the condition of substituted. There is a reference to specific gravity in the NRC proposed rule but there is no reporting range. In HHS**

guidelines a specific gravity measurement is conducted on a urine specimen that is less than a creatinine value of 20 mg/ dL.

Pg 50627

***Substituted specimen* means a specimen with creatinine and specific gravity values that are so diminished or so divergent that they are not consistent with normal human physiology. NRC needs to define the reporting criteria for specific gravity and the analytical tool (four place refractometer).**

Pg 50627

***Validity screening test* means the use of a non-instrumented testing device to determine the need for initial validity testing of a urine specimen. This definition is confusing and needs clarification. Are instruments that are used to perform validity test prohibited? Most if not all validity test performed in an HHS-certified lab use instruments to perform validity test (ex. Refractometer, multi assay screening instruments, and pH meter).**

Pg.50630

(iv) If a specimen must be collected under direct observation, the collector or an individual who serves as the observer, as permitted under § 26.115(e), may not have a personal relationship with the donor. In part 26.31 the proposed rule lists the condition for a direct observed collection for a urine specimen. But it fails to include the provision that the collection must be performed by the same gender.

Pg 50630

(i) In addition, licensees and other entities may consult with local law enforcement authorities, hospitals, and drug counseling services to determine whether other drugs with abuse potential are being used in the geographical locale of the facility and by the local workforce that may not be detected in the panel of drugs and drug metabolites specified in paragraph (d)(1) of this section. (A) When appropriate, the licensee or other entity may add other drugs identified in accordance with paragraph (d)(1)(i) of this section to the panel of substances for testing, but only if the additional drugs are listed in Schedules I–V of section 202 of the Controlled Substances Act [21 U.S.C. 812]. (B) The licensee or other entity shall establish appropriate cutoff limits for these substances. NRC is setting a bad precedence in allowing other drugs to be tested and will be difficult to assure that all licensees operate under the same cutoff (When appropriate, the licensee or other entity may add other drugs).

Pg 50641

Coloring agents may not interfere with drug or validity tests. This makes no sense and should be removed.

Pg 50641

A collector of the same gender as the donor shall accompany the donor into the area that will be used for specimen collection, but remain outside of the stall. Why does the proposed rule require that a collector be of the same gender when collecting a

specimen under this condition, but makes no requirement for this type of gender collection during a direct observed collection? This should not be required.

Pg. 50641

When an individual has been notified of a requirement for testing and does not appear at the collection site within the time period specified by FFD program procedures. What is the time period? Please indicate it in the proposed rule.

Pg. 50645

The collector shall instruct the donor to urinate into either a specimen bottle or a specimen container. Using this collection procedure will likely produce conflicting results for the Bottle A and B, if a donor attempts and successfully adulterates one bottle and the lab identifies the adulterant. The donor can challenge the lab result by requesting the B bottle tested and it would be a different result; there by canceling the test. Recommend to NRC that the collection of the urine specimen be collected in a collection cup and that the collector transfers the urine specimen into the A and B bottles.

Pg. 50645

The donor has presented, at this collection, a urine specimen that falls outside the required temperature range, and (i) Either the donor declines to provide a measurement of body temperature; or (ii) The donor's measured body temperature varies by more than 1EC/ 1.8EF from the temperature of the specimen. The NRC has not defined 1EC/1.8 EF. There could be a problem when comparing the temperature from a strip and the temperature from a device and assume that they will yield the same result. The likely outcome is that the temperature device is a better indicator then the temperature strip. NRC should reconsider this comparison.

Pg. 50647

Licensee testing facilities shall develop, implement, and maintain written procedures for remedial actions to be taken when systems and noninstrumented testing devices (if used for validity screening tests). The NRC proposed rule does not have a definition for non-instrumented testing devices, it would be helpful to give examples of these devices that NRC will allow to be used to tests specimen for validity tests.

Pg. 50648

Split specimens in Bottle B that are associated with non-negative specimens in Bottle A must also be maintained cooled (as previously specified) 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. Recommend that NRC maintain the split specimen together at all times. The licencee testing facility should send both the A and B bottles to HHS-certified

lab to confirm A bottle non-negative test results. With the B bottle accompanying the A bottle there will be less chance for a lost specimen and a faster turn-around time to complete testing of the B bottle.

Pg. 50648

At a minimum, the licensee testing facility shall test each urine specimen for creatinine, pH, and one or more oxidizing adulterants.

1) Creatinine is less than 20 milligrams (mg) per deciliter (dL)

The NRC proposed rule is silent to the requirement that specific gravity is performed on specimens that have a creatinine concentration less than 20 mg/dL, as required by HHS. NRC has not properly defined the dilution or substitution of urine specimen based on both the creatinine and specific gravity results of a urine specimen.

Pg 50649

§ 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 for the indicated drugs and drug. **NRC should reconsider this policy for amending the drug cutoff as stated in the proposed rule. How can a donor be judged uniformly if different licensees and other entities apply different drug cutoff?**

Pg 50649

The donor shall provide his or her written permission for the testing of Bottle B and neither the licensee, MRO, NRC, nor any other entity may order testing of Bottle B without the donor's written permission. **HHS in their Mandatory guidelines is silent on the requirement to have a donor's written permission to request the re-testing of the B bottle, HHS allows the donor to make contact with the MRO for the request to re-test the B bottle. Also HHS allows the Federal agencies to test the B bottle as part of a legal or administrative proceeding to defend an original positive, adulterated, or substituted result.**

Pg 50649

Licensee testing facilities may rely upon non-instrumented devices to perform validity screening tests to determine the need for initial tests of specimen validity. Licensee testing facilities shall use only non-instrumented devices to perform validity screening tests that meet the following criteria. **NRC proposed rule has not defined what a non-instrumented validity screening test is, nor has given examples of these devices. It**

would be helpful for the public to understand how these non-instrumented test devices are to be used and when they should be used.

Pg 50649

Licensee testing facilities shall use only non-instrumented devices to perform validity screening tests that meet the following criteria: (i) Either the device has been cleared by the U.S. Food and Drug Administration and placed upon the SAMHSA list of point-of-collection testing devices that are certified for use in the Federal Workplace Drug Testing Program in the Federal Register. **NRC should be aware that SAMHSA in its present Federal Workplace Drug Testing Program guidelines has no rules or regulations that permit the use of non-instrumented validity screening tests. NRC's proposed rule should reconsider the use of non-instrumented validity testing devices.**

Pg 50649

A total of 100 devices in representative numbers from all currently available manufactured lots of the device have been performance tested by the licensee testing facility or an HHS-certified laboratory following the manufacturer-specified testing procedures. **HHS does not perform this service to certify non-instrumented validity testing devices.**

Pg 50649

Licensee or other entity shall verify either that the device remains on the SAMHSA-certified list. **SAMHSA lists only laboratories that meet the minimum standards to be an HHS-certified laboratory to perform urine drug test.**

Pg 50650

Validity screening tests must measure a specimen's creatinine concentration to 1 decimal place. **The NRC proposed rule is silent on testing urine specimen that have a creatinine concentration less than 20 mg/dL and is followed with testing to determine the specific gravity of the urine specimen. HHS testing guidelines require this testing regiment.**

Pg 50650

Dipsticks, colorimetric pH tests that have a narrow dynamic range and do not support the 2–12 pH cutoffs, and pH paper may be used only for validity screening tests to determine whether initial validity tests must be performed. **This commenter has a hard time**

understanding this statement. NRC should clarify what it means by “pH tests that have a narrow dynamic range and do not support the 2-12 pH cutoffs”.

Pg 50650

Licensee testing facilities may not use non-instrumented immunoassay testing devices that are pending HHS/SAMHSA review and approval for initial drug testing under this part. NRC should know that HHS/SAMHSA does not review or approves non-instrumented immunoassay testing devices.

Pg 50650

Licensee testing facilities may perform multiple initial drug tests for the same drug or drug class, provided that all tests meet the cutoffs and quality control requirements of this part. Will the NRC proposed rule allow multiple analysis of a donor specimen for the same drug class? This rule is unclear and needs to be clarified. The concern is that NRC is promoting individual licensee testing as oppose to a standard that will apply throughout the NRC licensee testing facilities.

Pg 50651

One percent of each run or at least 1 sample (whichever is greater), must be blind performance test samples that appear as normal samples to the licensee testing facility technicians. How is the NRC proposed rule going to achieve this requirement when a donor must be present and identified by the licensee testing facility if that licensee testing facility is using non-instrumented testing devices to perform urine drug test? How will the blind specimen be introduced into the testing batch?

Pg 50651

The data in the annual report to the NRC must be presented for either the cutoff levels specified in this part, or for more stringent cutoff levels, if the FFD program uses more stringent cutoff levels for drugs and drug metabolites. If the FFD program tests for drugs and drug metabolites that are not specified in § 26.31(d)(1), the summary must also include the number of positive test results and the cutoff levels used for those drugs and drug metabolites. This NRC proposed rule is disturbing to this commenter in that the NRC is allowing each licensee to allow changes to both the cutoff for drug or drug metabolites and to add other drugs to the drug testing panel. Highly recommend that the NRC proposed rule have only one drug panel with only one drug cutoff for all of their testing designated personnel.

Pg 50654

Determine the specific gravity of every specimen for which the creatinine concentration is less than 20 mg/dL. The NRC proposed rule should indicate the type of

instrument to be used to perform a specific gravity test. HHS requires that all specific gravity test be performed using a four place refractometer.

From: "LoDico, Charles P. (SAMHSA/CSAP)" <Charles.LoDico@samhsa.hhs.gov>
To: <SECY@nrc.gov>
Date: Tue, Dec 20, 2005 2:05 PM
Subject: Commnets to the NRC proposed Fitness for Duty rule

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