UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555 - 0001

March 28, 2003

MEMORANDUM TO: Theodore R. Quay, Chief
Equipment and Human Performance Branch
Division of Inspection Program Management
Office of Nuclear Reactor Regulation

/RA/

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

SUBJECT: SUMMARY OF THE FEBRUARY 27, 2003, PUBLIC MEETING TO DISCUSS THE DEVELOPMENT OF A PROPOSED WORKER FATIGUE RULE

On February 27, 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 Electric Power Research Institute (EPRI), the power reactor licensee community, the Nuclear Energy Institute (NEI), and the Union of Concerned Scientists. The meeting agenda is provided as Attachment 2. The focus of the meeting was the staff’s presentation of draft language for the proposed rule (Attachment 3). Meeting attendees provided comments on the proposed rule language and methods proposed for achieving the objectives of the rule. A synopsis of stakeholder comments is provided in Attachment 4. Barry Quigley, the petitioner for this rulemaking, was unable to attend the meeting though he provided written comment (Attachment 5) on the draft of the proposed rule language.

In addition to the specific stakeholder comments summarized in Attachment 4, the industry task force proposed to develop several white papers addressing matters of particular interest to the industry stakeholders. The topics of the proposed white papers are:

1. the definition of "directing" as used in 26.30(a),

2. the basis for the task force position that individuals performing the watchperson function should not be included in the work scheduling controls,

3. the basis for approving a deviation as described in 26.30(b)(3)(ii)

4. the documentation to be required for a deviation as described in 26.30(b)(4), and

5. an alternative method for group work hour controls as described in 26.30(c).

The task force agreed to provide the NRC staff with the white papers in advance of the next public meeting so as to provide an opportunity for the staff to consider these views and proposals in development of the next revision of the rule language. Similarly, the staff agreed to make the revised text of the proposed rule publicly available a week in advance of the public meeting to allow stakeholders greater opportunity to review and prepare comment on the proposed text.

The staff closed the meeting with a commitment to consider the comments provided in developing a revised draft and to schedule a meeting for April 2003.

Attachments: As stated

5. an alternative method for group work hour controls as described in 26.30(c).

The task force agreed to provide the NRC staff with the white papers in advance of the next public meeting so as to provide an opportunity for the staff to consider these views and proposals in development of the next revision of the rule language. Similarly, the staff agreed to make the revised text of the proposed rule publicly available a week in advance of the public meeting to allow stakeholders greater opportunity to review and prepare comment on the proposed text.

The staff closed the meeting with a commitment to consider the comments provided in developing a revised draft and to schedule a meeting for April 2003.

Attachments: As stated

ADAMS #: ML03090036

DOCUMENT NAME:C:\ORPCheckout\FileNET\ML030900036.wpd
To receive a copy of this document, indicate in the box: "C" = Copy without enclosures **"E"** = Copy with enclosures **"N"** = No copy

OFFICE	IOHS/IEHB		IOHS/IEHB		IEHB/DIPM					
NAME	DDesaulniers		DTrimble		TQuay					
DATE	2/28/03		2/28/03		2/28/03					

OFFICIAL RECORD COPY

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

February 27, 2003

Attendance List

NAME	AFFILIATION
David Trimble	NRC/NRR
David Desaulniers	NRC/NRR
Chuck Dugger	Entergy
Getachew Tesfaye	CGG
David Lochbaum	Union of Concerned Scientists
Bob Evans	NEI
Jim Gallman	TXU
Bryan Dolan	Duke Energy
James Davis	NEI
David Ziebell	EPRI
Dave Shafer	AmerenUE
Clare Bleau	NMC
John Fee	SCE
Alan Roecklein	NRC/NRR
Martin Humphrey	FENOC
Garmon West	NRC/NSIR
J. Persensky	NRC/RES
Ronald Rose	NEI/FE
Marjorie Rothschild	NRC/OGC
Chris Nolan	NRC/NSIR
Ed Hellmer	
Brian Zaveski	ICF Consulting
Jenny Weil	McGraw-Hill

PROPOSED RULE CONCERNING WORKER FATIGUE
AT NUCLEAR POWER PLANTS

February 27, 2003

AGENDA

Morning Session

8:30-8:40	Introductions and Opening Remarks
8:40-9:00	Regulatory Analysis
9:00-9:30	Status of Security Worker Fatigue Orders
9:30-10:15	Written Policy and Procedures
10:15-10:30	Break
10:30-11:30	Work Scheduling Controls
11:30-12:00	Training
12:00-1:00	Lunch

Afternoon Session

1:00-2:00	Fatigue Assessment
2:00-2:45	Audits and Corrective Action
2:45-3:00	Break
3:00-3:30	Recordkeeping
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

DRAFT PROPOSED WORKER FATIGUE RULE LANGUAGE

Note: Draft language concerning worker fatigue appears in bold and as changes to the proposed draft revision of Part 26.

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 avoiding 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 **fatigue or any other** 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 fatigue is 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 a 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; 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 during a duty period that he or she is not fit for duty for reasons including illness, fatigue, or other potentially impairing conditions. The procedure shall describe individual and licensee responsibilities

and require the establishment of controls and conditions under which the individual can 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 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 a lack of adherence to 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 indications and risk factors for common sleep disorders and effective shiftwork strategies for obtaining adequate rest;

(10) Ability to identify 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 KSA, including at least one item for each KA. The examination must be administered under the supervision of a proctor. 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 nominal12-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 the training occurs and provide a qualified instructor or designated subject matter expert who is able to answer questions in the course of completion.

(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 structures, 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 XX.XX; or
(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 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.

[Comments received concerning impact of 10-hour break on quick turn arounds for 8-hour 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 forseen or controlled the circumstances necessitating the deviation,
(ii) the operations shift manager determines that the deviation is necessary to mitigate or prevent conditons adverse to safety, or the security shift manager determines that the deviation is necessary to maintain the security of the facility, and
(iii) a supervisor trained in the causes, symptoms, and effects of fatigue, performs an assessment in accordance with §26.32 and determines that the individual's fitness for duty will not be adversely affected by the additional work period to be authorized under the deviation and evaluates the need for 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 description of the safety or security condition necessitating the work schedule extension,

(ii) the basis for the determination that the individual's fitness for duty will not be adversely affected by the additional work period, and

(iii) an assessment of the potential for fatigue-related errors to affect the safe performance of the work and the use of any compensatory measures.

(5) The number and duration of approved deviations shall be limited to the extent practicable.

(6) The licensee shall monitor and control individual work hours to ensure that excessive work hours are not compromising worker alertness and performance.

(c) ***Group Work Hour Controls*****.**

(1) The average 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 a [shift] shall not exceed an average of 48 hours per person per week [averaged over a rolling consecutive period not to exceed six weeks. Worker absences and workers who were not assigned to the shift for the entire period shall be prorated when calculating the average.]

(2) The average work hours for personnel performing the functions identified in §26.30(a)(5) shall be controlled in accordance with the following limits:

(i) While the plant is operating, the average number of hours actually worked per person shall not exceed 48 hours per week [averaged over a rolling consecutive period not to exceed six weeks. Worker absences and workers who were not assigned to the shift for the entire period shall be prorated when calculating the average.]

(ii) While the plant is in a planned outage, the average number of hours actually worked per person shall not exceed 60 hours per week [averaged over a rolling consecutive period not to exceed six weeks.] For planned plant outage periods shorter than the averaging period, the limit is 60 hours averaged over the duration of the plant outage. [Part weeks, worker absences and workers who were not assigned to the shift for the entire period shall be prorated when calculating the average.]

(iii) During unplanned plant outages and following increases in security threat conditions, licensees are exempt from the requirements

of 26.30(c)(2)(i) and (ii), for a period not to exceed 90 days. For unplanned plant outages or increases in security threat conditions greater than 90 days, the licensee shall take prompt action to limit hours worked in accordance with 26.30(c)(2)(i).

(3) Licensees shall be exempt from the work scheduling controls of §26.30 during declared emergencies as defined in the facility's emergency plan.

§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 for honesty and integrity.

(2) Use of specimen collection services for drugs or alcohol at a local hospital or other organization 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.XX and 26.XX of this part;

(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 personal injury or illness that is recordable, at the time of the event, under the U.S. Department of Labor standards contained in 29 CFR 1907.4, and subsequent amendments thereto,

(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 herein.

(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.

(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 detected drugs or 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 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 in accordance with the requirements of the HHS Guidelines.

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 published in the HHS Guidelines for initial and confirmatory drug testing. Licensees, at their discretion, may implement programs with lower cutoff levels. If a licensee or C/V implements lower cutoff levels than those published in the HHS Guidelines, 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 described in 26.XX of Subpart E of this part. 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.XX.

(i) 0.04 percent BAC at any time; or

(ii) 0.03 percent BAC or greater, if the individual has been in a work status for at least one or more hour (including any breaks for rest, lunch, dental/doctor appointments, etc.); or

(iii) 0.02 percent BAC or greater, if the individual has been in a work status for at least two or more hours (including any breaks for rest, lunch, dental/doctor appointments, etc.)

(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 illegal 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 shall not be used to conduct any other analysis or test without the permission of the tested individual.

§26.32 Fatigue Assessment

(a) Licensees shall assess workers 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 declaration by an individual that he or she is not fit for duty because of fatigue.
(3) Post-event. In response to events requiring post-event drug and alcohol testing as specified in §26.31(c)(3).

(b) Licensees shall assess the potential for fatigue induced worker impairment as part of authorizing individual work hour extensions in accordance with §26.30.

(c) Fatigue assessments shall be conducted by individuals trained in the symptoms, contributing factors, and effects of fatigue. The assessment shall address, as a minimum, the following factors:

(1) acute fatigue;
(2) cumulative fatigue; and
(3) circadian factors.

§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 to detect behaviors that may indicate possible possession, use or sales of illegal drugs, possession of alcohol on-site, or impairment **from fatigue or any other 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.

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. Licensees are not required to provide EAP services to C/V employees. Employee assistance programs must be designed to achieve early intervention and provide for confidential assistance. 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 on 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.

Each licensee subject to this part, and C/Vs with 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 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. 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. The review must be conducted by persons not associated with the administration of the FFD program, as described in §26.XX, and may include internal management. If the review finds in favor of the individual, the relevant records must be corrected. A licensee review procedure need not be provided 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 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 3-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) Licensees' FFD program elements that are implemented by C/Vs and FFD services provided to the licensee by personnel who are off site or not under the direct daily supervision or observation of licensee personnel 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 uses services that were not addressed by the HHS certification inspection. Any additional areas identified by licensees must be audited on a nominal 12-month frequency.

(3) 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 under §26.X of this part.

(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, and independent of both FFD program management and personnel directly responsible for implementation of 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 3 months of the change.

SUMMARY OF STAKEHOLDER COMMENTS

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

§26.27 Written Policy and Procedures

26.27(c)(6)	Evaluate whether fatigue should be explicitly identified in this paragraph to ensure NRC has an enforceable basis for requiring that licensee procedures adequately address process to be followed if an individual is impaired by fatigue.

§26.29 Training

26.29(a)(10)	Evaluate whether “decreased alertness” should be replaced by “fatigue.”

§26.30 Work Scheduling Controls

26.30(a)	Phrase limiting applicability of requirement to “licensees’ authorized to operate should be moved to scope section. The phrase limiting applicability to “licensees authorized to operate” would exclude licensees subject to confirmatory action letters.”
26.30(a)(5)	The “watchperson” function should be eliminated from the scope of the work scheduling requirements because staff personnel are occasionally assigned watchperson functions and the burden of limiting the hours would outweigh the benefit given the nexus of this function to safety.
26.30(b)(2)	The 10 hour break requirement interferes with routine scheduling practices for 8-hour shifts The 10 hour break may prevent individual from returning to their normally scheduled shift if they work a double 8-hour shift or work more than 2 hours past the end of a 12-hour shift.
26.30(b)(3)(ii)	The criterion sets too high a threshold for authorizing a deviation. The criterion should focus on why the specific individual is necessary to work the hours rather than an individual who is below the threshold.

26.30(b)(3)(iii)	Replace “causes” with “contributors.”
	The supervisory assessment should focus on situational factors.
26.30(b)(4)	The documentation requirement should be limited to an indication that the assessments were done rather than the basis for the conclusion.
	The documentation requirements should directly coincide with the assessment requirements.
26.30(b)(5)	The requirement is redundant with other requirements and is not enforceable.
	The requirement suggests that compliance would be evaluated on the basis of the number of deviations authorized and may detract from a thoughtful use of the deviation process.
26.30(c)	The group work hour controls should be goals or actions thresholds requiring rather than limits.
	Specifying a group average limit requires licensees to maintain their work hours several hours lower to avoid exceeding the limit.
	The limit of a 48 hour average is too low. The staff should consider a limit on the order of 55 or 60 hours.

§26.32 Fatigue Assessment

26.32(a)	The assessments performed for the circumstances address in this requirement should be performed by an individual with more extensive training than required for the supervisory assessment necessary for authorizing a work threshold deviation.
26.32(b)	Decouple this assessment from other assessment in 26.32.

From: <QPIF@aol.com>
To: <drd@nrc.gov>
Date: 2/24/03 1:52PM
Subject: Comments on 1/21/03 version of Part 26

1. I am disappointed in the current language of the proposed rule; it essentially codifies GL82-12, and in some cases is even less restrictive i.e., overtime deviations can now be approved by the immediate supervisor instead of the plant manager.

2. One phrase that must stay in is
A rate of not greater than 10 percent unscheduled work hours, on a yearly basis, is considered acceptable.This phrase is the only hope in the rule as currently 6 proposed to address chronic fatigue. However it requires some clarification, is this 10% above 2080 hours? Otherwise the overtime can be scheduled and there would essentially be no cap to address chronic fatigue.

3. Also, early on one of the sleep experts (NSF or Moore-Eide) challenged the use of 16 hour shifts, how was this dissenting expert opinion resolved?

4. 26.27 discusses excessive fatigue while other sections just describe it as fatigue. Is there a difference? If so, we will have a hard time defining excessive.

5. I remain concerned that turnover time can be abused. We typically work people 13 hours and call the 13th hour turnover even though there is no turnover.

I am on vacation 3/31 thru 4/4 and would probably be able to attend a meeting in that time frame dependent on another personal commitment that is not under my complete control.

Respectfully,
Barry Quigley