UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

July 18, 2003

MEMORANDUM TO: William D. Beckner, Chief
Reactor Operations Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

/RA/

FROM: David C. Trimble, Chief
Operator Licensing and Human Performance Section
Reactor Operations Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

SUBJECT: SUMMARY OF THE MAY 29, 2003, PUBLIC MEETING TO DISCUSS THE DEVELOPMENT OF A PROPOSED WORKER FATIGUE RULE

On May 29, 2003, the staff held a public meeting regarding the development of a proposed rule concerning worker fatigue at nuclear power plants. The rulemaking has been proposed as an amendment to 10 CFR 26, "Fitness for Duty Programs." The meeting participants (see Attachment 1) included representatives from the power reactor licensee community, the Nuclear Energy Institute (NEI), the Professional Reactor Operator Society, and the Union of Concerned Scientists (UCS). The meeting agenda is provided as Attachment 2.

The focus of the meeting was discussion of draft proposed rule language (Attachment 3). The staff also provided a revision of the process charts for the proposed rule that were presented at the April 24, 2003, public meeting (Attachment 4). A synopsis of stakeholder comments on the draft rule language is provided in Attachment 5.

The staff set a target date of July 9, 2003, for the next stakeholder meeting.

Attachments: As stated

Public Meeting to Discuss Development of a Proposed Rule Concerning
Worker Fatigue at Nuclear Power Plants

May 29, 2003

Attendance List

NAME	AFFILIATION
David Trimble	NRC/NRR
David Desaulniers	NRC/NRR
Craig Seaman	APS- Palo Verde
Terry Matlosz	SCE&G
Bryan Dolan	Duke Energy
Robert Evans	NEI
Jim Gallman	TXU
John Fee	Southern California Edison
Ralph Mullis	Progress Energy
Jennifer Dixon-Herrity	NRC/OE
Marjorie Rothschild	NRC/OGC
Steven Turrin	PROS (via teleconference)
Getachew Tesfaye	CEG
Autumn Szabo	NRC/RES
June Cai	NRC/NRR
Garmon West	NRC/NSIR
J. Persensky	NRC/RES
David Lochbaum	Union of Concerned Scientists
Jim Davis	NEI

Attachment 1

MEETING WITH STAKEHOLDERS TO DISCUSS DEVELOPMENT OF A
PROPOSED RULE CONCERNING WORKER FATIGUE
AT NUCLEAR POWER PLANTS

May 29, 2003

AGENDA

Morning Session

8:30-8:40 Introductions and Opening Remarks

8:40-9:00 Written Policy and Procedures

9:00-9:30 Work Scheduling Controls - Scope
- Definition of Directing
- Fire Brigade
- Security

9:30-10:00 Work Scheduling Controls - Authorization Criteria

10:00-10:15 Break

10:15-11:00 Work Scheduling Controls - Deviation Authorization
- Supervisory assessment
- Senior management assessment
- Documentation
- Training

11:00-12:00 Work Scheduling Controls - Group Limits
- Basis for establishing group average

12:00- 12:45 Lunch

Afternoon Session

12:45-1:15 Work Scheduling Controls - Group Limits
- Monitoring and reporting

1:15-1:45 Monitoring individual work hours

1:45-2:30 Fatigue Assessment
- Self-declaration
- Observation

2:30-2:45 Break

2:45-3:30 Fatigue Assessment
- Post-Event

3:30-4:00 Meeting Summary and Future Schedule

Note: This is a Category 3 Meeting. The public is invited to participate in this meeting by providing comments and asking questions throughout the meeting.

Attachment 2

Part 26 Worker Fatigue Amendment
Draft Language

Redline-Strikeout Comparison of Rev. 4 to Rev. 3

May 29, 2003

Attachment 3

PART 26 – FITNESS FOR DUTY PROGRAMS

1. The authority citation for Part 26 continues to read as follows:

AUTHORITY: Secs. 53, 81, 103, 104, 107, 161, 68 Stat. 930, 935, 936, 937, 948, as amended, sec. 1701, 106 Stat. 2951, 2952, 2953 (42 U.S.C. 2073, 2111, 2112, 2133, 2134, 2137, 2201, 2297f); secs. 201, 202, 206, 88 Stat. 1242, 1244, 1246, as amended (42 U.S.C. 5841, 5842, 5846).

2. The text of 10 CFR Part 26 is amended as follows:

Subpart A - Administrative Provisions

§ 26.1 Purpose

This part prescribes requirements and standards for the establishment and maintenance of fitness-for-duty (FFD) programs.

§ 26.3 Scope

(a) The regulations in this part apply to licensees authorized to operate a nuclear power reactor.

(b) The regulations in this part apply to licensees authorized to possess, use, or transport formula quantities of strategic special nuclear material (SSNM) under Part 73 of this chapter.

(c) The regulations in this part apply to a Corporation that obtains a certificate of compliance or an approved compliance plan under Part 76 of this chapter only if the Corporation elects to engage in activities involving formula quantities of SSNM. When applicable, the requirements apply only to the Corporation and personnel specified in §26.25(a)(3).

(d) Combined operating permit holders, under Part 52, Subpart C of this chapter, or construction permit holders under §50.23 of this chapter, with a plant under active construction, shall comply with §§26.23 (Performance objectives), 26.41 (Audits), and 26.189 (Determination

of fitness) of this part, shall implement a drug and alcohol testing program, including random tests; and shall make provisions for employee assistance programs, imposition of sanctions, procedures for the objective and impartial review of authorization decisions, protection of information, and recordkeeping.

(e) Individuals who are performing activities under this part and who are also subject to a program regulated by another Federal agency or State need be covered by only those elements of a licensee's FFD program that are not included in the Federal agency or State program, as long as all of the following conditions are met:

(1) The individuals are subject to pre-access (or pre-employment), random, and for-cause testing for the substances specified in paragraph §26.31(d)(1) of this part at or below the cutoff levels specified in §26.163(a)(1) of this part;

(2) Breath specimens are subject to confirmatory testing with an evidential-grade breath alcohol analysis device that meets the requirements specified in §26.91 of this part;

(3) Urine specimens are tested for validity and the presence of drugs and drug metabolites at a laboratory certified by HHS, the College of American Pathologists or other comparable certification program;

(4) Training is provided to address the subjects listed in §26.29(a);

(5) An impartial and objective procedure is provided for the review of any findings of a FFD policy violation; and

(6) Provisions are made to ensure that the testing agency or organization notifies the licensee or C/V granting authorization of any FFD policy violation.

§ 26.5 Definitions

_____ ***Acute fatigue*** **means . . .**

~~*Circadian factors* means . . .~~**fatigue from causes (e.g., restricted sleep, sustained wakefulness, task demands) occurring within the past 24 hours.**

Alertness **means ability to remain awake and sustain attention.**

Circadian variations in alertness and performance **means the increases and decreases in alertness and cognitive/motor functioning caused by human physiological processes (e.g., body temperature, release of hormones) that vary on an approximate 24-hour cycle.**

Cumulative fatigue **means** ~~. .~~ **the increase in fatigue over consecutive sleep-wake periods resulting from inadequate rest.**

Directing **means** ~~face-to-face supervision~~**supervising the implementation of an** ~~ongoing~~ **operational** ~~evolution~~ **or maintenance** ~~task. ...~~**function that is subject to the work scheduling controls of this part, as a person responsible for the correct performance of the function.**

Fatigue **means degradation in an individual's cognitive and motor functioning resulting from inadequate rest.**

Hours actually worked **means** . . .

Self declaration **means an explicit statement by an individual to his or her supervisor of whether the individual is fit for duty.**

§ 26.7 Interpretations

no change

§ 26.9 Exemptions

no change

§ 26.11 Communications

no change

§ 26.13 Information collection requirements: OMB approval

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget (OMB) for approval as required by the Paperwork Reduction Act (44 U.S.C. 3501 et seq.). The NRC may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has approved the information collection requirements contained in this part under control number (update for proposed rule).

(b) The approved information collection requirements contained in this part appear in §§26.197, 26.199, 26.201, and 26.203.

§ 26.15 Future revisions

no change

Subpart B - Program Elements

§ 26.21 FFD program

Each licensee subject to this part shall establish and implement a FFD program that complies with the applicable requirements in this part.

§ 26.23 Performance objectives

Fitness-for-duty programs must:

(a) Provide high assurance that individuals subject to this part are trustworthy and reliable as demonstrated by the avoidance of substance abuse;

(b) Provide reasonable assurance that individuals subject to this part are not under the influence of any substance, legal or illegal, or mentally or physically impaired from any cause, which in any way adversely affects their ability to safely and competently perform their duties;

(c) Provide reasonable measures for the early detection of persons who are not fit to perform activities within the scope of this part; and

(d) Provide reasonable assurance that the workplaces subject to this part are free of the presence of illegal drugs and alcohol, and the effects of such substances.

(e) Provide reasonable assurance that ~~worker~~the fatigue ~~is~~and alertness of persons subject to this part are managed commensurate with maintaining public health and safety.

§ 26.25 Individuals subject to the FFD program

(a) The following individuals shall be subject to the FFD program:

(1) All persons granted unescorted access to nuclear power plant protected areas;

(2) All persons required by the licensee to physically report to the licensee's Technical Support Center or Emergency Operations Facility, in accordance with licensee emergency plans and procedures;

(3) SSNM licensee and transporter personnel who:

(i) Are granted unescorted access to Category IA Material;

(ii) Create or have access to procedures or records for safeguarding SSNM;

(iii) Measure Category IA Material;

(iv) Transport or escort Category IA Material; or

(v) Guard Category IA Material.

(4) All FFD program personnel involved in the day-to-day operations of the program, as defined by licensee or C/V procedures, who:

(i) Can link test results with the individual who was tested before a FFD policy violation determination is made;

(ii) Make determinations of fitness;

(iii) Make authorization decisions;

(iv) Are involved in the selection or notification of individuals for testing; or

(v) Are involved in the collection or onsite testing of specimens.

(b) The following individuals are not subject to the FFD program:

(1) Persons who are not employed by the licensee's or C/V's FFD program, who do not routinely provide FFD program services, and whose normal workplace is not at the licensee's or C/V's facility, but who may be called upon to provide a FFD program service, including, but not limited to, collecting specimens for drug and alcohol testing, performing behavioral observation, or providing input to a determination of fitness. Such persons may include, but are not limited to, hospital, employee assistance program (EAP), or substance abuse treatment facility personnel, or other medical professionals;

(2) NRC employees, law enforcement personnel, or offsite emergency fire and medical response personnel while responding onsite;

(3) SSNM transporter personnel who are subject to U.S. Department of Transportation drug and alcohol fitness programs that require random testing for drugs and alcohol.

§ 26.27 Written policy and procedures

(a) General. Each licensee subject to this part, and each C/V with a licensee-approved FFD program, shall establish, implement, and maintain written policies and procedures designed to meet the general performance objectives and applicable requirements of this part.

(b) Policy. Licensees and C/Vs shall prepare a clear and concise FFD policy statement and make the most current revision of this statement readily available to all individuals subject to the policy. Methods of making the statement readily available include, but are not limited to, posting the policy in multiple work areas, providing individuals with brochures, or allowing individuals to print out the policy from a computer. The policy statement must be written in sufficient detail to provide affected individuals with information on what is expected of them and

what consequences may result from lack of adherence to the policy. At a minimum, the written statement shall:

(1) Describe the consequences of the use, sale, or possession of illegal drugs on or off site, and the abuse of legal drugs, including alcohol;

(2) Describe the expectation that individuals who are notified that they have been selected for random testing will report to the collection site within the time period specified by the licensee or C/V;

(3) Describe the consequences of refusals to provide a specimen for testing and subversion of the testing process;

(4) Prohibit the consumption of alcohol, at a minimum:

(i) Within an abstinence period of 5 hours preceding any scheduled working tour; and

(ii) During the period of any working tour.

(5) Convey that abstinence from alcohol for the five hours preceding any scheduled working tour is considered to be a minimum that is necessary but may not be sufficient to ensure the individual is fit for duty;

(6) Address other factors that could affect fitness for duty such as mental stress, fatigue, illness, and the use of prescription and over-the-counter medications that could cause impairment;

(7) Provide a description of programs that are available to personnel desiring assistance in dealing with drug, alcohol, **fatigue,** or other problems that could adversely affect the performance of activities within the scope of this part;

(8) Describe the consequences of violating the policy;

(9) Describe the individual's responsibility to report any legal actions, as defined in §26.5; and

(10) Describe the individual's responsibility to report FFD concerns.

(c) Procedures. The licensee and C/V shall prepare written procedures that describe the methods to be used in implementing the FFD policy and the requirements of this part. The procedures shall:

(1) Describe the methods and techniques to be used in testing for drugs and alcohol, including procedures for protecting the individual providing a specimen and the integrity of the specimen, and the quality controls used to ensure the test results are valid and attributable to the correct individual.

(2) Describe immediate and follow-up actions that will be taken, and the procedures to be used, in those cases where individuals subject to this part are determined to have:

(i) Been involved in the use, sale or possession of illegal drugs;

(ii) Consumed alcohol during the mandatory pre-work abstinence period, while on duty, or to excess before reporting to duty, as demonstrated with a test that can be used to determine BAC;

(iii) Attempted to subvert the testing process by adulterating or diluting specimens (in vivo or in vitro), substituting specimens, or by any other means;

(iv) Refused to provide a specimen for analysis; or

(v) Had legal action taken on a drug- or alcohol-related charge.

(3) Describe the process to ensure that persons called in to perform an unscheduled working tour are fit for duty, and the requirements for licensee and C/V personnel who are scheduled by licensee emergency plans and procedures to physically report to a licensee's Technical Support Center or Emergency Operations Facility. Consumption of alcohol during the abstinence period shall not by itself preclude a licensee from using individuals needed to respond to an emergency. At a minimum:

(i) The procedure must require a statement to be made by a called-in person as to whether the individual considers himself or herself fit for duty and whether the individual has consumed alcohol within the pre-duty abstinence period stated in the policy;

(ii) If alcohol has been consumed within this period and the person is called in, the procedure must:

(A) Require a determination of fitness by breath alcohol analysis or other means; and

(B) Require the establishment of controls and conditions under which the individual who has been called-in can perform work, if necessary.

(iii) If the individual reports that he or she considers himself or herself unfit for duty for other reasons, including illness, fatigue, or other potentially impairing conditions, and the person is called in, the procedure must require the establishment of controls and conditions under which the individual can perform work, if necessary.

(4) Describe the process to be followed when a ~~worker declares, while on duty, that he or she is not fit for duty~~person makes a self declaration of not being fit for duty for any part of a working tour for reasons including illness, fatigue, or other potentially impairing conditions and, subsequent to the declaration, the person is permitted or required to work during the tour of duty. The procedure shall describe individual and licensee responsibilities and require the establishment of controls and conditions under which the individual ~~can~~is permitted or required to perform work~~, if necessary~~.

(5) Describe the process for implementing the work scheduling controls.

(**6**) Describe the process to be followed if an individual's behavior raises a concern regarding possible possession, use or sale of illegal drugs, possession or use of alcohol on-site, or impairment of any kind that may constitute a risk to the health and safety of the public. The procedure must require that persons who have a FFD concern about another individual's

behavior contact the personnel designated in licensee and C/V procedures to report the concern. The procedure also must state that the decision to conduct a determination of fitness of an individual who may be impaired, which may include, but is not limited to, testing for drugs and alcohol, shall be made by appropriate personnel.

§ 26.29 Training

(a) Content of training. Licensees and C/Vs must ensure that individuals subject to this part have the knowledge and abilities (KAs) required to implement their responsibilities under the FFD policy, as follows:

(1) Knowledge of the policy and procedures that apply to the individual and the consequences of violating the policy;

(2) Knowledge of the individual's role and responsibilities under the FFD program;

(3) Knowledge of the roles and responsibilities of others, such as the MRO, and the human resources, FFD and EAP staffs;

(4) Knowledge of the EAP services available to the individual;

(5) Knowledge of the personal and public health and safety hazards associated with abuse of illegal and legal drugs, including alcohol;

(6) Knowledge of the potential effects on job performance of prescription and over-the-counter drugs, dietary conditions, illness, mental stress, and fatigue;

(7) Knowledge of prescription and over-the-counter drugs and dietary conditions that have the potential to affect drug and alcohol test results;

(8) Ability to recognize drugs and indications of the use, sale, or possession of drugs;

(9) Knowledge of the contributors to worker fatigue, circadian variations in alertness and performance, indications and risk factors for common sleep disorders

~~and effective~~**, shiftwork strategies for obtaining adequate rest, and the effective use of fatigue countermeasures;**

(10) Ability to identify symptoms of worker fatigue and contributors to decreased alertness in the workplace ~~and the effective use of fatigue countermeasures~~**;**

(**11**) Ability to observe and detect performance degradation, indications of impairment, or behavioral changes; and

(**12**) Knowledge of the individual's responsibility to report fitness concerns; and ability to initiate appropriate action, including referral to the person(s) designated by the licensee or C/V to receive fitness concerns and to the EAP.

(b) Comprehensive examination. Successful completion of training must be demonstrated by passing a comprehensive examination that addresses the KAs in paragraph (a) of this section. The examination must include a comprehensive random sampling of all KAs with questions that test each KA, including at least one item for each KA. The examination must be administered under the supervision of a proctor as defined by licensee or C/V training requirements. The minimum passing score required shall be 80%. Remedial training and testing is required for individuals who fail to answer correctly at least 80% of the test questions. The examination may be administered using a variety of media, including, but not limited to, hard-copy test booklets with separate answer sheets or computer-based administration.

(c) Training administration. Licensees and C/Vs shall ensure that individuals performing activities under this part are trained, as follows:

(1) Training for all personnel must be completed prior to an initial assignment of duties within the scope of this part.

(2) Refresher training must be completed on a nominal 12-month frequency, or more frequently where the need is indicated. Individuals who pass a comprehensive annual

examination that meets the requirements in paragraph (b) of this section may forgo the refresher training.

(3) Initial and refresher training may be delivered using a variety of media, including, but not limited to, classroom lectures, required reading, video, or computer-based training systems. The licensee or C/V must monitor that training is completed and provide a qualified instructor or designated subject matter expert to answer questions in the course of training.

(4) Licensees may accept training of individuals who have been subject to a Part 26 program and who have had initial or refresher training, or successfully passed a comprehensive examination that meets the requirements in paragraph (b) of this section, within the prior 12 months.

§26.30 Work Scheduling Controls

(a) Work scheduling controls shall be implemented at nuclear power reactors authorized to operate. These controls shall apply to the following categories of job functions:

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

(2) maintenance or directing the maintenance of structures, systems and components that a risk-informed evaluation process has shown to be significant to public health and safety;

(3) performing the duties of a Health Physics or Chemistry technician required as part of the minimum shift complement for the on-site emergency response organization;

(4) performing the duties of a Fire Brigade member responsible for understanding the effects of fire and fire suppressants on safe shutdown capability ~~as required by 10 CFR 50, Appendix R, Paragraph H, "Fire Brigade.";~~

(5) performing security duties as an armed member of the security force, central alarm station operator, secondary alarm station operator, security shift supervisor, or watchperson.

(b) *Individual Work Hour Controls*. ~~Personnel~~Individuals performing the functions identified in §26.30(a) shall be subject to the following work scheduling controls:

(1) Individuals shall not work more than the following limits, excluding shift turnover time:

(i) 16 hours in any 24 hour period,

(ii) 26 hours in any 48-hour period, and

(iii) 72 hours in any 7-day period.

(2) Individuals shall have a minimum 10-hour break between work periods. Participation in shift turnover is permitted during the break period. An 8-hour break is permitted as an exception to the 10-hour break requirement if the 8-hour break is necessary to accommodate a scheduled transition of a crew between work schedules or shifts.

(3) Licensees may authorize individual workers to deviate from the requirements of §26.30(b)(1) and (2) provided:

(i) the licensee could not have reasonably foreseen or controlled the circumstances necessitating the deviation,

(ii) ~~the~~an operations shift manager determines that the deviation is necessary to mitigate or prevent conditions adverse to safety, or ~~the~~a security shift manager determines that the deviation is necessary to maintain the security of the facility, and

(iii) a supervisor ~~trained in the contributors, symptoms, and effects of fatigue~~, qualified to direct the work to be performed and trained in accordance with the requirements of this part, assesses the individual's fitness for duty and determines that ~~it~~there is reasonable assurance that the individual will ~~not~~ be ~~adversely affected by~~fit for duty for the additional work period to be authorized under the deviation. As a minimum, the assessment shall address the individual's work history for the past 7 days, circadian variations in alertness and performance, the potential for fatigue-related errors to affect the safe performance of the work, and the ~~use of~~need for any compensatory measures.

(4) The basis for individual deviations from the requirements of §26.30(b)(1) and (2) shall be documented. The documented basis shall include:

(i) a statement of the scope of work for which the individual work limit extension is approved and a description of the circumstances causing the need for the work schedule extension to be unforseen or uncontrollable,

(ii) the basis for the determination that the work schedule extension is necessary to mitigate or prevent conditions adverse to safety or maintain the security of the facility,

(iii) the basis for the determination of reasonable assurance that the ~~individual's fitness~~individual will be fit for duty ~~will not be adversely affected by~~for the additional work period to be authorized under the deviation, including the ~~use of~~need for any compensatory measures.

(c) *Group Work Hour Controls*. —

~~[Deferred pending issuance of Compensatory Measures]~~

(1) The work hours for personnel performing the functions identified in §26.30(a)(1)-(4) shall be controlled in accordance with the following limit. While the plant is operating, the number of hours actually worked by personnel within each job function category shall not exceed an average of 48 hours per person per week.

(2) The hours actually worked by personnel performing the functions identified in §26.30(a)(5) shall be controlled in accordance with the following limits:

TBD

(3) Hours actually worked shall be averaged over a period not greater than 3 calendar months. Individuals who did not work at least 75 percent of the normally scheduled hours during the averaging period shall not be included when calculating the average.

(4) If the group average for any job function category exceeds 48 hours per person per week, the licensee shall take corrective action to restore the average to 48 hours or less within the next quarter.

(5) If the group average for any job function category exceeds Y [value of Y TBD] hours per person per week, the licensee shall notify the NRC in writing of the conditions causing the average to exceed 48 hours and the actions being taken to restore the average to less than 48 hours within the next quarter.

(6) If the group average for any job function category exceeds, or is projected to exceed, 48 hours per person per week in any two consecutive quarters, the licensee shall take the actions specified 26.30(c)(5) and notify the NRC in writing of the conditions causing the average to exceed 48 hours and the actions being taken to restore the average to less than 48 hours as soon as practicable.

(d) Licensees shall be exempt from the individual and group work scheduling controls during declared emergencies as defined in the facility's emergency plan.

(e) Licensees shall monitor and control individual ~~work hours to ensure that worker alertness and performance are not compromised~~hours actually worked to provide reasonable assurance that fatigue does not compromise worker fitness for duty. As a minimum, the plant manager, or ~~designee~~a designated senior site manager, shall perform a quarterly review ~~individual~~of hours actually worked ~~on a quarterly basis to ensure that workers are not being assigned hours that can compromise their alertness and performance.~~to (1) verify that the number of hours actually worked by individuals is not compromising their fitness for duty

and (2) verify that group averages for each job function category indicate adequate staffing for all jobs in the group.

§ 26.31 Drug and alcohol testing

(a) General. To provide a means to deter and detect substance abuse, licensees shall implement drug and alcohol testing programs for persons subject to this part.

(b) FFD program personnel.

(1) Licensees and C/Vs shall carefully select and monitor FFD program personnel, as defined in 26.25(a)(4) of this subpart, based upon the highest standards for honesty and integrity, and shall implement measures to ensure that these standards are maintained. These measures must ensure that the honesty and integrity of such persons is not compromised or subject to influence attempts due to personal relationships with any individuals subject to testing, an undetected or untreated substance abuse problem, or other factors. At a minimum:

(i) Supervisors, co-workers within the same work group, and relatives of the individual being tested shall not perform any assessment or evaluation procedures. The integrity of specimen collections in these instances may be assured through monitoring of the collection by an independent individual designated by the licensee or C/V for this purpose, including, but not limited to, security force or quality assurance personnel who have been trained to monitor specimen collections and the preparation of specimens for shipping;

(ii) Appropriate background investigations, 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 must be periodically updated.

(iii) FFD program personnel shall be subject to a behavioral observation program designed to assure that they continue to meet the highest standards of honesty and integrity.

(2) Use of specimen collection services for drugs or alcohol at a local hospital or other organizations that meet the requirements of 49 CFR 40, “Procedures for Department of Transportation Workplace Drug and Alcohol Testing Programs” (65 FR 41944, August 9, 2001) is acceptable for FFD program personnel listed in 26.25(a)(4) of this part.

(c) Conditions for testing. Licensees shall administer drug and alcohol tests under the following conditions:

(1) Pre-access. Within 30 days before the assignment to activities within the scope of this part, unless the individual meets the conditions for an exemption described in §§26.9 or 26.25(b);

(2) For cause. In response to any observed behavior or physical condition that creates a reasonable suspicion of possible substance abuse or after receiving credible information that an individual is abusing drugs or alcohol;

(3) Post-event. As soon as practical after an event involving a failure in individual performance that resulted in:

(i) A significant injury or illness that results in death, days away from work, restricted work or transfer to another job, medical treatment beyond first aid, or loss of consciousness, or a significant injury or illness diagnosed by a physician or other licensed health care professional, even if it does not result in death, days away from

work, restricted work or job transfer, medical treatment beyond first aid, or loss of consciousness;

(ii) A radiation exposure or release of radioactivity in excess of regulatory limits, or

(iii) Actual or potential substantial degradations of the level of safety of the plant.

(4) Return to duty. Before an individual's authorization is reinstated following a violation of the substance abuse provisions of the FFD policy;

(5) Follow-up. As part of a follow-up plan to verify continued abstinence from substance abuse; and

(6) Random. On a statistically random and unannounced basis so that all persons in the population subject to testing have an equal probability of being selected and tested.

(d) General requirements for drug and alcohol testing.

(1) Substances tested. Licensees shall, at a minimum, test for marijuana, cocaine, opiates, amphetamines, phencyclidine, and alcohol.

(i) In addition, licensees may consult with local law enforcement authorities, hospitals, and drug counseling services to determine whether other substances 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 specified in (d)(1) of this paragraph.

(A) When appropriate, other substances so identified may be added to the panel of substances for testing.

(B) Appropriate cutoff limits must be established by the licensee for these substances and management actions must be the same for the additional substances as for those in the required panel of drugs specified in (d)(1) of this paragraph.

(C) The licensee shall establish rigorous testing procedures for these substances that are consistent with the intent of this part, so that the appropriateness of the use of these substances can be evaluated by the MRO.

(ii) Licensees may also test for any illegal drugs or any other substances suspected of having been abused by an individual and may consider any detected drugs or metabolites when determining appropriate action under Subpart D of this part. Any substances detected, including, but not limited to drugs or drug metabolites, may be considered in the analysis of any specimen suspected of being adulterated, diluted (in vivo or in vitro), substituted, or tampered with by any other means.

(2) Random testing.

(i) Random testing must include testing during all types of work periods, including weekends, backshifts, and holidays.

(ii) At a minimum, random tests must be administered by the FFD program on a nominal weekly frequency and at various times during the day.

(iii) Individuals selected for random testing must be required to report to the collection site as soon as reasonably practicable after notification, within the time period specified in FFD program procedures.

(iv) Reasonable efforts must be made to test persons selected for random testing. Persons offsite when selected for testing, and not reasonably available for testing when selected, must be tested at the earliest reasonable and practical opportunity when both the donor and collectors are available to collect specimens for

testing and without prior notification to the individual that he or she has been selected for testing.

(v) A person completing a test shall be immediately eligible for another unannounced test.

(vi) The sampling process used to select individuals for random testing shall ensure that the number of random tests performed annually is equal to at least 50% of the workforce population that is subject to the FFD program.

(3) Drug testing.

(i) Testing of urine specimens for drugs, except initial tests performed by licensees under paragraph (ii) below, must be performed in a laboratory certified by HHS for that purpose consistent with its standards and procedures for certification. Specimens sent to HHS-certified laboratories must be subject to initial validity and drug testing by the laboratory. Specimens screened as non-negative must be subject to confirmatory testing by the laboratory, except for invalid specimens that cannot be tested. Licensees shall ensure that laboratories report results for all specimens sent for testing, including blind performance test specimens.

(ii) Licensees may conduct initial validity and drug tests of urine aliquots to determine which specimens are valid and negative and need no further testing, provided the licensee's staff possesses the necessary training and skills for the tasks assigned, the staff's qualifications are documented, and adequate quality controls for the testing are implemented.

(iii) Licensees and C/Vs must, at a minimum, apply the cutoff levels specified in §26.163(a)(1) of this part for initial drug testing and in §26.163(b) of this part for confirmatory drug testing. Licensees, at their discretion, may implement programs with

lower cutoff levels for drug testing. If a licensee or C/V implements lower cutoff levels, and an individual is determined to have a confirmed positive test result using the licensee's or C/V's more stringent cutoff levels, the individual must be subject to all management actions and sanctions required by the licensee's or C/V's policy and this part, as if the individual had a confirmed positive test result using the cutoff levels specified in this part.

(4) Alcohol testing. Initial tests for alcohol must be administered by breath or oral fluids analysis using alcohol analysis devices that meet the requirements of §26.91. If the initial test shows a BAC of 0.02 percent or greater, a confirmatory test for alcohol must be performed. The confirmatory test must be performed with a breath alcohol analysis device meeting the evidential standards described in §26.91(a).

(5) If an individual has a medical condition that makes collection of breath, oral fluids, or urine specimens difficult or hazardous, the MRO may authorize an alternative evaluation process, tailored to the individual case, for determining whether a violation of the FFD policy has occurred, provided this process includes measures to prevent subversion and can achieve results comparable to those produced by urinalysis for drugs and breath analysis for alcohol.

(6) Specimens collected under NRC regulations may only be designated or approved for testing as described in this part and may not be used to conduct any other analysis or test without the permission of the donor.

§26.32 Fatigue Assessment

(a) Licensees shall assess ~~workers~~individuals for fatigue ~~induced impairment~~ in the following circumstances:

(1) For-cause. In response to any observed behavior or physical condition that creates reasonable suspicion that an individual is not fit-for-duty.

(2) Self-declaration. In response to a self declaration by an individual that he or she is not fit for duty because of fatigue. No fatigue assessment is required if the licensee restricts the individual from performing activities under this part for a minimum of 10 hours following the self declaration.

(3) Post-event. In response to events requiring post-event drug and alcohol testing as specified in ~~§26.31(c)(3)~~this part.

(b) Fatigue assessments shall be conducted by individuals trained in accordance with the ~~symptoms, contributing factors, and effects~~requirements of ~~fatigue~~this part. The assessment shall address, as a minimum, the following factors:

(1) acute fatigue;

(2) cumulative fatigue; and

(3) circadian ~~factors~~variations in alertness and performance.

§ 26.33 Behavioral observation

Licensees and C/Vs with approved FFD programs must assure that individuals performing activities under this part are subject to behavioral observation by observers trained in accordance with §26.29 of this part to detect behaviors that may indicate possible possession, use or sales of illegal drugs, possession or use of alcohol on-site, or impairment **from fatigue or** any cause that, if left unattended, may constitute a risk to the health and safety of the public. Individuals assigned to perform activities within the scope of this part must report fitness concerns to the licensee or C/V personnel designated in the FFD policy. When the MRO is on-site at a licensee's facility, the MRO must be subject to behavioral observation.

§ 26.35 Employee assistance programs

(a) Each licensee subject to this part, and each C/V with a licensee-approved FFD program, shall maintain an employee assistance program (EAP) to strengthen the FFD program by offering assessment, short-term counseling, referral services, and treatment monitoring to its employees with problems that could adversely affect the performance of activities within the scope of this part. Employee assistance programs must be designed to achieve early intervention and provide for confidential assistance.

(b) Licensees are not required to provide EAP services to C/V employees.

(c) The EAP staff shall inform licensee or C/V management, as appropriate, when a determination has been made that any individual's condition constitutes a hazard to himself or herself or others, including those who have self-referred.

§ 26.37 Protection of information

(a) Each licensee subject to this part, and any C/V upon which a licensee relies, that collects personal information about an individual for the purpose of complying with this part, shall establish and maintain a system of files and procedures for the protection of the personal information. Records shall be maintained and used with the highest regard for individual privacy.

(b) A signed consent that authorizes the disclosure of the personal information collected and maintained under this part must be obtained by the licensee or C/V prior to disclosure of the personal information, except for disclosures to the following individuals:

(1) The subject individual or his or her representative, when the representative has been designated in writing by the individual for specified FFD matters;

(2) Assigned MROs;

(3) NRC representatives;

(4) Appropriate law enforcement officials under court order;

(5) Licensee and C/V representatives who have a need to have access to the information in performing assigned duties, including determinations of fitness, audits of licensee or C/V FFD programs, and human resources or personnel functions;

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

(7) Persons deciding matters on review or appeal; and

(8) Other persons pursuant to court order.

(c) Personal information collected under this part shall be disclosed to other licensees and C/Vs, or their authorized representatives, legitimately seeking the information as required by this part for authorization decisions and who have obtained a release from the subject individual.

(d) Upon receipt of a written request by the subject individual or his or her designated representative, the licensee, C/V, or HHS-certified laboratory possessing such records shall promptly provide copies of all records pertaining to the determination of a violation of the FFD policy, including test results, MRO reviews, and management actions pertaining to the subject individual. Records relating to the results of any relevant laboratory certification review or revocation of certification proceeding must be obtained from the relevant laboratory and provided to the subject individual upon request.

(e) Licensee and C/V contracts with HHS-certified laboratories and procedures for a licensee's testing facility shall require that test records be maintained in confidence, except as provided in paragraphs (b), (c) and (d) of this section.

(f) This section does not authorize the licensee or C/V to withhold evidence of criminal conduct from law enforcement officials.

§ 26.39 Review process for FFD policy violations

(a) Each licensee subject to this part, and C/Vs with licensee-approved FFD programs, shall establish a procedure, for their respective employees and applicants for unescorted access, for the review of a determination that the individual has violated the FFD policy. The procedure must provide for an objective and impartial review of the facts relating to the determination that the individual has violated the FFD policy.

(b) The procedure must provide notice to the individual of the grounds for the determination that the individual has violated the FFD policy, and must provide an opportunity to respond and to submit additional relevant information.

(c) The review must be conducted by persons not associated with the administration of the FFD program (see description of FFD program personnel in §26.25(a)(4) of this part), and may include licensee or C/V management personnel.

(d) If the review finds in favor of the individual, the relevant records must be corrected.

(e) A review procedure need not be provided by the licensee to employees of C/Vs when the C/V is administering a drug and alcohol testing program for its applicants and employees.

§ 26.41 Audits and corrective action

[Requirements concerning fatigue TBD]

(a) General. Each licensee subject to this part is responsible for the continuing effectiveness of the FFD program, including FFD program elements that are provided by C/Vs, the FFD programs of any C/Vs that are accepted by the licensee, and the

programs of the HHS-certified laboratories relied upon by a licensee and its C/Vs. Each licensee shall ensure that audits of these programs are conducted and that corrective actions are taken to resolve any problems identified.

(b) FFD program. Each licensee subject to this part, and C/Vs with licensee-approved FFD programs, shall ensure that the complete FFD program is audited as needed but no less frequently than every 36 months. Licensees and C/Vs are responsible for determining the appropriate frequency, scope, and depth of additional auditing activities within the three-year period based on review of program performance indicators such as the frequency, nature, and severity of discovered problems, testing errors, personnel or procedural changes, previous audit findings, and "lessons learned."

(c) C/Vs and HHS-certified laboratories.

(1) FFD services provided to the licensee by C/V personnel who are off site or are not under the direct daily supervision or observation of licensee personnel, including but not limited to, contracted MRO, EAP and specimen collection services, shall be audited on a nominal 12-month frequency.

(2) Annual licensee and C/V inspections and audits of HHS-certified laboratories need not duplicate areas inspected in the most recent HHS certification inspection. However, licensees and C/Vs must review the HHS certification inspection records and reports to identify any areas in which the licensee or C/V uses services that were not addressed by the HHS certification inspection. Any additional areas identified by licensees or C/Vs must be audited on a nominal 12-month frequency. Organizations and professionals that provide FFD program services, but who are not routinely involved in providing services to a licensee’s or C/V’s FFD program, as specified in §26.25(b)(1), are exempt from this requirement.

(d) Contracts. Licensee's contracts with C/Vs and HHS-certified laboratories must reserve the right to audit the C/V, the C/V's subcontractors providing FFD program services, and the HHS-certified laboratories at any time, including at unannounced times, and to obtain all information and documentation reasonably relevant to the audits. Licensee contracts with C/Vs and HHS-certified laboratories must also provide the licensee with the ability to obtain copies of any documents, including reviews and inspections pertaining to a laboratory's certification by HHS, and any other data that may be needed to assure that the C/V, it's subcontractors, or the HHS-certified laboratory are performing their functions properly and that staff and procedures meet applicable requirements. In addition, before the award of a contract, the licensee shall ensure completion of pre-award inspections and/or audits of the procedural aspects of the C/V's or the HHS-laboratory's operations.

(e) Conduct of audits. Audits must focus on the effectiveness of the program and be conducted by individuals qualified in the subject(s) being audited. The individuals performing the audit must be independent from both FFD program management and from personnel directly responsible for implementing the FFD program.

(f) Audit results. The result of the audits, along with recommendations, if any, must be documented and reported to senior corporate and site management. C/Vs with licensee-approved FFD programs must also provide the licensees they serve with copies of the audit report. Each audit report must identify conditions adverse to the proper performance of the FFD program, the cause of the condition(s) and, when appropriate, recommend corrective actions. Management shall review the audit findings and take corrective actions, including re-audit of the deficient areas where indicated, to

preclude, within reason, repetition of the condition. The resolution of the audit findings and corrective actions must be documented.

(g) Sharing of audits. Licensees may jointly conduct audits, or accept audits of C/Vs and HHS-certified laboratories that were conducted by other licensees subject to this part, when the services provided to the sharing licensees by the C/Vs and HHS-certified laboratories are the same.

(1) Licensees shall review audit records and reports to identify the areas not covered by the shared or accepted audit.

(2) Sharing licensees need not re-audit the same C/V or HHS-certified laboratory for the same period of time, except to audit program elements and services used by the licensee that were not addressed in the shared audit.

(3) Each sharing licensee and C/V shall maintain a copy of the shared audit and HHS certification inspection records and reports, to include findings, recommendations and corrective actions.

(4) If an HHS-certified laboratory loses its certification, in whole or in part, a licensee or C/V is permitted to immediately use another HHS-certified laboratory that has been audited within the previous 12 months by another NRC licensee having the same drug panel and cut-off levels. The licensee or C/V must ensure completion of an audit of any areas not audited by another licensee or C/V within three months of the change.

SUMMARY OF STAKEHOLDER COMMENTS CONCERNING DRAFT WORKER FATIGUE RULE LANGUAGE, REVISION 4

The following synopsis of stakeholder comments was derived from staff meeting notes.

26.23 Performance objectives

26.23(e) The term alertness should not be used in the performance objective statement because it broadens the scope of the regulation to matters such as boredom that are beyond the proposed rulemaking. The NRC noted that the term is used to incorporate the concept of circadian variations in alertness. The industry working group committed to provide a white paper addressing the wording of the performance objective.

26.27 Written policy and procedures

26.27(b) Stakeholders were in general agreement with the proposed procedural requirement concerning self-declaration. The term "tour of duty" should be defined or otherwise clarified.

26.29 Training

Stakeholders were in general agreement with the learning objectives as currently specified.

26.30 Work scheduling controls

26.30(a)(4) The work scheduling controls should not be applied to fire brigade personnel. The requirements, as written, do not allow the current practice of 24-hour shifts for dedicated fire brigades

26.30(b) Individual work hour controls

26.30(b) The current language is not clear concerning whether an individual that performs functions within the scope of the work scheduling controls must have a deviation to exceed the thresholds for work outside the scope of functions subject to the work scheduling controls. Not documenting such circumstances could pose challenges for inspectors and licensees if reviews of work scheduling records find no deviation approvals for individuals in excess of the guidelines.

26.30(b)(3) The current language is not clear concerning who the authorizing official is for work hour deviations.

The criteria limiting deviations to circumstances that could not be reasonably foreseen could result in conditions that are adverse to safety. The staff noted that the intent of the criteria is to prevent the use of deviations as a means of

addressing known discrepancies between scheduler goals and available staffing.

The industry task force will provide proposed wording for the deviation criteria that would provide senior plant manager discretion in determining whether a deviation should be authorized. The staff reiterated its concern that management discretion in the authorization of deviations creates the potential for abuse and unenforceable requirements because of the lack of criteria for judging the acceptability of the authorizations. The UCS noted that allowing deviations for conditions unrelated to maintaining safety may undermine the scoping of functions subject to the work scheduling controls.

The staff committed to review the criteria of 26.30(a)(1) and 26.30(3)(ii) for consistency.

Concern was expressed that limiting fitness for duty assessments to supervisors as specified in 26.30(b)(3)(iii) was too limiting given Institute of Nuclear Power Operations (INPO) accreditation requirements for supervisors. A proposal was made to allow the assessment to be made by the "supervisor/manager in charge of the individual/unit." A recommendation was also made to replace the term "compensatory measures" with "measures to prevent or mitigate errors due to fatigue" and deleting the term "alertness" from the specification of factors the fatigue assessment shall address.

26.30(b)(1)(iii)

The UCS questioned whether a review of work history for the past 7 days was sufficient for assessing cumulative fatigue.

26.30(b)(4)

The industry task force recommended removing the requirement to document why the condition requiring a deviation was unforseen or uncontrollable.

The industry task force questioned the level of documentation that is necessary for assessment. The staff reasserted that whereas the documented bases did not have to be long narratives, signatures alone would not be considered sufficient.

The PROS committed to provide a recommendation concerning the assessment and documentation.

26.30(c) Group work hour controls

The UCS questioned why group work hour controls did not apply to outages given the potential for long outages and insights concerning shutdown risk. The industry task force asserted that group work hour controls would not be an effective means of addressing shutdown risk.

The industry task force noted that it was collecting work hours data from 9 plants as part of an effort to develop recommendations for a metric for the group work hour controls and provided the following questions and comments concerning the group work hour control metric:

The metric should not include turnover time because most plants do not currently track turnover.

The small size of groups for chemistry, health physics, and fire brigade personnel are expected to cause greater variability in group work averages and difficulty for licensees in maintaining averages below a limit.

Should a monitoring period for normal operations end with the beginning of an outage or should it resume at the conclusion of an outage? Maintaining fixed monitoring periods would allow licensees to align monitoring periods with payroll periods.

Does the first day of an outage count towards the outage limit or the normal operations limit?

Recommended piloting the group work hour metric.

The task force noted that it will provide a paper with recommendations concerning the group work hour control metric.

26.30(e) The industry task force was concerned that the term “verify” was not appropriate for the plant manager review of group averages. The task force proposed changing the wording to require a program effectiveness review. The task force noted that the proposed requirement was confusing because it addressed both individual and group work hour controls. The staff committed to revise the language to clarify the proposed requirements.

26.32(b) The staff noted that the proposed requirement is incomplete. The requirement does not specify actions to be taken in response to the outcomes of a fatigue assessment.

July 18, 2003

MEMORANDUM TO: William D. Beckner, Chief
Reactor Operations Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

/RA/

FROM: David C. Trimble, Chief
Operator Licensing and Human Performance Section
Reactor Operations Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

SUBJECT: SUMMARY OF THE MAY 29, 2003, PUBLIC MEETING TO DISCUSS THE DEVELOPMENT OF A PROPOSED WORKER FATIGUE RULE

On May 29, 2003, the staff held a public meeting regarding the development of a proposed rule concerning worker fatigue at nuclear power plants. The rulemaking has been proposed as an amendment to 10 CFR 26, "Fitness for Duty Programs." The meeting participants (see Attachment 1) included representatives from the power reactor licensee community, the Nuclear Energy Institute (NEI), the Professional Reactor Operator Society, and the Union of Concerned Scientists (UCS). The meeting agenda is provided as Attachment 2.

The focus of the meeting was discussion of draft proposed rule language (Attachment 3). The staff also provided a revision of the process charts for the proposed rule that were presented at the April 24, 2003, public meeting (Attachment 4). A synopsis of stakeholder comments on the draft rule language is provided in Attachment 5.

The staff set a target date of July 9, 2003, for the next stakeholder meeting.

Attachments: As stated

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