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NUCLEAR ENERGY INSTITUTE

(84)

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December 21, 2006

The Honorable Dale E. Klein
Chairman
U.S. Nuclear Regulatory Commission
Mail Stop O-16 C1
Washington, DC 20555-0001

SUBJECT: Draft 10 CFR Part 26 Fitness-for-Duty

PROJECT NUMBER: 689

Dear Chairman Klein:

On October 24, 2006, the Nuclear Regulatory Commission (NRC) posted on its website 10 CFR Part 26 Fitness-for-Duty (FFD) provisions that were described as early draft final rule language. These provisions include Subpart I, "Managing Fatigue," and Subpart K, "Modified FFD Programs for Construction Sites." The Nuclear Energy Institute (NEI) [1] appreciates the NRC action to make this rule language available to the public. This letter provides industry's perspective on the draft final rule language.

The nuclear industry remains committed to fitness-for-duty of plant personnel, including appropriate drug and alcohol testing and work hour requirements. The exemplary safety performance of the existing fleet of plants could not be accomplished without this commitment. While NEI supports the vast majority of the final Part 26, we are concerned that a few specific elements of the rule lack a sound technical basis, or would impose an unnecessary regulatory burden without a commensurate safety benefit.

Subpart I – Managing Fatigue

Industry reviews of plant operating and human performance data provided to the NRC during this rulemaking have shown no correlation between fatigue and actual human performance at power reactor sites. However, the NRC staff has proposed multiple layers of work hour control requirements.

[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including the regulatory aspects of generic operational and technical issues. NEI's members include all entities licensed to operate commercial nuclear power plants in the United States, nuclear plant designers, major architect/engineering firms, fuel fabrication facilities, nuclear materials licensees, and other organizations and individuals involved in the nuclear energy industry.

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The NRC staff has proposed a 34-hour break in any 9-day period. Incorporating the 34-hour break requirement with the specific individual limits for 24 hours, 48 hours, 7 days, and breaks between work periods included in the rule addresses both acute and cumulative fatigue. The rule also contains a requirement for performance reviews of actual work hours and performance of individuals and if problems are found requires corrective actions to be taken under the licensee's corrective action program.

The industry understands the science indicates that a 34-hour break with two rest periods is fully restorative and addresses the concern about cumulative fatigue. Therefore, the additional proposed work hour control requirement for minimum number of days off during normal and outage periods is unnecessary in light of the science of fatigue management.

We believe some requirements create a significant administrative and potential operational burden with no commensurate safety benefit. Therefore, the industry believes: (1) The minimum days off per shift is unnecessary and should be eliminated; (2) The 3 days off every 15 during an outage should be changed to a 34-hour break in any 9-day period; (3) The requirement related to two or more successive outages that start less than two weeks apart should be eliminated; and (4) Security officers should have the same work hour controls as workers performing nuclear safety tasks.

Enclosure 1 provides a more detailed discussion of our recommendations and bases.

Subpart K – Fitness-for-Duty Program at Construction Sites

This subpart would impose under Part 26 a fitness-for-duty program at construction sites that is essentially the same as at operating plants. Imposing the same operating reactor fitness-for-duty requirements on construction sites is unnecessary considering there is no radiological hazard at construction sites before nuclear fuel is received. In addition, there are a variety of both NRC and licensee activities aimed at ensuring that a plant is constructed and will function as designed. These activities include quality assurance (QA) and quality control (QC) programs, the NRC construction inspection program, construction testing, pre-operation testing and start-up testing programs. Given that the construction workforce could number up to 2,000 individuals at a single-unit site, the proposed program would impose a significant burden on the industry without a commensurate safety benefit.

As part of its business and asset protection program, licensees will have a drug and alcohol testing regime consistent with standard construction site practices. All workers would be subject to pre-employment testing, and testing for cause or following a construction accident. These programs do not require NRC regulatory scrutiny for the reasons mentioned in the above paragraph.

In addition to the non-regulated programs identified above, NEI recommends that NRC establish regulatory requirements for QA and QC personnel to be subject to random testing consistent with Part 26 requirements for operating plants. These personnel will be responsible for ensuring that key construction activities are performed and documented in accordance with design requirements and construction procedures

Finally, prior to the receipt of nuclear fuel on the construction site, the licensee will perform a "lockdown and secure" procedure. At this point, Part 26 would become effective for all employees and contractors within the scope of the rule. Enclosure 2 provides additional details and recommended changes to Section 26.4 and Subpart K.

Drug and Alcohol Requirements for Operating Reactors

Enclosure 3 provides a few specific comments on the proposed drug and alcohol requirements for operating reactors that we believe would enhance the overall effectiveness of the rule.

Again, we commend the Commission for making the early draft final rule language available. If you have any questions, please contact me at 202-739-8125; msf@nei.org.

Sincerely,

Marvin S. Fertel

Enclosures

c: The Honorable Edward McGaffigan, Jr., Commissioner, NRC
The Honorable Jeffrey S. Merrifield, Commissioner, NRC
The Honorable Gregory B. Jaczko, Commissioner, NRC
The Honorable Peter B. Lyons, Commissioner, NRC
Mr. Luis A. Reyes, Executive Director for Operations, NRC
Mr. William F. Kane, Deputy Executive Director for Reactor and Preparedness Programs, NRC
Mr. James E. Dyer, Director, Office of Nuclear Reactor Regulation, NRC
Mr. Roy P. Zimmerman, Director, Office of Nuclear Security and Incident Response, NRC

Comments on Draft 10 CFR Part 26
Subpart I (Managing Fatigue)

I. Introduction

Background

On October 24, 2006, the NRC posted on its web site some provisions of 10 CFR Part 26 Fitness-for-Duty "draft final rule language" available for public viewing only, specifically Subpart I, "Managing Fatigue," The posting stated that "The NRC is not soliciting formal public comments on these draft final rule language provisions. No stakeholder requests for a comment period will be granted at this stage in the rulemaking process."

Significant Issues

The industry believes there are still four significant issues as follows:

1. During outages, the proposed limit of 3 days off every 15 days is unnecessary to address acute and cumulative fatigue and will have a significant negative impact on the ability to attract the quality supplemental workers needed during an outage and can have unintended consequences from increased work hand-offs.
2. The rule has a "60-day clock" that allows more work hours during outages. If someone works two or more successive outages that start less than two weeks apart, the rule specifies that the "60-day clock" starts from the beginning of the first outage. After 60 days, a worker must adhere to the normal operation work hour limits of 48-52 hours per week. This requirement is unnecessary to address either acute or cumulative fatigue.
3. During non-outage periods, the minimum days off requirement is unnecessary to address acute and cumulative fatigue given the individual limits of 16 hours in 24 hours, 26 hours in 48 hours, and 72 hours in 7 days coupled with the requirement to have one 34-hour break period in each 9 days. This redundant requirement is an unnecessary administrative and potential operational burden.
4. Security officers have different work hour controls as workers performing nuclear safety tasks. No scientific basis for this difference is provided by the NRC.

NEI recommends the following:

1. Change the outage requirement for 3 days off in each successive (non-rolling) 15-day block of the outage to a 34-hour break in any 9-day period.
2. Remove the requirement for additional restrictions after 60 consecutive days of outage work.
3. Remove the third "layer" requiring a minimum days off for normal and outage operations. The first two "layers" including the 34-hour break provide the necessary protection against cumulative fatigue.
4. Security officers should have the same work hour controls as workers performing nuclear safety tasks.

II. Plant Human Performance Data Review

As discussed in NEI's comment letter of December 20, 2005, actual plant performance does not show any significant fatigue related issues. Throughout this rulemaking effort, there has been no correlation between the claimed impacts of fatigue and actual human performance at power reactor sites.

In proposing the rulemaking, an assessment was cited by NRC showing that: "There are only a limited number of events at U.S. nuclear power plants that have been attributed to fatigue. In addition, the overall number of events at nuclear power plants has been declining for the past several years." (See SECY-01-0113, Page 3 (June 22, 2001)). In individual vote sheets on this rulemaking, Commissioners also recognized that there were few events in the industry. (See SRM-SECY-01-0113 (January 8, 2002)).

The industry conducted a review of all significant events over an 8-year period and found that none of the events reviewed were attributed to fatigue as a cause. These facts show that there is no need to significantly expand fatigue provisions beyond those contained in Generic Letter 82-12.

Some questioned the results of the industry study with the presumption that the industry root cause analyses were flawed. In response to this criticism, the industry has more recently conducted a review of human performance indicators, independent of cause, to determine if there were any trends that could be attributed to fatigue-induced errors. Two specific fatigue concerns discussed in the rule package were investigated; 1) working more than six days; and 2) outages longer than eight weeks.

The industry investigated the rule package assertion that individuals who work more than six days are causing fatigue induced errors. The review looked at human performance events on each day of the shift cycle. The second review focused on human performance during an extended outage. A week-by-week review of human performance was conducted. Again, the results do not support the assertions in the rule package. These results were provided in a 48 page NEI letter to Michael Case, NRC, dated February 3, 2006.

The analysis included human performance measures routinely maintained by facilities. The data reviewed included:

- Human Performance Data (Index or Event)
- Industrial Safety Data (lost time, OSHA reportable, number of reports, and/or minor injuries)
- Number of Corrective Action Reports (e.g. Level A and Level B-the top two tiers)
- Mispositionings (Components Out of Position)
- Events reported in the Corrective Action Program
- Apparent Cause Reports
- Rework
- Schedule Adherence.

Many operating crews on 8-hour shift rotations have schedules that include seven days on a particular shift cycle. In some cases, with the addition of training days at the beginning of the cycle, a particular shift would work eight or nine days in a row. Human performance data was collected for each day of the shift week for a period of at least a year. Most cases analyzed had the same 7-day length for each shift rotation, day, evening, and midnight shifts. In these cases, data could be compared directly on a day-by-day basis. In the few cases where training added at the beginning of shifts affected the number of days in each rotation, the data was "normalized" to ensure valid comparison.

We emphasize that no adverse trend in crew performance beyond the sixth day was shown in any of the data reviewed. Actual industry data does not support the rule package contention that increased fatigue after the sixth day of work affects human performance.

The industry also conducted a review of human performance data related to working outages longer than eight weeks. This review looked for any human performance data that would indicate the adverse trend projected in the rule

package. This review did not look at the cause of the performance issue and trended all indicators. The same measures discussed above were evaluated. The data was analyzed for outages between five and thirteen weeks in length and the human performance indicators were evaluated on a week-by-week basis. In each outage evaluated, there was a clear downward trend in human performance errors as the outage progressed. Some data was reevaluated and normalized based on the hours worked during each week to see if the downward trend could be attributed to a decrease in work intensity. However, the data still showed a decrease in human performance error indicators as the outage progressed.

Human performance indicators did not show a negative trend during any outage evaluated. Actual data from power reactor outages does not support the rule package contention that fatigue is an issue for outages in which individuals work up to 72 hours per week for periods in excess of eight weeks.

III. Discussion of Layers of Work Control Limits

The rule has several "layers" of work control limits. The first "layer" addresses acute fatigue (from causes occurring within the past 24 hours). The combination of the first, second and third "layers" addresses cumulative fatigue (the increase in fatigue over consecutive sleep-wake periods resulting from inadequate rest) and the need for a recovery period. We believe that the third "layer" is unnecessary and is an administrative and potential operational burden

The first "layer" is that licensees shall control the work hours of covered individuals as follows:

> Except as permitted by waivers and exceptions, licensees shall ensure that any individual's work hours do not exceed the following limits:
>
> - 16 work hours in any 24-hour period
> - 26 work hours in any 48-hour period
> - 72 work hours in any 7-day period

A 10-hour break between successive work periods, or an 8-hour break between successive work periods when a break of less than 10 hours is necessary to accommodate a crew's scheduled transition between work schedules or shifts.

The second "layer" is a 34-hour break in any 9-calendar day period. This layer was added by the NRC staff during the public comment period on the proposed rule. As discussed below, it is established that a 34-hour break with two rest periods is fully restorative, eliminating the potential for cumulative fatigue.

The third "layer" sets a minimum number of days off. This layer was substituted for collective work hours by the NRC staff during the public comment period on the proposed rule. The requirement is specified as a minimum weekly average for 8-, 10-, and 12-hour shift durations. The requirements are for an average over the shift cycle of 6 weeks, 1 day for 8-hour shift, 2 days for 10-hour shift, and 2.5 days for 12-hour shift. Security personnel who are working 12-hour shift schedules shall have at least 3 days off per week, averaged over the shift cycle.

The rule also contains another requirement for reviews and corrective actions under the licensee's corrective action program. These requirements can be considered another "layer" of an average of 54 hours per week. Section 26.205 Work hours, requires the licensee to review the actual work hours and performance of individuals. At a minimum, this review must address:

- Individuals whose actual hours worked during the review period exceeded an average of 54 hours per week in any shift cycle.
- Individuals who were granted more than one waiver during the review period.
- Individuals who were assessed for fatigue.

The licensee must also record, trend, and correct, under the licensee's corrective action program, any problems identified in maintaining control of work hours consistent with the specific requirements and performance objectives of the rule.

The draft final language also adds an exception for outages from the requirements for minimum days off that would be required during normal operations. The exception would be allowed during the first 60 days of a unit outage, security outage, or increased threat condition. During these periods, the draft final language would require that individuals, other than security officers, have a minimum 3 days off in each successive (non-rolling) 15-day block of the outage. Security officers have a different requirement, 4 days off in each successive (non-rolling) 15-day block of the outage. There is no scientific evidence for the different number of days off. As discussed below, it is established that a 34-hour break with two rest periods is fully restorative, eliminating the potential for cumulative fatigue.

Justification of 34-Hour Break Requirement to Address Cumulative Fatigue

It has been established that a 34-hour break with two rest periods is fully restorative, eliminating the potential for cumulative fatigue. The Federal Motor Carrier Safety Administration (FMCSA) published on August 25, 2005 (*Federal Register*, Vol. 70, No. 164), its final rule governing hours of service for commercial

motor vehicle (CMV) drivers. The rule addresses requirements for driving, duty, and off-duty time; a recovery period, sleeper berth, and requirements for short-haul drivers. The rule allows a driver to be on duty for 60 hours in any seven consecutive days or 70 hours in any eight consecutive days. After the 60/70 hours of duty, a recovery period is required.

The rule is based on a 34-hour recovery period. FMCSA stated in the Statements of Consideration (*Federal Register*, Vol. 70, No. 164 / 50026) for the rule that "In adopting a 34-hour recovery period, FMCSA has taken into account the weekly accumulation of driving and on-duty time allowed during each 7- and 8-day period, the adequacy of the 34-hour recovery, the cost/benefit ratio, the overwhelming support of the 34-hour recovery by the transportation industry, including motor carriers and drivers, the long-term effect on driver health, and the overall safety aspects of retaining this provision. FMCSA is charged with creating minimum safety standards for CMV drivers under the Motor Carrier Safety Act of 1984 [49 U.S.C. 31136(a)]. The Agency is also required to consider the economic costs and benefits that the rule would impose on the trucking industry and the public [49 U.S.C. 31136(c)(2)(A) and 49 U.S.C. 31502(d)]. As a regulatory Agency, FMCSA must sift through general, and often conflicting, scientific data and attempt to apply it "in the real world." When considering previous studies cited in the 2003 rule in support of the 34-hour recovery period and subsequent studies cited in comments to the 2005 NPRM, the Agency determined that, in light of the scientific evidence, FMCSA's best judgment is that 34 hours provides a minimum amount of time for a majority of drivers to recover from any cumulative fatigue that might occur during any multi-day duty period." (Emphasis added.)

IV. Discussion of Impacts of New Outage Requirements

The requirement for 3 days off each in each successive (non-rolling) 15-day block of the outage requirement will discourage highly skilled and efficient construction mechanics from accepting employment offers from outside contractors hired by licensees during outages, because they can accept offers of employment on jobs at non-regulated facilities that afford them the opportunity to increase their earnings. The outage time-off requirements is only applicable for 60 days. If someone works two or more successive outages that start less than two weeks apart, the rule specifies that the "60-day clock" starts from the beginning of the first outage. After 60 days, a worker must adhere to the normal operation work hour limits of 48-52 hours per week.

This will be a significant impact on outage contractors and utility outage services personnel who go from outage to outage. After 60 consecutive days, an individual will be limited to 48-52 hours per week for a period of two weeks, at which point the

"60-day outage clock" will be reset and the individual may again work "outage hours" for another 60 days.

Potential unintended consequences of the NRC's proposed outage break requirements are as follows:

- Craft labor has become very difficult to obtain. There is a current and long term projected shortage of craft. In particular, Iron Workers, Welders, Carpenters, Mechanics, MOV Testers, RP Technicians, and Electricians. The short outages in nuclear don't attract the limited craft available, especially in the building trades.
- New working limits that make nuclear even less attractive will only compound the issue. It would be very unfortunate to have this initiative further compound the difficulty getting high quality craft.
- The quality of the work force working on our plants may be reduced.
- Unnecessary cost without a commensurate safety benefit will be higher for all areas due to additional personnel, more per diem, more in-processing, more people to train, more supervision required, incentives, etc. required to get the work done with more days off. NRC staff has not provided the public with an analysis of the regulatory or practical impact. We believe these costs may not pass a backfit test.

V. Recommendation

The NRC staff has not provided the public with an adequate scientific or regulatory basis for either of these proposed new requirements (e.g., the minimum number of days off per shift cycle or the requirement for the minimum number of days of each 15-day period during an outage). Further, the NRC staff has not provided the public with an analysis of the regulatory or practical impact of these proposed new requirements.

NEI recommends the revisions to Section 26.205 below that will:

- Address acute and cumulative fatigue
- Establish a clear, logical, and practical rule
- Establish the same requirements for normal operations and outages
- Establish the same requirement for all individuals subject to work hour controls
- Establish 34-hour recovery periods that are used by the Federal Motor Carrier Safety Administration and are based on scientific evidence

- Provide for reviews and corrective actions under the licensee's corrective action program

§ 26.205 Work hours.

(a) *Individuals subject to work hour controls.* Any individual who performs duties identified in § 26.4(a)(1) through (a)(5) shall be subject to the requirements of this section.

(b) *Calculating work hours.* For the purposes of this section, a licensee shall calculate the work hours of individuals who are subject to this section as the amount of time the individuals perform duties for the licensee. Except as permitted by paragraphs (b)(1) through (b)(5) of this section, the calculated work hours must include all time performing duties for the licensee, including all within-shift break times and rest periods during which there are no reasonable opportunities or accommodations appropriate for restorative sleep.

(1) Shift turnover. Licensees may exclude shift turnover from the calculation of an individual's work hours. Shift turnover includes only those activities that are necessary to safely transfer information and responsibilities between two or more individuals between shifts. Shift turnover activities may include, but are not limited to, discussions of the status of plant equipment, and the status of ongoing activities, such as extended tests of safety systems and components. Licensees may not exclude work hours worked during turnovers between individuals within a shift period due to rotations or relief within a shift. Activities that licensees may not exclude from work hours calculations also include, but are not limited to, shift holdovers to cover for late arrivals of incoming shift members; early arrivals of individuals for meetings, training, or pre-shift briefings for special evolutions; and holdovers for interviews needed for event investigations.

(2) Within-shift break and rest periods. Licensees may exclude from the calculation of an individual's work hours only that portion of a break or rest period during which there is a reasonable opportunity and accommodations for restorative sleep (e.g., a nap).

(3) Beginning or resuming duties subject to work hour controls. If an individual begins or resumes performing for the licensee any of the duties listed in § 26.4(a) during the calculation period, the licensee shall include in the calculation of the individual's work hours all work hours worked for the licensee, including hours worked performing duties that are not listed in § 26.4(a), and control the individual's work hours under the requirements of paragraph (d) of this section.

(4) Unannounced emergency preparedness exercises and drills. Licensees may exclude from the calculation of an individual's work hours the time the individual works unscheduled work hours for the purpose of participating in the actual conduct of an unannounced emergency preparedness exercise or drill.

(5) Incidental duties performed off site. Licensees may exclude from the calculation of an individual's work hours unscheduled work performed off site (e.g., technical assistance provided by telephone from an individual's home) provided the total duration of the work does not exceed a nominal 30 minutes during any single break period.

(c) *Work hours scheduling.* Licensees shall schedule the work hours of individuals who are subject to this section consistent with the objective of preventing impairment from fatigue due to the duration, frequency, or sequencing of successive shifts.

(d) *Work hour controls.* Licensees shall control the work hours of individuals who are subject to this section.

(1) Except as permitted in § 26.207, licensees shall ensure that any individual's work hours do not exceed the following limits:

(i) 16 work hours in any 24-hour period;

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

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

(2) Licensees shall ensure that individuals have, at a minimum, the rest breaks specified in this paragraph. For the purposes of this subpart, a break is defined as an interval of time that falls between successive work periods, during which the individual does not perform any duties for the licensee other than one period of shift turnover at either the beginning or end of a shift but not both. Except as permitted in § 26.207, licensees shall ensure that individuals have, at a minimum,—

(i) A 10-hour break between successive work periods or an 8-hour break between successive work periods when a break of less than 10 hours is necessary to accommodate a crew's scheduled transition between work schedules or shifts; and

(ii) A 34-hour break in any 9-day period.

(e) *Reviews.* Licensees shall evaluate the effectiveness of their control of work hours of individuals who are subject to this section. At a minimum, licensees shall conduct the reviews twice per calendar year. The two reviews need not cover periods of equal duration but must collectively cover the entire calendar year. If any plant or security system outages or increased threat conditions occurred since the licensee completed the most recent review, the licensee shall include in the review an evaluation of the control of work hours during the outages or increased threat conditions. Licensees shall complete the review within 30 days of the end of the review period. Licensees shall—

(1) Review the actual work hours and performance of individuals who are subject to this section for consistency with the requirements of § 26.205(c). At a minimum, this review must address—

(i) Individuals whose actual hours worked during the review period exceeded an average of 54 hours per week in any shift cycle while the individuals' work hours are subject to the requirements of § 26.205(d);

(ii) Individuals who were granted more than one waiver during the review period; and

(iii) Individuals who were assessed for fatigue under § 26.201 during the review period.

(2) Review individuals' hours worked and the waivers under which work was performed to evaluate staffing adequacy for all jobs subject to the work hour controls of this section;

(3) Document the methods used to conduct these reviews and the results of the reviews; and

(4) Record, trend, and correct, under the licensee's corrective action program, any problems identified in maintaining control of work hours consistent with the specific requirements and performance objectives of this part.

Comments on Draft 10 CFR Part 26

Changes to Proposed 10 CFR Part 26, Subpart K (Modified FFD Programs for Construction Sites)

NEI recommends the deletion of Subpart K. However, NEI recommends that NRC establish regulatory requirements for quality assurance (QA) and quality control (QC) personnel to be subject to random testing consistent with Part 26 requirements for operating plants.

NEI recommends the revision of 26.4 as follows:

> § 26.4 FFD program applicability to categories of individuals.
> (e) Any individual whose duties for the licensees and other entities in § 26.3(c) require him or her to perform quality assurance or quality control activities, as specified in Appendix B to part 50, at the location where the nuclear power plant will be constructed and operated shall be subject to an FFD program that meets all of the requirements of this part, except subpart I.

The final rule, if approved, would result in the full NRC fitness-for-duty program that is applied at operating plants to be imposed on a large segment of the construction workforce. We do not believe that this is necessary since there is no radiological hazard on construction sites before nuclear fuel is received. The requirement does not consider the licensee's quality assurance and quality control programs, the intensive NRC construction inspection program, and the detailed and rigorous plant start-up testing program. If imposed, the requirements would impose a substantial resource burden on the licensee with no clear commensurate safety benefit.

As part of prudent business and asset protection practices, licensees will have fitness-for-duty programs for drugs and alcohol on the construction sites. We do not believe such a program requires regulatory scrutiny as there is no impact on the public health and safety nor the common defense and security during the construction period prior to receipt of fuel. At a predetermined date prior to fuel receipt, a licensee would implement a "lockdown and secure" procedure. At which point, the NRC fitness-for-duty requirements for an operating plant would become effective and would be met.

The NRC staff rationale for Subpart K requirements presented at the November 7th public meeting is protecting the common defense and security during construction, and preventing potential impacts on public health and safety from errors during construction. Yet, there can be no impact on the common defense and security during construction until nuclear fuel arrives on the construction site. With regard

to any NRC staff concerns about the transmittal of sensitive information to unauthorized sources, there are other well established requirements for assuring that information is secured and not transmitted to unauthorized personnel.

The intensive quality assurance and control requirements including material certifications, the ITAAC Program which includes significant onsite inspection act ivies, and the full range of start-up testing ensures safety related systems, structures and components will function as designed.

The draft final rule language is not necessary or practical. For example, it would require several hundred workers to be employed solely for escorting and monitoring workers during the construction period. To ensure visiting and transient workers, such as delivery drivers and other construction workers are fit for work and are following procedures. QA and QC procedures together with the vast array of NRC construction inspection activities provide assurance that procedures are followed.

The current draft final rule language requires workers on systems, structures, and components (SSC) described in Safety Analysis Reports (SAR) to have drug and alcohol testing prior to initial construction site access, for cause, post accident, and as a follow-up for a rehabilitation program. It also requires a random test program or monitoring program and a behavior observation program. Since essentially all SSCs are described in the SAR and construction workers need to be able to work in numerous areas of the plant, the requirement would apply to the complete construction workforce.

The draft final rule language requires a very resource intensive and burdensome drug and alcohol testing program for all construction workers for the complete construction period with no commensurate decrease in risk to either the public health and safety or the common defense and security. We believe it is much more appropriate to use a conventional construction site program which our contractors use at their other construction projects.

Comments on Draft 10 CFR Part 26
Operating Plant Drug and Alcohol Testing

On December 20, 2005, NEI provided 57 pages of comments on the proposed requirements for operating power reactors. NRC has incorporated many of these comments which we feel has improved the rule. There are a number of comments which were not incorporated which we feel are significant enough to warrant further consideration before the rule is finalized. It is important to note that for operating reactors the program is now very effective with positive test rates of a fraction of one percent. The issues described below could actually lead to a decrease in program effectiveness, or cause licensees to incur significant costs with no commensurate increase in program effectiveness.

The draft final language for §26.31(d)(2)(i)(A) states: "Take reasonable steps to either conceal from the workforce that collections will be performed during a scheduled collection period or create the appearance that specimens are being collected during a portion of each day on at least 4 days in each calendar week at each site; and." Regarding the 4-day requirement, the industry commented "The proposed §26.31(d)(2)(i)(A) however takes from the unpredictability by very prescriptively requiring specimen collection at least four days in a calendar week. This would permit members of the work force to determine whether specimens must be collected during the later days of the week to be in compliance with the regulation." It actually decreases the effectiveness of the program. It also creates issues during weeks with significant holidays such as Thanksgiving, Christmas, and New Years Day. The industry recommends the 4-day requirement be deleted and that the rule read: "Take reasonable steps to conceal from the workforce that collections will be performed during a scheduled collection period."

The draft final language for §26.39(c) states: "The procedure must ensure that the review is conducted by more than one individual and that the individuals who conduct the review are not associated with the administration of the FFD program [see the description of fitness-for-duty (FFD) program personnel in § 26.4(g)]. The individuals who conduct the reviews may be management personnel." The industry's concern is that this is inconsistent with the review process required in 10 CFR 73.56(e) that does not require more than one individual. Since one of the stated goals of the Part 26 Rulemaking is "Improve consistency between FFD requirements and access authorization requirements established in 10 CFR 73.56, as supplemented by orders to nuclear power plant licensees dated January 7, 2003", and licensee review processes are the same for both FFD and Access Authorization the industry feels this is added burden with no justification and it is contrary to a stated goal of the rulemaking which the industry supports. The industry recommends the requirement be changed to "The procedure must ensure that the review is conducted by an individual not associated with the administration of the

FFD program [see the description of FFD program personnel in § 26.4(g)]. The individual who conducts the review may be member of management."

The draft final language for §26.63(c) states: "The licensee or other entity shall ensure that the suitable inquiry has been conducted, on a best effort basis, by questioning former employers, and the employer by whom the individual claims to have been employed on the day before he or she completes the employment history, if an employment history is required under § 26.61." In attempting to acknowledge that many outage contractor employees are hired the day of in-processing or one or two days prior, industry recommended "If the individual is hired within three business days from completion of the self disclosure the present employer need not be queried." Industry experience is that the query of the "employer by whom the individual claims to have been employed on the day before he or she completes the employment history" provides no useful information given the one day employment term. Likewise, employment for two or three days provides no useful information. The industry recommends the requirement be changed to require "The licensee or other entity shall conduct the suitable inquiry, on a best effort basis, by questioning both present and former employers. If the individual is hired within three business days from completion of the self disclosure the present employer need not be queried."

The draft final language for §26.69(e)(1) states: "If an individual leaves the FFD program in which a treatment and follow-up testing plan was required under paragraphs (b), (c), or (d) of this section, and is granted authorization by the same or another licensee or entity, the licensee or other entity who grants authorization to the individual shall ensure that any treatment and follow-up testing requirements are met, with accountability assumed by the granting licensee or other entity." The industry understands the need to ensure the follow-up testing is done to protect public health and safety. However, having the granting licensee or other entity ensure that treatment requirements are met, is a burden with no commensurate reduction in risk to public health and safety. This requirement would generally be applicable to outage workers who may be working on a site for as little as two or three weeks. The industry has already incorporated the ability to track follow-up testing from site to site into PADS. However, there is (practically speaking) no way to manage the treatment aspect of the requirement appropriately to affect the outcome being sought. The industry recommends the requirement be changed to "If an individual leaves the FFD program in which a treatment and follow-up testing plan was required under paragraphs (b), (c), or (d) of this section, and is granted authorization by the same or another licensee or entity, the licensee or other entity who grants authorization to the individual shall ensure that any follow-up testing requirements are met, with accountability assumed by the granting licensee or other entity."

The draft final language for §26.91(c)(2) states: "Assigns a unique number to each completed test, which the collector and donor can read before each test and which is printed on each copy of the test result." Many licensees have machines which assign a number only after the test, not before. The requirement to be able to read the number before the test would require many licensees to discard perfectly-good evidential breath testing devices (EBTs) and replace them with devices that meet the new and completely unnecessary requirement. The industry recommends the requirement be changed to "Assigns a unique number to each completed test that the collector and donor can read after each test."

The draft final language for evidential breath testing device (EBT) in §26.91(e) states:

"Quality assurance and quality control of EBTs:

1. Licensees and other entities shall implement the most recent version of the manufacturer's instructions for the use and care of the EBT consistently with the quality assurance plan submitted to NHTSA for the EBT, including performing external calibration checks no less frequently than at the intervals specified in the manufacturer's instructions.
2. When conducting external calibration checks, licensees and other entities shall use only calibration devices appearing on NHTSA's CPL for "Calibrating Units for Breath Alcohol Tests."
3. If an EBT fails an external check of calibration, the licensee or other entity shall take the EBT out of service. The EBT may not be used again for alcohol testing under this subpart until it is repaired and passes an external calibration check."
4. In order to ensure that confirmed positive alcohol test results are derived from an EBT that is calibrated, the licensee or other entity shall implement one of the following procedures:
    - If an EBT fails any external check of calibration, cancel every confirmed positive test result that was obtained using the EBT from any tests that were conducted after the EBT passed the last external calibration check; or
    - After every confirmed positive test result obtained from using an EBT, conduct an external check of calibration of the EBT in the presence of the donor. If the EBT fails the external calibration check, cancel the donor's test result and conduct another initial and confirmatory test on a different EBT as soon as practicable.

    (Subparagraphs (4) and (5) are not included as they are not pertinent to the issue.)"

Many manufacturers' instructions do not describe external calibration tests. Licensees believe if they are following manufacturers' instructions, that their action should be sufficient for compliance with regulation. If this requirement remains, licensees will be forced to discard perfectly-good EBTs and buy new EBTs only from manufacturers who have an external calibration test described in their instructions. The industry recommends the NRC rewrite 26.91(e) to require calibration as described in manufacturers' instructions.

The draft final language for §26.91(e)(4)(i) states: "If an EBT fails any external check of calibration, cancel every confirmed positive test result that was obtained using the EBT from any tests that were conducted after the EBT passed the last external calibration check; ..." This is very difficult or impossible because immediately after a positive test, licensees take action to deny access and impose sanctions up to and including termination of employment. These actions are taken rapidly to protect public health and safety and to protect the common defense and security. The ability to undo such actions is very limited. The NRC staff must prioritize the protection of public health and safety and the protection of the common defense and security against the rights of individuals. The industry recommends NRC delete §26.91(e)(4)(i) and leave the requirement as written in §26.91(e)(4)(ii).

The draft final language for §26.187 provides requirements for a Substance Abuse Expert (SAE). The draft final language for paragraph 26.189 (a)(5) mentions an MRO who is also an SAE. The industry believes 26.187 should clearly state that an MRO may also be an SAE as long as the SAE qualifications are met.

The draft final language for §26.189(c) states: "A determination of fitness that is conducted "for cause" must be conducted through face-to-face interaction between the subject individual and the professional making the determination. Electronic means of communication may not be used." The decision on the appropriate approach to this determination should be left to the professional making the determination. The draft final language for §26.189(a) provides extensive criteria for the qualifications of the professional that will make the determination. As in other parts of the rule, the professional would be expected to make that determination using techniques that are generally acceptable in the professional community. In many cases, this may require a face-to-face interview with the individual. However, there may be cases where this approach is not required. For example, if the ultimate issue is whether a certain psychoactive medication will prevent an individual from performing assigned duties, a clinical psychologist may be able to provide the needed determination without a face-to-face interaction. The industry believes the NRC is being unnecessarily prescriptive by dictating practice requirements for the professionals making the "for cause" determination. Further, the industry believes that a face-to-face interaction is not required when there is

"credible information that an individual is engaging in substance abuse" as stated in the draft final rule language in §26.31(c)(2). The industry recommends §26.189(c) be rewritten to state: "A determination of fitness that is conducted "for cause" in response to an individual's observed behavior or physical condition must be conducted through an interaction determined between the subject individual and the professional making the determination. The method of the interaction will be determined by the professional based on the specifics of the individual's behavior or condition."

Finally, the NRC has made significant changes to §26.168, *Blind Performance Testing*, and §26.169, *Reporting Results,* beyond the text published for comment in the *Federal Register*. These changes add significant burden to licensees with no discernible benefit to an improved FFD program. The changes are so extreme that there is concern about the ability to get the samples required.

§26.168(b) now requires: "Approximately 60 percent of the blind performance test samples submitted to the laboratory must be positive for one or more drugs or drug metabolites per sample ..." In the rule published for comment **it** was 15 percent and did not include metabolites. §26.168(b)(1) and §26.168(b)(2) were not included in the rule published for comment. They now require blind performance test samples that are positive for marijuana metabolite at least two times each quarter and blind performance test samples that are positive for cocaine instead of the required sample that is positive for PCP. §26.168(e) now requires blind samples each quarter that are appropriately adulterated, diluted, or substituted, in the amount of 20 percent of the specimens submitted that quarter or at least three samples per quarter (one each that is adulterated, diluted, or substituted), whichever is greater. In the rule published for comment, the requirement was for 5 percent. §26.168(g)(1) now requires "A negative blind performance test sample may not contain a measurable amount of a target drug analyte and must be certified by immunoassay and confirmatory testing." Previously, the proposed rule required that a negative sample may not contain the target drug analyte at a concentration greater that 10 percent of the confirmatory cutoff. §26.168(g)(2) now requires: "These samples must contain a measurable amount of the target drug or analyte in concentrations ranging between 150 and 200 percent of the initial cutoff values and be certified by immunoassay and confirmatory testing to contain one or more drug(s) or drug metabolite(s)." The proposed requirement was: "The drug or drug metabolite concentration in the sample must be at least 20 percent above the designated cutoff for either the initial drug test or the confirmatory drug test." §26.168(g)(3) was not in the proposed rule and now requires a blind sample for false negatives." §26.168(g)(4) has been changed significantly and now requires: "The adulterated blind performance test sample must have a pH of less than or equal to 2, or greater than or equal to 12, or a nitrite or other oxidant concentration equal to or greater than 500 mcg/mL, equal to or greater than 50 mcg/mL chromium (VI)-

equivalents, or a halogen concentration equal to or greater than the LOD. Blind performance test samples for other adulterants must have adulterant concentrations equal to or greater than (or equal to or less than, as appropriate) the initial cutoff levels used by the licensee's or other entity's HHS-certified laboratory." Previously, it required pH less than 2.75 or greater than 11.25, nitrite at least 20 percent above the cutoff, and concentration of an oxidant at a level sufficient to challenge a lab's ability to identify and confirm the oxidant. §26.168(g)(5) now requires: "The dilute blind performance test sample must contain a creatinine concentration that is equal to or greater than 5 mg/dL but less than 20 mg/dL, and the specific gravity must be greater than 1.0010 but less than 1.0030." The proposed rule had creatinine between 0 and 20mg/dL and specific gravity less than or equal to 1.0050 or between 1.0170 and 1.0230. §26.168(g)(6), 26.168(h)(3), and 26.168(i)(1)(2)(3) are all new, not being in the proposed rule.

§26.169(c) added a requirement for an invalid specimen. §26.169(c) inexplicably removed dilute specimens.

In summary, the changes to §26.168, *Blind Performance Testing* and §26.169, *Reporting Results,* are broad, not justified, and will add significant cost to implementation if they can be implemented at all. NEI recommends the NRC adopt the language that was published in August 2005 in the *Federal Register*. The industry found that language to be adequate.

From: Annette Vietti-Cook
To: Billie Champ; Evangeline Ngbea; Linda Mike; Sheila McKelvin
Date: 12/21/2006 5:07:19 PM
Subject: Fwd: Draft 10 CFR Part 26 Fitness-for-Duty

Another letter from NEI, EDO AA, copy to RF

Van, should this go on docket?

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