April 27, 2004

MEMORANDUM TO: Glenn M. Tracy, Director
Division of Nuclear Security
Office of Nuclear Security
and Incident Response

FROM: Garmon West, Acting Chief /RA/
Licensee Personnel Security Section
Division of Nuclear Security
Office of Nuclear Security
and Incident Response

SUBJECt: SUMMARY OF THE APRIL 13, 2004, PUBLIC MEETING TO DISCUSS DRAFT REVISIONS TO 10 CFR PART 26 (FITNESS-FOR-DUTY RULE)

On April 13, 2004, the NRC staff held a public meeting with representatives of the Nuclear Energy Institute (NEI), utility stakeholders and members of the public. The purpose of this meeting was to further discuss the draft language changes to 10 CFR 26, the Fitness-for-Duty (FFD) Rule, and related matters.

The meeting was noticed on March 30, 2004. The notice is available electronically at the NRC's Electronic Reading Room at http://www.nrc.gov/NRC/ADAMS/index.html. From this site, the public can gain entry into the NRC's Agencywide Document Access and Management System (ADAMS), which provides text and image files of NRC's public documents, including the meeting notice, agenda and list of specific items that were discussed at the meeting, all of which may be found under accession number ML040900158. The draft Part 26 rule text, draft regulatory analysis and draft resolution of public comments regarding OMB clearance for the withdrawn 2000 affirmed FFD rule were placed on the NRC's rulemaking website prior to the meeting, and may be found at:
http://ruleforum.llnl.gov/cgi-bin/library?source=*&library=Part26_risk_lib&file=*&st=risk.

A list of the meeting attendees is included in Attachment 1. Additional items to be discussed were handed out at the meeting, and are included as Attachment 2. Slides presented by NRC at the meeting are included as Attachments 3 and 4.

The meeting focused on the 19 technical items included in the meeting notice, as well as the additional items included in Attachment 2. Time was also allotted to stakeholders to discuss any further items from the draft rule text and draft regulatory analysis. Many issues and concerns were raised and discussed in detail. Stakeholders summarized their major items of concern as:

- Stakeholders were concerned that the logic and flow of Subpart C had become complex and suggested simplifying the language structure to facilitate ease of use.

- Stakeholders questioned the definition of "applicant status", which is used to define when applicants for unescorted access are placed into the normal random drug and

alcohol testing pool. Stakeholders suggested their preferred approach would be to place applicants in the pool at the time their pre-access drug and alcohol testing is performed.

- Stakeholders objected to deletion of a requirement that all individuals subject to the rule report FFD concerns, but instead require supervisors and above to report concerns, and provide a mechanism for all individuals to report concerns. Stakeholders asked that all individuals be required to report FFD concerns, and that to do otherwise would severely undermine FFD programs.

Several stakeholders planned to followup in subsequent weeks with written comments, in addition to providing oral feedback at the meeting.

The above information and the documents described above were shared and discussed between NRC staff, NEI representatives, utility and public stakeholders and are not intended as verbatim records.

CONTACT: Dr. Garmon West
(301) 415-0211

Attachments:
1. List of Attendees
2. Planned Notable Changes Since 3/29/04 Draft Rule Text
3. Part 26 Rulemaking Public Meeting
4. Part 26 Rulemaking: Draft Regulatory Analysis

cc w/att: See next page

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cc w/att: See next page

* see previous concurrence ML041190211

OFFICE	LPSS/DNS	E	NRR		LPSS/DNS	
NAME	B. Baxter		R. Karas		G. West	
DATE	4 / 26 /04		4 / 23 /04		4 / 27 /04	

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List of Attendees

Name	Representing
Sharon Blue	Southern California Edison
Loren Bush	Self
David Bonthron	Florida Power & Light
Kathy Burkett	KEB Consulting
Ronald Casey	Entergy
Randy Cleveland	Nuclear Management Company
Jim Davis	Nuclear Energy Institute
Craig Dean	ICF Consulting
Pete DeFilippi	Westinghouse
Dave Desaulniers	U.S. NRC/NRR
Nick DiPietro	First Energy
Dan Dorman	NRC/NSIR
Sherry Eckert	Rochester Gas & Electric
Robert Evans	Nuclear Energy Institute
Peter Fowler	Duke Energy
Cathy Haney	U.S. NRC/NRR
Lane Hay	Bechtel Power
Tammy Huffer	Rochester Gas & Electric
Bill Isom	Progress Energy
Becky Karas	U.S. NRC/NRR
Ruben R. Kelm	Nuclear Energy Institute/PADS
Sheila Litchfield	Duke Cogema Stone & Webster
Rob Mandle	ICF Consulting
Lisa Matula	South Texas Project
Keith McDaniel	U.S. NRC/NMSS
Brian Richter	U.S. NRC/NRR
Marjorie Rothschild	U.S. NRC/OGC
Carlos Sisco	Winson & Strom
Dave Skeen	U.S. NRC/NRR
Susan Techau	Exelon
Kay Wallace	Tennessee Valley Authority
Judy Wasieczko	South Carolina Electric & Gas
Jenny Weil	McGraw-Hill
Garmon West, Jr.	U.S. NRC/NSIR
Glenn Wilson	Dominion
Brian Zaleski	ICF Consulting

Planned Notable Changes
Since 3/29/04 Draft Rule Text

Addendum to Notable Change Item #2: Additional Policy Changes related to Subpart C, "Granting and Maintaining Authorization:"

a. Revise the definition of "applicant status," as follows: "Applicant status means that an individual has applied for authorization under this part, but has not yet been granted or denied authorization. The period of time during which an individual is in applicant status begins on the day upon which a licensee **takes the first formal action towards satisfying any of the requirements for such authorization** ~~receives a self-disclosure from the individual~~ and ends on the day upon which the licensee grants or denies authorization to the individual.

b. Revise §26.31(b)(1)(ii), as follows: Appropriate background investigations, credit and criminal history checks, and psychological evaluations of the FFD program personnel must be completed before assignment to tasks directly associated with administration of the FFD program. The credit and criminal history checks **and psychological evaluations** must be updated nominally every 5 years; and

c. Revise §26.65(c)(2)(i), as follows: "The licensee shall subject the individual to random selection for pre-access drug and alcohol testing at a one-time probability that is equal to or greater than the normal testing rate specified in §26.31(d)(2)(vi) calculated for a **30-day period**.

d. Revise §26.65(f) [Alternatives to pre-access testing], as follows:
~~(1) If an individual previously held authorization under this part and has been subject to a licensee-approved behavioral observation and arrest-reporting program from the date upon which the individual's last authorization was terminated through the date upon which the individual enters applicant status, then the granting licensee may forego the pre-access testing that is required for individuals whose authorization has been interrupted for period of more than 5 days but not more than 30 days.~~
(~~2~~1) If an individual previously held authorization under this part and has been subject to **both** a licensee-approved drug and alcohol testing program that included random testing **and a licensee-approved behavioral observation and arrest reporting program** from the date upon which the individual's last authorization was terminated through the date upon which the individual enters applicant status, then the granting licensee may forego ~~the~~ pre-access testing **of the individual**~~that is required for individuals whose authorization has been interrupted for a period of 31 days or more~~.
(~~3~~**2**) If an individual has negative test results from drug and alcohol tests that were performed in accordance with the requirements of this part within the 30-day period ending on the day that authorization is granted or denied **and the individual has been subject to a licensee-approved behavioral observation and arrest reporting program from the date upon which the individual's last authorization was terminated through the date upon which the individual enters applicant status**, the granting licensee may forego ~~the~~ pre-access testing **of the individual**~~that is required for individuals whose authorization has been interrupted for a period of 31 days or more~~.

Notable Change Item #20:

Additional revisions from a preliminary review of the HHS Specimen Validity Testing Guidelines (available for review at http://www.samhsa.gov/hottopics/click_drugtesting.html, to be published in the Federal Register on April 13, 2004).

a. Add a new paragraph to §26.89 [Preparing to collect specimens for testing] which requires the collector to inform the donor that, if the donor leaves the collection site before all of the collection procedures are completed or refuses to cooperate in the collection procedures, it will be considered a "refusal to test" and sanctions for subverting the testing process will be imposed in accordance with §26.75(b) (i.e., permanent denial of authorization).

b. Add text to §26.103(b) after the sentence, "The donor shall allow the collector to make this observation," to read: "If the donor refuses to show the collector the items in his or her pockets, this is considered a refusal to test. If an item is found that appears to have been brought to the collection site with the intent to adulterate the specimen, the collector shall contact the MRO or FFD program manager to determine whether a directly observed collection is required. If the item appears to be inadvertently brought to the collection site, the collector shall secure the item and continue with the normal collection procedure."

c. Change the creatinine cutoff concentration used in confirmatory testing for substituted, dilute, and invalid specimens from 5 mg/dL to 2 mg/dL in §26.161(d), (e), and (f)(1), respectively. In addition, revise §26.185(h) to eliminate the requirement for the MRO to request the quantitative creatinine concentration for the specimen from the laboratory in (h)(1) and the requirement for a directly observed collection in (h)(2).

d. Add two specimen characteristics that would indicate an invalid specimen at the end of §26.161(f), to include: (1) The physical appearance of the specimen is such that testing may damage the laboratory's instruments, and (2) The physical appearances of Bottles A and B (when a split specimen collection is used) are clearly different, and either the test result for Bottle A indicated it is an invalid specimen or the specimen in Bottle A was screened negative for drugs, or both.

e. Change Footnote #4 for the table of confirmatory drug test cutoff levels in §26.163(b)(1) to require that, for a methamphetamine positive, the specimen must have an amphetamine concentration of 200 ng/mL or more, rather than 100 ng/mL.

f. Add a paragraph at the end of §26.165 [Testing split specimens and retesting single specimens] to clarify that licensees shall proceed with management actions and impose sanctions on the basis of an MRO-confirmed non-negative test result, whether or not the donor requests Bottle B to be tested or an aliquot of a single specimen to be retested.

g. Add a paragraph to §26.169 [Reporting results] related to the laboratory's summary report to the licensee, as follows: "In order to avoid sending data from which it is likely that information about a donor's test result can be readily inferred, the laboratory may not send a summary report if the agency has fewer than 10 specimen test results in the 1-year period addressed by the report."

h. Add text to §26.169(l) [Retesting authorized] to direct the MRO to cancel the test if the donor requests that Bottle B be tested or that an aliquot of a single specimen be retested and either Bottle B or the single specimen are not available for retesting due to circumstances outside of the donor's control, including, but not limited to, circumstances in which there is an insufficient specimen volume in a single specimen to permit retesting, either Bottle B or the original single specimen was lost in transit, Bottle B has been lost.