July 14, 2009

MEMORANDUM TO: Craig Erlanger, Chief
Integrated Security Coordination and Policy Branch
Division of Security Policy
Office of Nuclear Security and Incident Response

FROM: Paul Harris, Senior Program Manager ***/RA/***
Integrated Security Coordination and Policy Branch
Division of Security Policy
Office of Nuclear Security and Incident Response

SUBJECT: SUMMARY OF PUBLIC MEETING TO DISCUSS THE POTENTIAL IMPACT OF THE REVISED U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES DRUG TESTING GUIDELINES ON U.S. NUCLEAR REGULATORY COMMISSION FITNESS FOR DUTY REQUIREMENTS

On June 24, 2009, the U.S. Nuclear Regulatory Commission (NRC) staff held a public meeting to discuss the potential impact of the November 25, 2008 "HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs," (73 FR 71858) on NRC fitness for duty requirements. These requirements are described in Title 10 of the *Code of Federal Regulations* (10 CFR), Part 26, "Fitness for Duty Programs." The NRC is considering possible Part 26 rulemaking to correct editorial and technical errors and to address other technical issues as a result of differences between Part 26 to the Department of Homeland Security (HHS) Guidelines published in the Federal Register on November 25, 2008. The meeting was held at the NRC headquarters located at 11555 Rockville Pike, Rockville, MD 20852.

The meeting was noticed on June 1, 2009. The notice is available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/adams.html where the public can access the text and image files of NRC's public documents in the NRC's Agencywide Documents Access and Management System (ADAMS) utilizing accession number ML091410294.

Meeting participants are listed in Enclosure A. Participants included NRC staff and contractors, members of the power reactor licensee community, and a representative from the Nuclear Energy Institute (NEI).

The meeting began with introductory remarks regarding the HHS Guidelines, which must be implemented by HHS-certified laboratories by May 1, 2010. The staff then summarized

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discussions that occurred during an NRC public meeting on February 24, 2009, (ADAMS accession nos. ML090420577 and ML090771060), in particular, the need for rulemaking for Item 1 listed in Enclosure B. Enclosure B details all the staff-presented issues that were discussed at the June 24, meeting.

During the meeting, NEI presented the NRC staff with a memorandum (Enclosure C, ML091910480) regarding the impacts of the HHS Guidelines on licensee programs. In addition, NEI provided an email to the staff after the meeting describing additional considerations (Enclosure D, ML091890196).

Enclosures:
As stated

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As stated

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ADAMS ACCESSION NO.: ML091910511.

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OFFICIAL RECORD COPY

Attendance List

NAME	AFFILIATION
In Attendance	
Howard Benowitz	U.S. Nuclear Regulatory Commission (NRC)
Wayne Chalk	NRC
John Collier	ICF International (ICF)
Paul Harris	NRC
Robert Kelm	Nuclear Energy Institute, contractor
Georgia Thu	ICF
Brian Zaleski	ICF
Christine Secor	NRC
Via webinar/phone	
Valerie Barnes	NRC
Ron Flegel	Dept. of Health and Human Services
Kim Hanlon	(1)
Margaret Lowe	(1)
Pamela O'Connor	(1)
Billie Rooks	(1)
Russell Sears	(1)
Theodore Shults	ICF contractor
Susan Techau	Exelon Nuclear, Exelon Corporation

Note (1) – Affiliation not ascertained.

NRC-Staff Hand-out

Notes:
1. Minor editorial changes were made to this enclosure to correct formatting and spelling.
2. The yellow and green highlighting and redline/~~strike-out~~ used throughout this handout was used for emphasis.

Item 1

QV/QC Requirements for Initial Drug and Validity Testing (Meeting Notice Item 7)

Enforcement Guidance Memorandum, EGM-09-003; ML090760728
Regulatory information Summary, RIS 2009-008, ML091910511

Use of the phrase "donor specimen," rather than "normal specimen," is inconsistent with the intent of the rule. If the specimen was required to be a "donor specimen," licensees would then be required to assign the roles of specimen collector and LTF technician to different persons, which is not intended for initial drug and validity performed at LTFs. If left uncorrected, the final rule would represent an unnecessary cost and burden on licensees because procedure changes would be necessary and an additional trained and qualified person would be required to implement these tests. The majority of LTFs utilize a single LTF technician to collect specimens and to perform specimen testing. That practice is consistent with the former and proposed rules, and the intent of the final rule.

The language in Section 26.137(e)(6)(v) will prevent licensees from using the same QC sample to test both the accuracy of testing and implementation of custody-and-control procedures. The former and proposed rules were not intended to require a specimen that "appears to be a normal specimen" to be certified by an HHS-certified laboratory to be a positive QC sample (i.e., a sample that contains drugs or drug metabolites at a concentration that exceeds the applicable cutoff levels for initial drug tests in 10 CFR Part 26). Requirements for positive QC samples are addressed in other provisions of this same section of the rule. Furthermore, the former and proposed rules permitted this sample to be negative or to have positive characteristics in order to evaluate the accuracy of licensee testing procedures and equipment. This flexibility is appropriate and consistent with the intent of the final rule.

10 CFR Part 26

SOC 17086 provides discussion. In particular:

Section 26.137(d)(5)

Incorrect — Each analytical run performed to conduct initial validity testing shall include at least one quality control sample that appears to be a donor specimen to the laboratory analysts.

Correct — Each analytical run performed to conduct initial validity testing shall include at least one quality control sample that appears to be a normal specimen to the licensee testing facility technicians.

Section 26.137(e)(6)(v)

Incorrect At least one positive control, certified to be positive by an HHS-certified laboratory, that appears to be a donor specimen to the laboratory analysts.

Correct At least one quality control sample that appears to be a normal specimen to the license testing facility technicians.

Note: Current NRC rulemaking is designed to change "laboratory analyst" to "licensee testing facility technician."

HHS Guidelines

Subpart K - Laboratory
Section 11.12 What are the batch quality control requirements when conducting an initial drug test?
(a) Each batch of specimens must contain the following QC samples:
(1) At least one control certified to contain no drug or drug metabolite;
(2) At least one positive control with the drug or drug metabolite targeted at 25 percent above The cutoff;
(3) At least one control with the drug or drug metabolite targeted at 75 percent of the cutoff; and
(4) At least one control that appears as a donor specimen to the laboratory analysts.

Item 2, New item

Applicability of Drug & Alcohol Testing during Pre-assignment

Part 26

SOC 17158, The conditions that can lead to drug and alcohol testing of an individual specified in § 26.405(c)(1) through (c)(4) parallel generally the conditions listed in § 26.31(c)(1) through (c)(4), with changes to reflect the different reasons for testing individuals identified in § 26.4(f) under Subpart K and testing individuals at an operating nuclear reactor under Part 26.

§ 26.405 Drug and Alcohol Testing
(c) Individuals identified in 26.4(f) shall be subject to drug and alcohol testing under the following conditions:
(1) Pre-assignment. Before assignment to construct or direct the construction of safety- or security-related SSCs:

§ 26.4 FFD program applicability to categories of individuals.
(f) Any individual who is constructing or directing the construction of safety or security-related SSCs shall be subject to an FFD program that meets the requirements of subpart K of this part, unless the licensee or other entity subjects these individuals to an FFD program that meets all of the requirements of this part, except for subparts I and K of this part.

HHS Guidelines

tbd

Item 3, New Item

10 CFR 55.53(k) reference to Drug and Alcohol Testing

Revision of § 55.53(k) to ensure that NRC-licensed operators and those directing operations will be subject to the fatigue management provisions of Part 26.

For example:

§ 55.53, Conditions of licenses
(k) "Each licensee at power reactors shall ~~participate in the drug and alcohol testing~~ be subject to the fitness-for-duty program~~s~~ established by the facility licensee pursuant to 10 CFR part 26."

§ 26.4 FFD program applicability to categories of individuals.

(a) All persons who are granted unescorted access to nuclear power reactor protected areas by the licensees in § 26.3(a) and, as applicable, (c) and perform the following duties shall be subject to an FFD program that meets all of the requirements of this part, except subpart K of this part:

(1) Operating or onsite directing of the operation of systems and components that a risk-informed evaluation process has shown to be significant to public health and safety;

Item 4, New Item

10 CFR 26.719(b)(2) Reference to Part 52 – Operator Licensing Applicability

Propose a revision/correction to § 26.719(b)(2) to remove the reference to Part 52, Licenses, Certifications, and Approvals for Nuclear Power Plants, i.e., new reactor construction.

Part 52 is the licensing provision for, in part, NRC issuance of early site permits, standard design approvals, combined licenses, and manufacturing licenses for nuclear power facilities.

Part 52 does not license operators; this is accomplished by 10 CFR Part 55, “Operators’ Licenses.”

§ 26.719 Reporting requirements.

(b) *Significant FFD policy violations or programmatic failures.* The following significant FFD policy violations and programmatic failures must be reported to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers the violation:

(2) "Any acts by any person licensed under 10 CFR part~~s 52 and/or~~ 55 to operate a power reactor, as well as any acts by SSNM transporters, FFD program personnel, or any supervisory personnel who are authorized under this part, if such acts..."

HHS Guidelines

not applicable

Item 5

MRO Review of pH as a Function of Temperature Considerations

Part 26

§ 26.161 Cutoff levels for validity testing.
(b) *Initial validity testing.* The HHS certified laboratory shall perform initial validity testing of each specimen as follows:
(3) Determine the pH;
(f) *Results indicating an invalid specimen.* The laboratory shall report a specimen as invalid when the laboratory obtains any one or more of the following validity testing results:
(2) The pH is equal to or greater than 3 and less than 4.5, or equal to or greater than 9 and less than 11, using either a colorimetric pH test or pH meter for the initial test and a pH meter for the confirmatory test on two separate aliquots;

There are no conflicts with cut-off levels for specimen validity, except the pH levels for declaring a specimen invalid. Part 26 has guidance on medical reasons for pH, but does not have guidance for MROs on technical reasons (e.g., high temperature).

HHS Guidelines

Section 13.4 What must an MRO do when reviewing a test result?
(f) When an HHS-certified laboratory reports an invalid result on the primary (Bottle A) urine specimen, the MRO contacts the donor to determine if there is a legitimate medical explanation for the invalid result. In the case of an invalid result based on pH of 9.0 to 9.5, when an employee has no other medical explanation for the pH in this range, the MRO must consider whether there is evidence of elapsed time and high temperature that could account for the pH value. The MRO may contact the collection site, IITF, and/or laboratory to discuss time and temperature issues (*e.g.*, time elapsed from collection to receipt at the testing facility, likely temperature conditions between the time of the collection and transportation to the testing facility, specimen storage conditions).

(ii) If the donor is unable to provide an acceptable medical explanation or if the MRO determines that time and temperature fail to account for the pH in the 9.0–9.5 range, the MRO reports a test cancelled result with the reason for the invalid result and directs the Federal agency to immediately collect another specimen from the donor using a direct observed collection.

SOC 71871 of the HHS Guidelines states that a specimen that has been exposed to high temperatures during storage or transport could have a high pH level that would meet the criteria for invalid specimen. Thus, MROs can consider time and temperature as a non-medical reason for an invalid result. So, if MROs do not look at the history of specimen, specimens could be incorrectly declared as invalid.

Item 6

Academic Requirements for Certifying Scientists.

Part 26

§ 26.155 Laboratory personnel.
(b) *Certifying scientist*
(2) A certifying scientist shall be an individual with at least a bachelor's degree in the chemical or biological sciences, medical technology, or an equivalent field who reviews all pertinent data and quality control results.

HHS Guidance

SOC 71867 The Department has decided to retain the bachelor's degree or equivalent requirement for the certifying scientist qualifications as described in the current Guidelines.

Section 11.5 What qualifications must an individual have to certify a result reported by an HHS-certified laboratory?
(a) The certifying scientist must have:
(1) At least a bachelor's degree in the chemical or biological sciences or medical technology, or equivalent;

Item 7, New Item

Disclosure of Information

Identified as a result of a stakeholder provided Frequently Asked Question (FAQ), additional clarification may be necessary.

§ 26.37 Protection of information.

(b) Licensees and other entities shall obtain a signed consent that authorizes the disclosure of the personal information collected and maintained under this part before disclosing the personal information, except for disclosures to the following individuals:

(6) The presiding officer in a judicial or administrative proceeding that is initiated by the subject individual;

We desire to address:

1. wrongful termination for an FFD violation

2. that a disclosure of information to a licensee's attorney is limited to those attorneys involved in the FFD wrongful termination proceeding,

3. that the information disclosed to the attorneys and presiding officer is limited to the personal FFD information about the individual that is at issue in the proceeding

4. that the information disclosed to the attorneys is the same information given to the presiding officer

5. that the disclosure must include a binding stipulation that the presiding officer and attorneys will not make the information publicly available.

Item 8

Cutoff concentrations for certain illegal drugs (e.g., cocaine and amphetamines).

Initial and confirmatory test requirements for MDMA designer drugs, *Ecstasy*.

Part 26

INITIAL TEST CUTOFF LEVELS FOR DRUGS & DRUG METABOLITES, 26.133 Drug or metabolites Cutoff level (ng/mL)		CONFIRMATORY TEST CUTOFF LEVELS FOR DRUGS AND DRUG METABOLITES, 26.163 Drug or metabolites	Cutoff level (ng/mL)
Marijuana metabolites	50	Marijuana metabolite1	5
Cocaine metabolites	300	Cocaine metabolite 2	150
Opiate metabolites	2000	<u>Opiates</u>	
Phencyclidine (PCP)	25	Morphine	2000
		Codeine	2000
		6-acetylmorphine 3	10
		Phencyclidine (PCP)	25
Amphetamines		<u>Amphetamines</u>	
1000		Amphetamine	500
		Methamphetamine.[4]	500

1 As delta-9-tetrahydrocannabinol-9-carboxylic acid.
2 As benzoylecgonine.
3 Test for 6–AM when the confirmatory test shows a morphine concentration exceeding 2,000 ng/mL.
4 Specimen must also contain amphetamine at a concentration equal to or greater than 200 ng/mL.

<u>HHS Guideline</u>

Section 3.1 Which drug and specimen validity tests are conducted on a urine specimen?
A Federal agency: (a) Must ensure that each specimen is tested for marijuana and cocaine metabolites as provided under Section 3.4
(b) Is authorized to test each specimen for opiates, amphetamines, and phencyclidine, as provided under Section 3.4;

Section 3.2 May a specimen be tested for additional drugs?
(a) A specimen may be tested for additional drugs, on a case-by-case basis, when a Federal agency is conducting a specimen collection for reasonable suspicion, post accident, or unsafe practice testing.
(b) A Federal agency covered by these Guidelines must petition the Secretary in writing for approval to routinely test for any drug class not listed in Section 3.1.

Section 3.3 May any of the specimens be used for other purposes?
(b) These Guidelines are not intended to prohibit any Federal agency specifically authorized by law to test a specimen for additional classes of drugs in its workplace drug testing program.

Section 3.4 What are the cutoff concentrations for drug tests? YELLOW indicates Part 26 differences.

Initial test analyte	Initial test cutoff concentration		Confirmatory test analyte		Confirmatory test cutoff concentration
Marijuana metabolites	50 ng/mL NRC	50	THCA1 ... 15 NRC		15 ng/mL 100 ng/mL
Cocaine metabolites	150 ng/mL NRC	300	Benzoylecgonine	- -	2000 ng/mL .....
Opiate metabolites					
Codeine/Morphine 2 ..	2000 ng/mL NRC	2000	Codeine NRC	2000	2000 ng/mL
			Morphine NRC	2000	10 ng/mL ... 25 ng/mL
6-Acetylmorphine .					
Phencyclidine	10 ng/mL	- -			
	25 ng/mL NRC	25	6-Acetylmorphine NRC	10	250 ng/mL 250 ng/mL
Amphetamine . AMP/MAMP4			Phencyclidine NRC	25	250 ng/mL 250 ng/mL
MDMA	500 ng/mL NRC	1000			250 ng/mL
			Amphetamines 3. NRC	500	
	500 ng/mL	- -	Methamphetamine 5 . 500 NRC		
			MDMA6 ..		
			MDA7 .		
			MDEA8		

1 Delta-9-tetrahydrocannabinol-9-carboxylic acid (THCA).
2 Morphine is the target analyte for codeine/morphine testing.
3 Either a single initial test kit or multiple initial test kits may be used provided the single test kit detects each target analyte independently at the specified cutoff.
4 Methamphetamine is the target analyte for amphetamine/methamphetamine testing.
5 To be reported positive for methamphetamine, a specimen must also contain amphetamine at a concentration equal to or greater than 100 ng/mL.
6 Methylenedioxymethamphetamine (MDMA).
7 Methylenedioxyamphetamine (MDA).

Item 9

Training requirements for Trainers who Train Collectors

Part 26

COLLECTION
§ 26.85 Collector qualifications and responsibilities.
(a) *Urine collector qualifications*.
Urine collectors shall be knowledgeable of the requirements of this part and the FFD policy and procedures of the licensee or other entity for whom collections are performed, and shall keep current on any changes to urine collection procedures. Collectors shall receive qualification training that meets the requirements of this paragraph and demonstrate proficiency in applying the requirements of this paragraph before serving as a collector. At a minimum, qualification training must provide instruction on the following subjects:

ACCESS
(d) Licensees and other entities shall take the following measures to prevent unauthorized access to the collection site that could compromise the integrity of the collection process or the specimens.
(1) Unauthorized personnel may not be permitted in any part of the designated collection site where specimens are collected or stored;
(2) A designated collection site must be secure. If a collection site is dedicated solely to specimen collection, it must be secure at all times. Methods of assuring security may include, but are not limited to, physical measures to control access, such as locked doors, alarms, or visual monitoring of the collection site when it is not occupied;

Who Can Collect?
(1) A collector who meets the requirements of paragraphs (a) or (b) of this section cannot reasonably be made available at the time the collection must occur;
(2) The individual is not employed by the licensee's or other entity's FFD program and his or her normal workplace is not at the licensee's or other entity's facility;
(3) The individual does not routinely provide FFD program services to the licensee or other entity;
(4) The individual is licensed or otherwise approved to practice in the jurisdiction in which the collection occurs; and
(5) The individual is provided with detailed, clearly-illustrated, written instructions for collecting specimens under this subpart and follows those instructions.

HHS Guidelines

Section 4.1 Who may collect a specimen?
(a) A collector who has been trained to collect urine specimens in accordance with these Guidelines.
(b) The immediate supervisor of a Federal employee donor may only collect that donor's specimen when no other collector is available. The supervisor must be a trained collector.

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

Section 4.2 Who may not collect a specimen?
(a) A Federal agency employee who is in a testing designated position and subject to the Federal agency drug testing rules must not be a collector for co-workers who are in the same testing pool or who work together with that employee on a daily basis.
(b) A Federal agency applicant or employee must not collect his or her own urine.
(c) An employee working for an HHS certified laboratory or IITF must not act as a collector if the employee could link the identity of the donor to the donor's drug test result.
(d) To avoid a potential conflict of interest, a collector should not be someone that is related to the employee (e.g., spouse, ex-spouse, relative) or a close personal friend (*e.g.,* fiance´).

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

Section 5.2 What are the requirements for a collection site?
A facility that is used as a collection site must have the following:
(a) Provisions to ensure donor privacy during the specimen collection procedure in accordance with Section 8.1;
(b) A suitable clean surface area not accessible to the donor, for handling the specimens and completing the required paperwork;
(c) A secure temporary storage capability to maintain a specimen until it is transferred to an HHS-certified laboratory or IITF;
(d) The ability to restrict access to only authorized personnel during the collection;
(e) The ability to restrict access to collection supplies;
(f) The ability to store records securely; and
(g) The ability to restrict the donor access to potential diluents in accordance with Section 8.2.

Item 10

Split sampling of and volume requirements for urine specimens

Part 26

§ 26.109 Urine specimen quantity.
(a) Licensees and other entities who are subject to this subpart shall establish a predetermined quantity of urine that donors are requested to provide when submitting a specimen.

At a minimum, the predetermined quantity must include 30 milliliters (mL) to ensure that a sufficient quantity of urine is available for initial and confirmatory validity and drug tests at an HHS certified laboratory, and for retesting of an aliquot of the specimen if requested by the donor under § 26.165(b).

The licensee's or other entity's predetermined quantity may include more than 30 mL, if the testing program follows split specimen procedures, tests for additional drugs, or performs initial testing at a licensee testing facility. Where collected specimens are to be split under the provisions of this subpart, the predetermined quantity must include an additional 15 mL.

§ 26.113 Splitting the urine specimen.
(a) Licensees and other entities may, but are not required to, use split specimen methods of collection.
(b) If the urine`1 specimen is to be split into two specimen bottles, hereinafter referred to as Bottle A and Bottle B, the collector shall take the following steps: (1) The collector shall instruct the donor to urinate into a specimen container; (2) The collector, in the presence of the donor and after determining specimen temperature as described in § 26.111(a), shall split the urine specimen. The collector shall pour 30 mL of urine into Bottle A and a minimum of 15 mL of urine into Bottle B.

§ 26.135 Split specimens.
(a) If the FFD program follows split specimen procedures, as described in § 26.113, the licensee testing facility shall analyze aliquots of the specimen for the licensee's or other entity's purposes as described in this part.

§ 26.165 Testing split specimens and retesting single specimens.
(a) *Testing split specimens.*
(1) If a specimen has been split into Bottle A …
(2) If a specimen was initially tested at a LTF and positive or questionable validity test results were obtained then the HHS-certified laboratory shall perform initial and confirmatory testing, if required, of the specimen in Bottle A.
(3) At the licensee's or other entity's discretion, Bottle B must either be forwarded to the HHS-certified laboratory or maintained in a secure storage at the licensee testing facility, as required by § 26.135(a) and (c), as applicable. If the specimen in Bottle A is free of any evidence of drugs or drug metabolites, and is a valid specimen, then the licensee testing facility or HHS-certified laboratory may discard the specimens in Bottles A and B.
(b) *Donor request to MRO for a retest of a single specimen or testing Bottle B of a split specimen.* (1) For a confirmed positive, adulterated, or substituted result reported on a single specimen of 30 mL or more, or a specimen in Bottle A of a split specimen which the donor submitted to the licensee or other entity, a donor may request (through the MRO) that an aliquot from the single specimen or the split (Bottle B) specimen be tested by a second HHS-certified laboratory to verify the result reported by the first laboratory. For an invalid test result, a donor may not request that an aliquot from the single specimen or the split specimen in Bottle B be tested by a second HHS-certified laboratory.

§ 26.168 Blind performance testing.
(i)(3) The licensee or other entity shall ensure that all blind performance test samples include split samples, when the FFD program includes split specimen procedures.

<u>HHS Guidelines</u>

Section 2.3 How is each specimen collected?
Each specimen is collected as a split specimen as described in Section 2.5.

Section 2.4 What volume of urine is collected?
A donor is expected to provide at least 45 mL of urine for a specimen to be tested at an HHS-certified laboratory or IITF.

Section 2.5 How does the collector split the urine collected?
The collector pours at least 30 mL into a specimen bottle that is labeled Bottle A (primary) and then pours at least 15 mL into a specimen bottle that is labeled Bottle B (split).

Item 11

Use of privately owned and operated "Instrumented Initial Test Facilities."
Part 26
Should Part 26 Enable to use of IITFs?
Additional costs to licensees for certification and audits

HHS Guidelines
IITFs are certified to do initial tests for all drugs
IITFs are certified by HHS

Subpart I of HHS Guidelines provide for HHS Certification of Laboratories and IITFs

Item 12

Use of refractometers, to 3 or 4 decimal places, for specific gravity of urine specimens.

§ 26.161 Cutoff levels for validity testing.
(d) *Results indicating a substituted specimen.* The laboratory shall report a specimen as substituted when the specimen's creatinine concentration is less than 2 mg/dL and its specific gravity is less than or equal to 1.0010, or equal to or greater than 1.0200, on both the initial and confirmatory creatinine tests (i.e., the same colorimetric test may be used to test both aliquots) and on both the initial and confirmatory specific gravity tests (i.e., a refractometer is used to test both aliquots) on two separate aliquots.

SOC 17080 In contrast to the requirements for initial validity testing in the HHS Guidelines, the final rule does not permit licensee testing facilities to evaluate the specific gravity of any specimens. To determine if a specimen is dilute or substituted, specific gravity testing is required. If the creatinine concentration of a specimen is less than 20 mg/dL, the final rule requires the licensee testing facility to forward the specimen to the HHS-certified laboratory to complete the testing, where the specimen's specific gravity will be measured. The final rule differs from the HHS Guidelines in this provision because the costs of the instruments (i.e., refractometers) that are required in the Guidelines for measuring specific gravity are high. Some licensee testing facilities are currently measuring the specific gravity of specimens. However, the cutoff levels established in the Guidelines require more sensitive measurement and licensee testing facilities would be required to purchase new equipment in order to test at the new HHS specific gravity cutoff levels. Therefore, the final rule requires licensee testing facilities to transfer all specimens with creatinine concentrations less than 20 mg/dL to an HHS-certified laboratory to complete the initial testing process and does not include cutoff levels for specific gravity or quality control requirements for measuring specific gravity.

§ 26.167 Quality assurance and quality control.
(c) *Quality control requirements for performing initial and confirmatory/validity tests.*
(2) Requirements for performing specific gravity tests:

(i) The refractometer must report and display the specific gravity to four decimal places, and must be interfaced with a laboratory information management system, or computer, and/or generate a hard copy or digital electronic display to document the numerical result;

HHS Guidance

Item 13

Use of the terms "controlled substance" and "illegal drug."

Throughout the rule, change "controlled substance" to the phrase that is correct or insert the exact substances we mean.

Part 26

SOC 17168, Section 26.719(b)(2)(i) retains former § 26.73(a)(2)(i). The provision requires licensees and other entities to report any acts by the subject individuals that involve the use, sale, or possession of a controlled substance.

§ 26.5 Definitions.
Illegal drug means, for the purposes of this regulation, any drug that is included in Schedules I to V of section 202 of the Controlled Substances Act [21 U.S.C. 812], but not when used pursuant to a valid prescription or when used as otherwise authorized by law.

§ 26.31 Drug and alcohol testing.
(d) *General requirements for drug and alcohol testing.* (1) Substances tested. At a minimum, licensees and other entities shall test for marijuana metabolite, cocaine metabolite, opiates (codeine, morphine, 6-acetylmorphine), amphetamines (amphetamine, methamphetamine), phencyclidine, adulterants, and alcohol.

(A) When appropriate, the licensee or other entity may add other drugs identified under 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 through V of section 202 of the Controlled Substances Act [21 U.S.C. 812].

§ 26.719 Reporting requirements.
(b) *Significant FFD policy violation or programmatic failures.* The following significant FFD policy violations and programmatic failures must be reported to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers the violation:
(2) Any acts by any person licensed under 10 CFR parts 52 and/or 55 to operate a power reactor, as well as any acts by SSNM transporters, FFD program personnel, or any supervisory personnel who are authorized under this part, if such acts—
(i) Involve the use, sale, or possession
of a controlled substance;

HHS Guidelines
only refers to the Controlled Substances Act
does not provide a definition for illegal drug

Item 14

Definitions of "split sample" and "dilute sample."

Discussed at the previous public meeting held on February 24, 2009.

Additional New Items

A. Point of Collection Testing
for urine and oral fluid specimens

Part 26

§ 26.87 Collection sites.
(a) Each FFD program must have one or more designated collection sites that have all necessary personnel, materials, equipment, facilities, and supervision to collect specimens for drug testing and to perform alcohol testing. Each collection site must provide for the collection, security, temporary storage, and shipping or transportation of urine specimens to a drug testing laboratory;
(f) In the exceptional event that a designated collection site is inaccessible and there is an immediate requirement to collect a urine specimen, including, but not limited to, an event investigation, then the licensee or other entity may use a public rest room, onsite rest room, or hospital examining room according to the following procedures:

HHS Guidelines

Subpart E—Collection Sites
Section 5.1 Where can a collection for a drug test take place?
(a) A collection site may be a permanent or temporary facility located either at the work site or at a remote site.
(b) In the event that an agency designated collection site is not accessible and there is an immediate requirement to collect a specimen (e.g., an accident investigation), a public restroom may be used for the collection, using the procedures for a monitored collection described in Section 8.11.

B. Alternate Testing

Oral fluid testing, sweat patch testing, hair testing, and associated issues
tbd

C. Standards for Trainers who Train the Collectors

Part 26 does not have requirements to train the trainer

D. Blood Alcohol Content and Abstinence Period

Revise § 26.103 to require individuals to be removed from performing covered duties when they report to work, are sent for an FFD test immediately upon reporting to work, and have a 0.03% BAC (or 0.02% after one hour, etc.). If an individual shows up for work with .03%, there's good reason to believe the individual violated the 5-hour pre-duty abstinence period.

E. Transporters of Category 1A Material

§ 26.3 Scope.
(b) Licensees who are authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under Part 70 of this chapter, and any corporation, firm, partnership, limited liability company, association, or other organization who obtains a certificate of compliance or an approved compliance plan under Part 76 of this chapter, only if the entity elects to engage in activities involving formula quantities of SSNM shall comply with the requirements of this part, except for subparts I and K of this part.

Section 26.4(d) includes individuals who transport Category IA material for licensees identified in Section 26.3(b).

§ 26.4 FFD program applicability to categories of individuals.
(i) The following individuals are not subject to an FFD program under this part:
(3) SSNM transporter personnel who are subject to U.S. Department of Transportation drug and alcohol FFD programs which require random testing for drugs and alcohol;

Section 26.4(i)(2) states that SSNM transporter personnel who are subject to a U.S. DOT drug and alcohol (D/A) fitness for duty program that require random testing for D/A are not subject to Part 26.

"SSNM transporters" in Section 26.719(b)(2) refers to the 26.4(d) SSNM transporter personnel who are not exempt from Part 26 under 26.4(i)(2).

SOC 17167. The final rule expands the former reporting requirement to include SSNM transporter personnel and FFD program personnel. The NRC has made this change to ensure that it is informed of events involving these individuals because of the important roles they play in assuring public health and safety and the common defense and security,

§26.719 **Reporting requirements.**
(b) *Significant FFD policy violations or programmatic failures.* The following significant FFD policy violations and programmatic failures must be reported to the NRC Operations Center by telephone within 24 hours after the licensee or other entity discovers the violation:
(2) Any acts by any person licensed under 10 CFR parts 52 and/or 55 to operate a power reactor, as well as any acts by SSNM transporters, FFD program personnel, or any supervisory personnel who are authorized under this part, if such acts—

F. Direct Observation of Urinalysis Collection

Court Case 08-2164
Argued March 26, 2008
Decided May 15, 2009

BNSF Railway Company, et. al with the International Association of Machinists and Aerospace Workers (Intervenor) vs Department of Transportation

Under the Dept of Transportation regulations, employees of aviation, rail, motor carrier, mass transit, maritime and pipeline industries who ether fail or refuse to take a drug test must successfully complete a drug treatment program and pass a series of urine tests as a condition of performing any safety-sensitive duties.

To prevent cheating, the DOT modified its regulations in 2008 to require that such tests be conducted under direct observation. Petitioners challenged the revised regulation, arguing that it violates the Fourth Amendment.

For the reasons set forth in the United States Court of Appeals for the District of Columbia on May 15, 2009, found that the DOT'S considered justification for its policy neither arbitrary nor capricious, and although the Court recognized the highly intrusive nature of direct observation testing, the Court concluded that the regulation complies with the Fourth Amendment.

The DOT interest in transportation safety is compelling to say the least.

Even the proliferation of cheating devices, the Court had little difficulty in concluding that direct observation furthers the government's interest in effective drug testing.

The court found that the government's interest in conducting the search outweighs the individual's privacy interest.

Armed with foreknowledge, returning employees can easily obtain and conceal cheating devices, keeping them handy even for unannounced follow-up testing.

Employees, who have intentionally violated a valid drug testing regulation, have a less legitimate interest in resisting a search intended to prevent future violations of that regulation than do employees who never violated the rule.

Direct observation is extremely intrusive, but that intrusion is mitigated by the fact that employees can avoid it by simply complying with the drug regulations.

Direct observation will significantly improve testing accuracy.

NEI Memo Containing Results of Industry Survey

Note: Below is a copy of the NEI memo provided to the staff during the June 24, 2009, public meeting. This memo can be located in ADAMS at accession no. ML091910480.

May 31, 2009

TO: C. Earls, Sr. Project Manager, Nuclear Energy Institute (NEI)

SUBJECT: Summary—Industry Survey Reponses to Changes inn the HHS Guidelines

In February 2009, the NRC held a public meeting to discuss changes to the HHS Mandatory Guidelines for Federal Workplace Drug Testing Programs. The NRC is reviewing the changes to the HHS document published on November 25, 2009. The NRC would like the input from interested parties on several issues.
The issues included:

1. Extending the split specimen requirement to all NRC licensed facilities;
2. Adoption of a new 7 drug panel as specified in November 25, 2008 HHS Guidelines document;
3. The need to increase the minimum amount of urine required during a collection;
4. Revising Part 26 collection procedures to coincide with the requirements of the HHS Guidelines; and
5. Adopting the use of the Instrumented initial Test Facility

The Advisory Task Force agreed to survey the licensee companies to obtain relevant input regarding these issues.

The survey was completed by 13 companies representing 37 individual plant sites. The results of the survey revealed that:

1. Approximately one-half of the sites responding to the survey employed split specimens as part of their 10 CFR Part 26 program. The comments revealed that those sites that do not split specimens do not want to change their processes as changes in the process must in many cases be negotiated with bargaining units. There was little or no impact on those licensee companies that already implemented split specimens.
2. While many of the respondents are in favor of expanding the panel, all companies responding to the survey responded that they would change their panel ***only*** if the NRC mandated the expansion of the panel to the 7 drugs specified in the HHS Guidelines. The reason is that many of the companies have had to negotiate with bargaining units on the drug testing process and expansion of the panel by the company without a mandate within the rule would subject the drug panel to the negotiation process and not guarantee its adoption. There would likely be some disparity within industry programs for a period of time.

3. The companies responding did not feel that the minimum quantity of urine provided at the time of collection would need to be increased due to the increase in the panel; however, there would be need to increase the minimum amount if splits specimens were mandated in a rule change.

4. The companies were essentially neutral on the adoption of the HHS collection process. The commenters did not see appreciable differences in the collection processes. The commenters did state that they did not believe that the use of DOT collection sites would be of a significant benefit and might cause some auditing problems (more sites to audit)
5. Finally, only two company favored adoption of the IITF concept and saw any benefit. One company's program uses a contractor to run and on-site laboratory that mimics the IIRT concept now. Having the concept in the rule would not cause any licensee company any hardship.

If you have any questions, please contact me at (419) 824-2111, by fax at (419) 882-5718 or by e-mail at robertkelm@aol.com.

Sincerely,

Robert R. Kelm, Sr.

RRK

Survey Questions—Changes to Mandatory Guidelines for Federal Workplace Drug Testing programs

1. Does your company split specimens in accordance with 10 CFR 26.113 as part of your licensee company fitness-for-duty program?
2. If the NRC does not mandate a change in the panel would your licensee company adopt the new panel and cutoffs?
3. If your licensee company were to adopt the new panel, would your company adjust the quantity of urine to be collected?
4. The NRC could revise the 10 CRR Part 26 collection process to be identical to the HHS DOT process so that collections performed at DOT collection sites would be acceptable under 10 CFR Part 26. What problems do you foresee for your organization?
5. The HHS Guidelines permit the use of an HHS-certified Instrumented Initial Test facility (IITF) that is a permanent location where initial testing, reporting of results and recordkeeping are performed under the supervision of a responsible technician. If adopted by the NRC would your licensee company adopt its use?

Additional Input from Stakeholders on the Effects of the HHS Guidelines on Part 26

Note: Below is a copy of the NEI email received by NRC. This email can be located in ADAMS at accession no. ML091890196

From: EARLS, Chris [cee@nei.org]
Sent: Wednesday, July 08, 2009 8:37 AM
To: Harris, Paul
Cc: EARLS, Chris; Susan.Techau@exeloncorp.com; RobertKelm
Subject: Differences Between HHS and Part 26

Paul,

The following is some feedback back from the industry regarding the differences between the HHS guidelines and Part 26. Please let me know if you have any questions.

Chris Earls
Senior Project Manager, Security

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nuclear. clean air energy.

Industry Questions/Comments:

8.3(e) and (f) Would like to see this added to Part 26 so that the collector does not have to explain every step of the process and allows the option for the individual to read the process themselves. May save time and money for licensee.

8.5(a) Why have the individual attempt to provide a specimen if they say that they cannot before allowing them to drink fluids?

8.6(a) does not allow for on-site testing and requires the sealing of "both" specimen bottles.
8.6(b) allows the donor to flush the toilet and Part 26 requires the collector to flush the toilet.

8.6(e)(1) and (2) requires 45ml and requires the collector to discard anything less that 45ml and re-collect. Part 26 only requires 30ml, prefer to keep the single specimen due to additional costs and administrative burden.

8.7(a)(b) requires split specimens and capping of both specimens, Part 26 allows for single specimen and aliquot testing, without immediate sealing. Prefer to keep the single specimen due to additional costs and administrative burden.

8.7(g) does not account that the collection and testing facility are in the same location, Part 26 does and this would add additional costs and additional burden to the licensee.

9.2(b)(1) HHS Certified lab audits - Part 26 is annual, new HHS is every 6 months, which will increase costs and administrative burden to licensee.

9.3(a) allows the PAT to contain 1 or more drug or drug metabolite, Part 26 does not allow this. Plus the concentration and cut-off levels are different throughout the section.

Sections 9.6 through 9.17 If this is meant to replace licensee on site testing facilities, then this will increase costs and administrative burden. If this is just another option for a licensee, then acceptable but unlikely that they will be used by a licensee.

New custody and control form - the current federal form does not take into consideration licensee conducting on-site testing (I understand it is currently out for review and comment. Can we get a copy?)

10.1 Blind sample submittals - Part 26 is 1% new HHS is 3%, this will increase costs and administrative burden to licensee.

10.2 like this requirement instead of Part 26.168(h)(1-3)

12.4 Does this section still only apply to HHS certified lab? Different cut-off levels than Part 26 for on-site specimen validity testing.

13.3(a) Requires MRO to review 5% of negatives, Part 26 does not require this and would be an administrative burden and add additional costs to licensee.

13.4(c)(1) Requires another collection if result is negative/dilute - part 26 does not allow this or to take any sort of administrative action at all. Like the new HHS option.