September 2, 2005

MEMORANDUM TO: Eileen McKenna, Acting Program Director
Reactor Policy and Rulemaking Program
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

FROM: Stephanie Coffin, Section Chief ***/RA George Mencisky For/***
Reactor Policy and Rulemaking Program
Division of Regulatory Improvement Programs
Office of Nuclear Reactor Regulation

SUBJECT: NOTICE CONCERNING PUBLIC MEETING TO SOLICIT COMMENTS ON THE PROPOSED FITNESS-FOR-DUTY RULE AND DISCUSS INDUSTRY PLANS FOR DEVELOPING IMPLEMENTATION GUIDANCE FOR THE FATIGUE MANAGEMENT PROVISIONS

DATE AND TIME: Wednesday, September 21, 2005
8:30 A.M. - 5:30 P.M.
Thursday, September 22, 2005
8:30 A.M. - 12:00 P.M.

LOCATIONS: Wednesday, September 21, 2005
Ramada Inn, "Randolph/Congressional" rooms
1775 Rockville Pike (Twinbrook metro stop)
Rockville, Maryland

Thursday, September 22, 2005
One White Flint North, Room O13B4
Room O13-B4
11555 Rockville Pike
Rockville, Maryland

PURPOSE: To solicit stakeholder feedback regarding the proposed 10 CFR Part 26 (Fitness-For-Duty) rule (Wednesday, September 21, 2005) and discuss industry plans for developing implementation guidelines for the fatigue management provisions (Thursday, September 22, 2005). The agenda for the meeting is provided as Attachment 1. Attachment 2 lists specific questions for public comment. The proposed rule was published in the Federal Register on August 26, 2005, and is available at www.regulations.gov.

CATEGORY 3: This meeting is a Category 3 public meeting. The public is invited to participate in this meeting by providing comments and asking questions throughout the meeting. Feedback forms will be made available. Wednesday's meeting will be transcribed and the transcription will be made available to the public after the meeting.

PARTICIPANTS:	NRC	STAKEHOLDERS
	M. Banic	
	R. Karas	J. Davis (NEI)
	D. Desaulniers	et al.
	J. Persensky	D. Lochbaum
	T. McCune	

A limited number of lines are available for interested members of the public to participate in this meeting via a toll-free teleconference. For details, please call one of the NRC meeting contacts listed below.

Attachments: As stated

cc: See next page

CONTACTS: Merilee Banic, NRR
301-415-2771,MJB@NRC.GOV

Dave Desaulniers, NRR
301-415-1043,DRD@NRC.GOV

DISTRIBUTION FOR MEETING NOTICE WITH STAKEHOLDERS ON SEPTEMBER 21-22, 2005

Hard copy:
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RPRP r/f
Receptionist (OWFN/TWFN)

E-mail

Glenn Tracy	GMT@NRC.GOV
Roy Zimmerman	RPZ@NRC.GOV
Garmon West	GXW@NRC.GOV
Timothy McCune	TSM5@NRC.GOV
Rebecca Karas	RLK@NRC.GOV
Brad Baxter	BXB@NRC.GOV
Bruce Boger	BAB2@NRC.GOV
Dave Matthews	DBM@NRC.GOV
Frank Gillespie	FPG@NRC.GOV
Frank Costello	FMC@NRC.GOV
Dave Desaulniers	DRD@NRC.GOV
Mike Case	MJC@NRC.GOV
Dave Trimble	DCT@NRC.GOV
June Cai	JXC11@NRC.GOV
Clare Goodman	CPG@NRC.GOV
Stephanie Coffin	SMC1@NRC.GOV
Brian Richter	BJR@NRC.GOV
Alzonia Shepard	AWS1@NRC.GOV
Mike Lesar	MTL@NRC.GOV
Molly Keefe	MJK2@NRC.GOV
J. Persensky	JJP2@NRC.GOV
Stu Treby	SAT@NRC.GOV
Tony DiPalo	AJD@NRC.GOV
F. Paul Bonnett	FPB@NRC.GOV
Keith McDaniel	KKM@NRC.GOV
W. Troskoski	WMT@NRC.GOV
Charlotte Abrams	CEA2@NRC.GOV
Lydia Chang	LWC1@NRC.GOV
Scott Moore	SWM@NRC.GOV
Tanya Mensah	TME@NRC.GOV
Drew Persinko	AXP1@NRC.GOV
David Brown	DDB@NRC.GOV
Chris Nolan	MCN@NRC.GOV
Bruce Palagi	BBP@NRC.GOV
A. Randolph Blough	ARB@NRC.GOV
Charles Casto	CAC1@NRC.GOV
Cynthia Pederson	CDP1@NRC.GOV
Dwight Chamberlain	DDC@NRC.GOV
Patrick Hiland	PLH@NRC.GOV
Eileen McKenna	EMM@NRC.GOV
Marisa Higgins	MCH5@NRC.GOV
Geary Mizuno	GSM@NRC.GOV
Vonna Ordaz	VLO@nrc.gov
Sheila Litchfield	sheila.litchfield@framatome-anp.com
Mary Birch	mbirch@duke-energy.com
Danielle Brian	info@pogo.org

Jenny Weil	jenny_weil@platts.com
Loren Bush	vimbush@aol.com
Edward Lyman	elyman@ucsusa.org
James Davis	JWD@NEI.ORG
David Lochbaum	dlochbaum@ucsusa.org
Robert Meyer	rnm@insightbb.com
Will Paul	will_paul@IBEW.org
Todd Newkirk	todd_newkirk@ibew.org
Randy Shotwell	rwshotwell@mcdermott.com
Ron Casey	rcasey1@entergy.com
Thomas Hyoe	madts20121@aol.com
James Kammer	jakammer@duke-energy.com
Peter Fowler	prfowler@duke-energy.com
Nick DiPietro	dipietron@firstenergycorp.com
Steve Turrin	sturrin@stpegs.com
Barry Quigley	qpif@aol.com
Carlos Sisco	Csisco@winston.com
Darrel Drobnich	ddrobnich@sleepfoundation.org
RidsOpaMail	
RidsAcrsAcnwMailCenter	
RidsOgcMailCenter	

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301-415-1043,DRD@NRC.GOV

Accession Number: ML052420363

OFFICE	RPRP	E	NSIR		DIPM		RPRP:SC G. Mencinsky For	
NAME	M. Banic		T. McCune		D. Desaulniers		S. Coffin	
DATE	09 / 01/05		09 /01 /05		09 /01/05		09/02/05	

OFFICIAL RECORD COPY

MEETING WITH STAKEHOLDERS TO OBTAIN COMMENTS ON PROPOSED PART 26

"FITNESS-FOR-DUTY" RULE

SEPTEMBER 21, 2005

8:00 A.M. - 8:30 A.M. REGISTRATION

8:30 A.M. - 8:45 A.M. INTRODUCTIONS AND OPENING REMARKS
- Purpose, need, and objectives for the meeting (NRC)
- Background Information (NRC)
- Format and procedures for participation in the meeting (NRC)
- Introductory remarks. (Stakeholders)

8:45 A.M.-10:30 A.M. COMMENTS ON DRUG AND ALCOHOL PROVISIONS OF PROPOSED PART 26 AND GENERAL RULEMAKING ISSUES
- Overview of notable changes to drug and alcohol provisions in the proposed rule (NRC)
- Comments/Questions on "Questions for Public Comment" (Questions 1-10, Attachment 2) (Stakeholders)
- Comments /Questions on other drug and alcohol provisions and general rulemaking issues (Stakeholders)

10:30 A.M.-10:45 A.M. BREAK

10:45 A.M.-12:00 P.M. CONTINUED COMMENTS ON DRUG AND ALCOHOL PROVISIONS

12:00 P.M.-1:00 P.M. LUNCH

1:00 P.M.-2:30 P.M. COMMENTS ON FATIGUE PROVISIONS OF PROPOSED RULE
- Overview of fatigue provisions of proposed rule (NRC)
- Comments /Questions on "Questions for Public Comment" (Questions 11-17, Attachment 2) (Stakeholders)
- Comments /Questions on other fatigue provisions (Stakeholders)

2:30 P.M.-2:45 P.M. BREAK

2:45 P.M.-5:15 P.M. CONTINUED COMMENTS ON FATIGUE PROVISIONS

5:15 P.M.-5:30 P.M. CLOSING REMARKS
- Closing remarks (NRC/Stakeholders)

Attachment 1

MEETING TO DISCUSS INDUSTRY PLANS FOR DEVELOPING IMPLEMENTATION

GUIDANCE FOR THE FATIGUE MANAGEMENT PROVISIONS

SEPTEMBER 22, 2005

8:00 A.M. - 8:30 A.M. REGISTRATION

8:30 A.M. - 8:45 A.M. INTRODUCTIONS AND OPENING REMARKS
- Purpose, need, and objectives for the meeting (NRC)
- Background Information (NRC)
- Format and procedures for participation in the meeting (NRC)
- Introductory remarks (Stakeholders)

8:45 A.M.-10:30 A.M. DISCUSSION OF INDUSTRY PLANS FOR DEVELOPING IMPLEMENTATION GUIDANCE
- Presentations/remarks on guidance document (Stakeholders)
- Comments and questions (Stakeholders/NRC)

10:30 A.M.-10:45 A.M. BREAK

10:45 A.M.-11:45 A.M. CONTINUATION OF DISCUSSION OF INDUSTRY PLANS FOR DEVELOPING IMPLEMENTATION GUIDANCE

11:45 A.M.-12:00 P.M. CLOSING REMARKS
- Closing remarks (NRC/Stakeholders)
- Comments/Questions (Public)

Attachment 1

QUESTIONS FOR PUBLIC COMMENT

PROPOSED DRUG AND ALCOHOL PROVISIONS:

1. Proposed sanction for attempted subversion of the testing process. Proposed §26.75 in Subpart D would increase the sanctions for certain testing-related actions by requiring that: "Any act or attempted act to subvert the testing process, including refusing to provide a specimen and providing or attempting to provide a substituted or adulterated specimen, for any test required under this part must result in permanent denial of authorization," and "for individuals whose authorization was denied for 5 years ... any subsequent violation of the drug and alcohol provisions of an FFD policy must immediately result in permanent denial of authorization." The NRC requests comments regarding these proposed changes specifically when compared to the 5-year ban available through the agency's enforcement policy for other acts of deliberate misconduct.

2. Need for "shy lung" procedures. Proposed §26.119 [Determining "shy" bladder] would establish a process for determining whether there is a medical reason that a donor is unable to provide a urine specimen of at least 30 mL. The NRC added this proposed section in response to stakeholder requests and adapted the process from the DOT's Procedures for Transportation Workplace Drug and Alcohol Testing Programs (49 CFR 40.197). The DOT Procedures also include processes for determining whether there is a medical reason that a donor is unable to provide a specimen of oral fluids (49 CFR 40.263) or a breath specimen (49 CFR 40.265) of sufficient quantity to support alcohol testing. The NRC invites comments on whether the NRC should consider incorporating these processes for insufficient oral fluids and breath specimens in Part 26.

3. Forensic toxicologist. Proposed §26.31(d)(3)(iii)(C) would permit licensees and other entities to specify more stringent cutoff levels for the panel of drugs for which testing is required under this part without informing the NRC within 60 days and without obtaining the written approval of the NRC. Proposed §26.31(d)(1)(i)(D) and (d)(1)(ii) would also permit licensees and other entities to test for drugs and drug metabolites in addition to those specified in proposed §26.31(d)(1) without informing or obtaining the written approval of the NRC. However, the proposed paragraphs would require that the scientific and technical suitability of the more stringent cutoff levels and of the assays and cutoff levels used to test for additional drugs or drug metabolites must be evaluated and certified, in writing, by a qualified, independent forensic toxicologist. Certification by a forensic toxicologist would not be required in three circumstances: (1) if the HHS issues more stringent cutoff levels in the HHS Guidelines and the licensee or other entity adopts the revised HHS cutoffs; (2) if the HHS Guidelines are revised to authorize use of the assay in testing for the additional drug or drug metabolites and the licensee or other entity uses the cutoff levels established in the HHS Guidelines for the drug or drug metabolites; and (3) if the licensee or other entity received written approval from the NRC for the lower cutoff levels and/or for testing for the additional drugs or drug metabolites, under current Section 1.1(2) in Appendix A to Part 26. The proposed paragraphs differ from the current requirement in Section 1.1(2) of Appendix A to Part 26. The NRC requests comments regarding these proposed changes.

4. Changes to opiate testing. Proposed §§26.133 and 26.163 would raise the cutoff levels fo initial and confirmatory tests for opiates from 300 nanograms (ng) per milliliter (mL) to 2,000 ng/mL. The proposed rule would also require testing for 6-acetylmorphine (6-AM), a metabolite that comes only from heroin, using a 10 ng/mL confirmatory cutoff level for specimens that tested positive on the initial test. The proposed cutoff levels and new test would be consistent with those used by HHS and DOT, and would reduce the number of specimens in Part 26 programs that test positive for opiates at an HHS-certified laboratory but are subsequently determined to be negative by the MRO after consultation with the donor. The NRC invites comment on these proposed changes.

5. Specimen validity testing. In proposed §§26.131, 26.137, 26.161, and 26.167, the NRC would add new requirements for validity testing of urine specimens to detect specimens that may have been adulterated, substituted, or diluted. The new requirements are adapted from practices the HHS published in the Federal Register on April 13, 2004 (69 FR 19643) as a final rule. The NRC invites public comment on the following issues related to the proposed validity testing requirements.

a. QA/QC requirements. Proposed §26.137 would establish quality assurance and quality control requirements for conducting validity and drug tests of urine specimens. The NRC seeks input regarding any technical and methodological barriers to implementing these requirements at licensee testing facilities.

b. Criteria for identifying a substituted specimen. Proposed §§26.161(d) and 26.185(h) would establish criteria and procedures for determining whether a specimen has been substituted. A specimen would be reported by the HHS-certified laboratory to the MRO as substituted if it has a creatinine concentration of less than 2 mg/dL and specific gravity of less than or equal to 1.0010, or equal to or greater than 1.0200. For the HHS-certified laboratory to report a specimen as substituted, results in these ranges would be necessary on both the initial and confirmatory creatinine and specific gravity tests on two separate aliquots of the specimen. The NRC invites comments on the proposed provisions.

6. MRO training. Proposed §26.183(a) requires that "The MRO shall be knowledgeable of this part and of the FFD policies of the licensees and other entities for whom the MRO provides services." The NRC invites comments on whether Part 26 should establish specific training requirements for the MRO related to this part and the licensee's or other entity's programs for which the MRO provides services.

7. Testing Bottle B of a split specimen. Proposed §§26.135(b) and 26.165(a)(4) and (b)(1) would prohibit licensees and other entities, the MRO, and the NRC from initiating testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission. The NRC is considering an alternative approach that would permit a licensee or other entity to initiate testing of the specimen in Bottle B or retesting an aliquot from a single specimen without the donor's written permission only if all of the following conditions are met: (1) the first results from testing the specimen were confirmed as non-negative by the MRO; (2) the donor has requested a review under proposed §26.39 or initiated legal proceedings; and (3) the testing is conducted in accordance with proposed §26.165(c)–(e), as applicable. Under either the proposed provisions or the alternative approach, the proposed rule would require the licensee or other entity to administratively withdraw the donor's authorization until the results from Bottle B or the retest results are available and to rely only on those results in determining whether the licensee or other entity would be required to take management actions or impose sanctions on the donor. The NRC is seeking an appropriate balance between protecting donors' rights to privacy and due process under the rule and the protection of public health and safety and the common defense and security, and invites public comment on the proposed and alternative approaches.

RULEMAKING ISSUES:

8. Non-instrumented validity tests. The NRC is considering incorporating future changes to the draft HHS Guidelines that were published as a proposed rule for public comment in the Federal Register on April 13, 2004 (69 FR 19672) relating to the permission in this proposed Part 26 rule for licensees and other entities to use non-instrumented validity tests to determine whether a urine specimen appears to be adulterated, diluted, or substituted and requires further testing at an HHS-certified laboratory. Proposed Part 26 would permit licensees and other entities to use these devices for validity screening tests, in lieu of the instrumented validity testing required in the April 13, 2004, final version of the HHS Guidelines. Should any changes be made to those draft HHS Guidelines between issuing this proposed rule and issuing the final 10 CFR Part 26 rule, those changes would be considered for incorporation. Any comments related to the potential incorporation of those changes are of interest.

9. Adopting future changes to the HHS Guidelines without backfit. The NRC is considering amending 10 CFR 50.109, 70.76, and 76.76 to exclude certain future changes to Part 26 from current backfit requirements. The scope of the exclusions would be limited to only those changes to Part 26 that would be necessary to incorporate relevant revisions to the HHS Guidelines when they are published by HHS as final rules. Examples of changes to the HHS Guidelines that may be incorporated into Part 26 in future rulemakings may include, but would not be limited to (1) adopting changes to the cutoff levels established in the Guidelines; (2) the addition or deletion of drugs and adulterants for which testing would be required; and (3) changes in the specimens, instruments, or assays used in drug and validity testing. The NRC requests comment on excluding such future changes to Part 26 from backfit analysis requirements.

10. Reporting burden. The NRC is seeking comments regarding the administrative reporting burden that the proposed rule provisions would create.

PROPOSED FATIGUE PROVISIONS:

11. Rest break provisions. Proposed §26.199(d)(2)(ii) and (d)(2)(iii) would require licensees to provide individuals who are subject to the proposed work hour limits with at least one 24-hour rest break in any 7-day period and at least one 48-hour rest break in any 14-day period, except during the first 14 days of any outage, as well as certain other circumstances for security force personnel. The NRC invites comment on these rest break provisions.

12. Waivers of work hour controls. Proposed §26.199(d)(3) would permit licensees to waive individual work hour limits and rest break requirements only in circumstances in which it is necessary to mitigate or prevent a condition adverse to safety, or to maintain the security of the facility. Proposed §26.197(e)(1) would require licensees to report the number of waivers granted in a year. The NRC invites comment on the provisions for granting waivers of the work hour controls.

13. 48-hour/week collective work hour limits. Proposed §26.199(f) would prohibit job duty groups that are subject to work hour controls from working more than a maximum collective average of 48 hours per person per week, except during the first 8 weeks of any outage, as well as certain other circumstances for security force personnel. The NRC invites comment on these collective work hour provisions.

14. Alternate work-scheduling examples. As a means of determining the flexibility of the proposed rule work hour controls in §26.199, the NRC is seeking public comment on work-scheduling examples that meet the requirements of the proposed rule and whether such schedules afford a reasonable degree of flexibility to licensee management.

15. Outage work scheduling. The NRC is seeking comment on the exclusions from certain work hour controls that would be allowed by proposed §§26.199(d)(2)(iii), (f)(1) and (f)(2) during maintenance and refueling outages, and how these exclusions could affect human error. The NRC is specifically interested in whether a more precisely defined rule scope with more limited outage exclusions would better meet the stated objectives of the rule.

16. Alternatives for addressing cumulative fatigue. The NRC is seeking public comment on alternatives to the group work hour controls that could also address cumulative fatigue, such as individual work hour limits based on a longer term (e.g., monthly or quarterly).

17. Defining job duty groups. Proposed §26.199(a) would require any individual who performs duties within specified job duty groups to be subject to the work hour control provisions in §26.199. Other individuals, beyond those specified within the scope of §26.199(a), might substantially impact the outcome of risk-significant work, such as certain engineers (e.g., Shift Technical Advisors). The NRC requests comment on the inclusion of other individuals in the scope of §26.199(a). The NRC is also seeking comments on an alternative approach for identifying the specific job functions that would be subject to these requirements. Specifically, the NRC is interested in whether, as an alternative, the scope should instead be structured to define attributes of the job functions (e.g., time-critical nature of decisions needed to ensure public health and safety, operational control of risk-important equipment) that would fall within the scope of the proposed work hour control provisions in §26.199. Under such an alternative, the licensee would then be required to identify the specific job functions that fit the defined attributes.