NUCLEAR ENERGY INSTITUTE

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VICE PRESIDENT, NUCLEAR OPERATIONS
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December 20, 2005

Secretary
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Attention: Rulemakings and Adjudications Staff

SUBJECT: Comments on Draft Fitness for Duty Rule, 10 CFR Part 26
(RIN 3150-AF12)

The Nuclear Energy Institute (NEI),[1] on behalf of the nuclear energy industry, submits the following response to the Nuclear Regulatory Commission in response to the request for public comments on the proposed rule amending 10 CFR Part 26, "Fitness for Duty Programs."[2] NEI submits these comments on Subpart I, the Work Hour portion of the rule. Separate comments are being submitted on the Drug and Alcohol portion of the rule. Detailed discussion of the industry's proposal is provided in the enclosure.

The industry supports most of the provisions of the work hour portion of this rule. Requirements for policies, procedures, training of all individuals, behavioral observation, and self-reporting of fatigue provide a sound foundation for fatigue management and will establish clarity, which is one of the rulemaking objectives. Codifying the proven individual work limits from Generic Letter 82-12 will eliminate any inconsistency in application of these limits.

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[1] NEI is the organization responsible for establishing unified industry policy on matters affecting the nuclear energy industry, including 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.

[2] 70 Fed. Reg. 50,442 (Aug. 26, 2005)

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The industry fully supports increasing the minimum break time from eight to ten hours. The industry believes that the 10-hour rest period is the most important improvement in the rule since it dramatically reduces the potential for cumulative fatigue. The industry also believes that the importance of this provision has been understated by the rule package.

New performance-based requirements in the rule will provide for effective licensee fatigue management programs in a complex work environment. The work hour scheduling guidance of Section 26.199(c) combined with recordkeeping, periodic reviews, and use of the corrective action program are important features of this rule.

The industry is concerned with the layering of new regulatory requirements in the proposed rule which prevent the management flexibility that the Commission directed as part of authorizing this rulemaking. The combination of fixed break requirements and cumulative work hour restrictions do not recognize the scheduling complexities facing this industry. There will be significant safety implications that have not been recognized in the rule package. For example, application of fixed break requirements could challenge the ability to restore inoperable equipment in a timely manner. The approach provided in the draft Subpart I will undermine the viability of eight hour shift rotations.

Following an extensive review of options and impacts, the industry is proposing an equally robust and more flexible approach to break requirements that will better accommodate eight to ten hour rotations, 12 hour rotations, and outage periods. Details of this proposal are provided in the enclosure.

The industry also believes that, with all the other rule provisions, cumulative fatigue is adequately addressed without the inclusion of cumulative work hour controls for any functional group except security. The adequacy of scheduling practices is better addressed in the performance-based requirements of this rule.

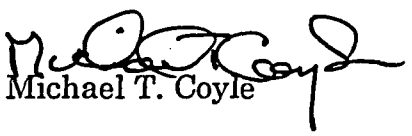
The backfit analysis provided in support of this rule is deficient. Although significant effort has been expended to estimate the cost, there is little meaningful discussion of the actual improvements in public health and safety. The relative importance of individual provisions is not addressed. The draft rule is very robust, with multiple features to address the potential for fatigue induced errors. Considering the rule as a whole, the industry believes that protection of public health and safety is not diminished if cumulative work hour limits are only applied to security personnel and a flexible approach is used for break requirements.

The industry believes that the changes proposed in the enclosure to this letter will result in an improved rule that will provide reasonable assurance against fatigue

induced errors. The changes also restore needed management flexibility, reduce the implementation burden, and eliminate many of the unintended consequences of the current draft rule.

If we can provide further information that would assist in resolving the concerns expressed in this letter, please contact me at mtc@nei.org or 202-739-8112; or Jim Davis at jwd@nei.org or 202-739-8105.

Sincerely,



Michael T. Coyle

Enclosure

Enclosure

Comments of the Nuclear Energy Institute on the Work Hour Portion of the Proposed Revision to 10 CFR Part 26, Fitness for Duty Requirements

Overview

The following comments are submitted by the Nuclear Energy Institute (NEI) on behalf of the nuclear industry, in response to the request for public comment on the Nuclear Regulatory Commission's (NRC) proposed rule amending 10 CFR Part 26, Fitness for Duty Programs.[1] Comments in this letter focus on the rule language in Subpart I, Managing Fatigue. NEI comments on the drug and alcohol portions of this draft rule are being submitted separately.

The industry supports managing fatigue and the appropriate use of work hour limits as part of an integrated program of fatigue management. For example, when there is a clear nexus with safety, the industry supports establishing consistent and appropriate limits on the hours worked by individuals in key functional groups. The work hour limits in this proposed rule are an extension of measures contained in NRC Generic Letter 82-12, which have been shown to be effective over the last 20 years. The industry recognizes that managing fatigue is a complex issue. Therefore, the industry endorses an integrated approach including performance-based regulation and use of defense-in-depth measures such as training, behavioral observation, self-declaration procedures, self assessment, and use of established corrective action programs. Such an integrated approach has been shown by scientific experts to be effective and appropriate in a variety of settings, including transportation, manufacturing, and electric generation.

The industry does not support several features of the draft rule, because these features are unnecessary, unsupported by scientific evidence, and untested in the workplace. Contrary to the integrated approach noted above (which is based on extending the measures in Generic Letter 82-12), these additional measures do not improve protection against fatigue beyond the protection already available in Generic Letter 82-12. These provisions, if implemented as proposed in the draft rule, will not result in a meaningful improvement in public health and safety, and will instead introduce restrictions on the ability to effectively schedule overall activities.

For example, the provision of a 24-hour break every seven days during normal operations will, by itself, challenge the future use of 8-hour shift rotations. An effective rule can be achieved by providing a more flexible approach to breaks than the requirements in the draft rule. Industry recommendations for modification

[1] 70 Fed. Reg. 50442 (Aug. 26, 2005)

include the removal of long-term limits on work hours for most functional groups, flexible break provisions, outage exemption extension, and reducing reporting requirements. The revisions proposed here by NEI will address significant unintended consequences, provide management flexibility needed to safely operate commercial nuclear reactors, and allow completion of outages in a manner that has been proven to be safe, timely, and cost effective.

The industry also has significant concerns with the supporting statements in the rule package and the quality of the regulatory analysis. The rule package should provide a more balanced discussion of the issues. Part of the challenge is in correlating available research findings to actual conditions and management approaches found in the power reactor industry. Many of the stated conclusions cannot be supported based on a review of actual plant human performance and other performance indicators of plant operational effectiveness.

The backfit analysis has serious deficiencies and does not provide the information needed to support a rational decision of the relationship between the projected burden and the benefit in improved public health and safety. Extensive effort was expended to develop the cost model that shows a continuing burden for each facility of at least $1.3 million per year. However, the "qualitative" statement that each element will provide substantial improvement in public health and safety is not supported by facts. The relative impact of individual provisions of the rule have not been adequately considered in relationship to rule, taken as a whole. Ultimately, the backfit analysis does not meet the intent of 10 CFR 50.109.

Implementation

In evaluating implementation issues, the industry has considered both the drug and alcohol portions and the work hour portions of the rule. Considering the significant changes involved in this rule, the industry believes that 12 months will be required for implementation of a majority of the new requirements once the final rule is published in the Federal Register.

The time period is driven by the need to modify or develop policies and procedures, put those procedures in place, and conduct the training on the new processes. Changes in the drug and alcohol program will also require significant effort to implement the new testing requirements, change contracts with supporting laboratories and, in some cases, acquire new analysis equipment.

There are several provisions of the rule that warrant special consideration. The industry supports the two year implementation time included in the draft rule to achieve the required qualification for the Medical Review Officer and the Substance Abuse Expert. The draft rule provides additional training criteria for individuals covered by the scope of the rule. Training procedures and testing practices can be

revised to meet rule requirements within the 1-year implementation time frame. For individuals who have current unescorted access, training on the new requirements should be conducted during the annual training update. Licensees should be allowed 18 months to complete all training required by the rule.

Several issues should be addressed in the final rule package to support the orderly implementation process.

- Most licensees have work hour limits contained in Technical Specifications. There needs to be an orderly process for removing these commitments from the Technical Specifications.
- The process for canceling the security work hour order should be addressed.
- There are portions of the access authorization order that may conflict with or differ slightly in wording from the revised 10 CFR Part 26. It is essential that continuity be maintained in the processing of individuals for unescorted access at power reactor sites. It should be clear that the rule provisions replace any conflicting order requirements.

As discussed in SECY-05-0074, the industry will prepare implementation guidance for 10 CFR Part 26.[2] This guidance will be submitted to the NRC for endorsement. To support the 12-month implementation period guidance needs to be finalized and endorsed within three months of the final rule being published in the Federal Register.

Current industry guidance for processing individuals for unescorted access authorization is contained in NEI 03-01 Revision 1, *Nuclear Power Plant Access Authorization Program,* which has been endorsed by the NRC as an acceptable approach for implementing the requirements of 10 CFR Part 26 as well as other related Regulations and Orders. This guide will be updated to reflect the changes in the drug and alcohol portions of 10 CFR Part 26, principally seen in Subparts B, C and D of the rule.

On September 22, 2005, the NRC hosted a public meeting to discuss areas where implementation guidance would be needed for the proposed Subpart I. During this meeting, there was general agreement on areas that needed to be addressed in an implementation guide. Based on that discussion, the industry is prepared to develop a separate implementation guide for fatigue management criteria contained in Subpart I of the rule. An outline of the draft guide will be provided in mid-January 2006 to support public meetings to discuss guidance details.

[2] SECY-05-0074, April 28, 2005, Page 6.

Supporting Material

The remainder of the NEI comments provides the following information:

Section 1 Discusses the areas of the proposed rule that the industry supports. We placed this discussion first because the supported elements provide the foundation for a very robust program for managing fatigue.

Section 2 Discusses the basis for the industry-recommended changes to Subpart I of the proposed rule, with specific focus on the layering of requirements, plant human performance data review, and 10-hour break requirement.

Section 3 Discusses the specific changes to Subpart I that the industry believes would significantly improve the proposed rule, and the basis for these proposed revisions.

Section 4 Provides comments on the rule package provided in the Federal Register Notice. This discussion supports the changes recommended in Section 2 and 3 of this comment letter.

Section 5 Provides additional comments on the regulatory analysis and backfit analysis provided in Attachment 4 to SECY-05-0074 (April 28, 2005). There are serious deficiencies in this analysis that need to be addressed before it meets the intent of 10 CFR 50.109.

Section 6 Responds to specific questions contained in Section VII of the Federal Register notice[3].

Section 7 Provides observations from the Department of Transportation, Federal Motor Carrier Safety Administration's (FMCSA) final rule on Hours of Service of Drivers.[4] FMCSA conclusions on chronic fatigue management are significantly different from those in the NRC Fitness for Duty rule package, yet both rule packages relied heavily on studies conducted in the transportation arena.

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[3] 70 Fed. Reg. 50,616 (Aug. 26, 2005).
[4] 70 Fed. Reg. 49,978 (Aug. 25, 2005)

Section 1
Industry supported rule provisions

The industry supports most of the provisions designed to address fatigue in the proposed amendments of 10 CFR Part 26. The supported provisions clarify Commission expectations for fatigue management and will address concerns with the different approaches used to implement the policies in Generic Letter 82-12. Licensees, in general, already have effective fatigue management programs, as seen in over 20 years of industry performance. This performance has been acknowledged by the NRC staff in public meetings, Commission statements and the rule package. The rule will codify the requirements of Generic Letter 82-12, which has been shown to provide a reasonable level of assurance against fatigue induced errors. The industry also supports a number of new provisions that will improve the effectiveness of the program and introduce elements of performance-based regulation.

1.1 Background

Over the last 20 years, the nuclear industry has made remarkable strides in the safety and reliability of U.S. nuclear plants.

As directed by the Commission, NRC licensees implemented the provisions of Generic Letter 82-12, in most cases, through changes to Technical Specifications that made specific commitments to work hour limits. A small number of facilities, with NRC approval, included their commitment in site procedures. Each of these commitments was specifically approved by the NRC staff. The fact that there are differences in the commitments made by licensees is the result of the regulatory process in effect at the time. Such differences are not evidence of a general industry failing as some have claimed in public meetings.

At the start of public discussion on work hours the industry believed that a consistent approach to work hour limits could be achieved through clarification of Generic Letter 82-12 requirements. However, after hearing widely differing views on what provisions were needed, the industry recognized that rulemaking would be the best approach to achieving the clarity and regulatory stability needed in this area. In August 2001, the industry recommended the following approach to the Commission:

> "We request that the Commission consider rulemaking that would lead to a performance-based approach to preventing fatigue-induced errors. Specifically:

- Modify 10 CFR Part 26, clarifying the guidance currently contained in Generic Letter 82-12 with the goal of achieving consistent application throughout the industry.
- Retain the current work hour guidelines as the point at which proactive management attention to the potential for fatigue is required.
- Work with the industry and other stakeholders to establish performance monitoring that improves the assessment of fatigue as a factor contributing to events.
- Require worker and supervisor training on recognizing and managing fatigue."[5]

The industry still believes that these remain as goals for this rulemaking effort. Indeed, expert scientific opinion agrees that hours of service regulations, management attention, assessment of fatigue and training and education are important elements in any program to manage or regulate the risk caused by fatigue.[6] Each of the four provisions are included in the draft Subpart I.

1.2 General Provisions that Mitigate Fatigue

The Work Hour portion of the proposed amendments to the NRC Fitness for Duty rule was developed independent of the drug and alcohol portion of the rule. As a result, a number of the overall fitness for duty provisions are not adequately credited in evaluating fatigue mitigation. The industry believes that other provisions in the proposed rule as a whole must be considered in determining which fatigue provisions of Subpart I are really needed to provide reasonable assurance of protection of public health and safety.

The following rule provisions will be effective in ensuring a work force that is fit to perform assigned duties. These general provisions also provide the clarity of requirements needed for consistent application across the industry.

In Subpart B the Fitness for Duty rule establishes clear expectations that every individual who works in the protected area of a nuclear reactor facility is required to be fit-for-duty. This applies to everyone in the protected area, not just the functional groups of proposed section 26.199(a). If an individual is not fit-for-duty, from any cause, including fatigue, then the individual, the supervisor, and ultimately the licensee would be expected to take action. The rule requirements and training requirements clearly establish the expectation that individuals will be "fit" and able to perform their duties.

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[5] Letter from NEI, Ralph Beedle to NRC, Chairman Richard Meserve dated Aug. 17, 2001.
[6] Dr. Mark R. Rosekind, Fitness for Duty Managing Fatigue and Safety in 24/7 Operational Settings, December, 2005.

Proposed Section 26.197(a) and (b) require a robust set of policies and procedures that provide for effective fatigue management and clear performance expectations. Setting clear expectations for individuals to self-declare and establishing a process for dealing with the potential for fatigue are key features of the proposed revision to 10 CFR Part 26. Most policy provisions will apply to all individuals in the protected area. Policy and procedure provisions from Section 26.27 also require addressing other factors that could affect fitness, including the individual's responsibility to report fitness concerns and the process for handling fitness concerns.

Proposed Section 26.197(c) requires supplementing the training of Section 26.29(a) to train all individuals with unescorted access on contributors to fatigue, the effects of fatigue, symptoms of fatigue, strategies for getting adequate rest, and other fatigue countermeasures. Training also covers policies and procedures, the ability to detect performance degradation and responsibilities to report fitness for duty issues. In addition to the two knowledge and abilities (KAs) listed in proposed Section 26.197(c), there are two additional KAs in Section 126.29(a) that have direct applicability to fatigue management.

The behavioral observation program discussed in Section26.33 provides for detection and correction of fitness issues from any cause. This would include potential fatigue issues and signs that an individual was not attentive.

Proposed Section 26.197(b)(1) and proposed section 26.19(e) provide a detailed process for individuals to self-report when they are not fit to perform their duties due to fatigue. Supervisor evaluation of individuals for potential fatigue is also required when there is a self-declaration or prior to granting waivers of individual limits.

1.3 Work Hour Controls

For the individuals specified in proposed Section10 CFR 26.199(a), the application of updated individual limits from Generic Letter 82-12 is supported. These limits are effective in preventing both acute and cumulative fatigue. These limits, from proposed Section 26.199(d)(1) and (d)(2)(i), include:

- Individual limit of working no more than 16 hours in a 24-hour period
- Individual limit of working no more than 26 hours in a 48-hour period
- Individual limit of working no more than 72 hours in any 7-day period
- A minimum break of 10 hours between work periods

The rule provides needed clarity of these requirements for consistent application across the industry.[7] **The increase from eight to ten hours is the most**

[7] 70 Fed. Reg. 50,667 (Aug. 26, 2005)

significant change in this rule to prevent the buildup of cumulative fatigue.

The change from the 8-hour break allowed by Generic Letter 82-12 to the 10-hour break in the draft rule significantly reduces the possibility of the accumulation of a sleep debt during a short duration heavy work period. It should also be clear that the normal break in the industry is at least 12 hours. Other individual limits preclude working a series of work periods with only a 10-hour break between work periods.

In his 2005 white paper, Dr. Rosekind confirms that the 10 hour break provides "sufficient sleep opportunity to meet an individual's sleep requirement and minimize or eliminate any acute sleep loss. Obviously, when the break period provides even more time off, such as 12 or 16 hrs of off-duty time, this creates an even greater buffer to minimize or eliminate any acute sleep loss. Therefore, acute sleep loss can be eliminated or significantly minimized by providing a sleep opportunity sufficient for an individual to meet their sleep need on a daily basis."[8]

1.4 Performance-Based Provisions

The addition of a performance-based requirement in proposed Section 26.199(c), which requires that routine schedules be structured in a manner to prevent fatigue impairment, is particularly notable. The importance of this provision is not adequately credited in the rule package.

The requirement in proposed Section 26.197(d) for licensees to maintain records combined with the reviews required in Section 26.199(j), provide an additional strong performance-based provision to the rule. These reviews and, where necessary, action under the Corrective Action Program, provide additional assurance that performance expectations are met. It also offers an opportunity to evaluate schedule adherence as on of the performance expectations.

[8] Rosekind, page 7.

Section 2
Basis for Industry Recommendations

The industry believes that several changes to the draft Fitness for Duty rule are warranted based on the multiple layers of requirements, a review of plant performance data, and the new 10-hour break requirement. Each of these is discussed below and recommended revised wording for proposed changes is provided in Section 3 of this letter. Specifically, the industry is proposing more flexible break requirements and does not find a need for long-term limits of any functional group other than Security.

Given the integration of aspects of the rule supported by the industry (as discussed in Section 1, above), the demonstrated record of improving industry performance, and the fact that the operating record indicates no significant events attributable to fatigue under the generally effective implementation of the provisions of Generic Letter 82-12, we submit that it is imprudent to add provisions and restrictions beyond what has generally been proven successful. There are several provisions of the proposed rule that add layers of limitations that are a significant burden to the industry, exceed the stated intentions of the rule, go far beyond the industry's recommendations in 2001, and are unnecessary to achieve reasonable assurance that fatigue will not cause adverse events. Some of the added provisions will clearly cause negligible improvement in safety and are not scientifically supported. In the aggregate, the added provisions are unreasonably burdensome to implement, to the point that 8-hour shift rotations will be challenged, and licensees' ability to conduct work important to safety will be impaired. Beyond the above objections, the additional untested provisions introduce the probability of unintended consequences.

When reviewed in the context of the other draft Fitness for Duty rule provisions and the need for management flexibility, the industry believes that there is an acceptable alternative to the break requirements of 26.199(d)(2)(ii) and (iii). The fatigue mitigation measures in Subpart I as a whole, including short term limits, break requirements, and performance-based provisions, will fully address cumulative fatigue. Cumulative work hour limits for any functional group, other than security, provide marginal improvement in public health and safety and are not warranted based on the burden imposed.

We believe these added requirements will result in challenges to the safe operation of the plant that have not been adequately considered in the rule package. To achieve the appropriate balance, the industry believes that the recommended changes are needed.

2.1 Layering of the Rule

The impact of this rule on the nuclear industry is significantly heightened by the "layering" of new requirements. In our view, the rule packages has not adequately accounted for this cumulative impact in the regulatory analysis or in other discussions of the rule. Public meeting discussion of the Part 26 amendments tended to address rule sections one requirement at a time without adequately considering each proposed provision in the overall context of the rule. The rule package justification also fails to address the cumulative impact with the review of elements one at a time, section by section. Even though some provisions may seem to be reasonable when viewed in isolation, they become unnecessary regulatory burdens and significant implementation problems when combined with other existing and proposed new limits.

In this regard, two issues must be considered. First, in some instances, provisions that appear to be reasonable when viewed in isolation, are, in fact, highly restrictive when considered in the context of other rule provisions. Second, the rule package appears to overstate the effect of many individual fatigue-related provisions by the repeated claim that each will significantly increase protection of public health and safety. Making the same claim repeatedly throughout the rule package for each new fatigue provision does not appear to consider the collective impact of the rest of the rule. When considered in the context of other rule provisions, some proposed elements will provide marginal or no gain in safety at a very high cost. In some cases the unintended consequences of the provision may include a genuine negative safety impact.

The scientific opinion on how to handle the complexity of fatigue is substantially different than the proposed layering approach we take issue with. Instead of handling the complexity of fatigue by adding ever more restrictive rules, the practicality of historical precedent, especially in high-performing industries, and the mutual economic goals of worker and manager provide a stable environment which should not be arbitrarily disturbed.

New proposed rule provisions should be discussed in context of the rest of the rule. Every individual in the protected area is expected to be fit to perform his or her duties. The rule contains several provisions that address the potential for fatigue, including:

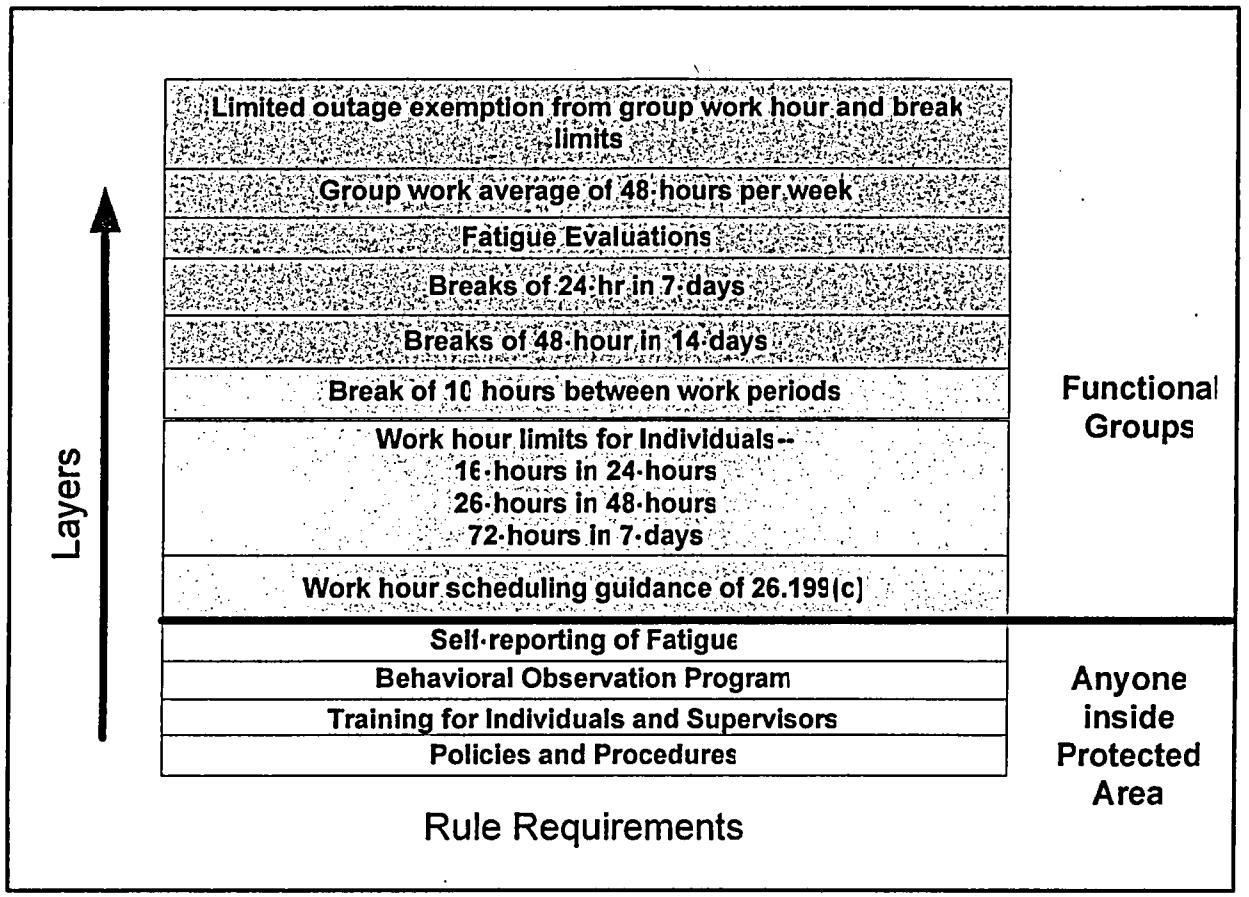
- Well-defined policies and procedures that set expectations and process.
- Training of all individuals who have access to the plant on the key techniques for recognizing and managing the potential for fatigue.
- A behavioral observation program that goes beyond drug and alcohol issues and addresses the general area of fitness.

- Self-reporting, when combined with behavioral observation, provides another level of protection against fatigue-affected performance from any cause.[9]

For the functional groups, short term individual limits in the proposed rule address elements of both acute fatigue and cumulative fatigue. The positive impact of this total set of limits on preventing cumulative fatigue has not been adequately credited. The layers in the following graph reveal the following:

- The Generic Letter 82-12 guidance for adequate manning is codified in proposed Section 26.199(c).
- The acute fatigue limits of 16/24, 26/48 and 72/7 have the effect of forcing breaks longer than the 10-hour minimum. A 12-hour break will be the norm.
- The minimum10-hour break provides reasonable assurance that there is no buildup of cumulative fatigue in the few cases where it would be used.
- While the industry agrees that break requirements are necessary, the 48-hour/14 day and 24-hour/7 day provisions would undermine the viability of 8-hour shift rotations, constrain scheduling flexibility, and potentially have adverse safety impacts. In addition, the need for restorative rest periods (given the daily 10 hour break, an 8 hour sleep opportunity) is scientifically shown to be completely unnecessary for periods of continuous duty days of up to at least 14 days (Van Dongen, H. P., Maislin, G., Mullington, J. M., & Dinges, D. F. (2003). The cumulative cost of additional wakefulness: dose-response effects on neurobehavioral functions and sleep physiology from chronic sleep restriction and total sleep deprivation. Sleep, 26(2), 117-26.)
- Finally, collective work hour controls have been added to address chronic fatigue. However, other proposed rule provisions provide reasonable assurance that there will not be a chronic fatigue issue.

[9] As believed by many in the industry and acknowledged in both the NRC and DOT rulemaking packages, off-duty activities likely play a more important role in sleep deprivation than hours worked. Therefore, the training and observation parts of the rule are necessary to help mitigate these potential causes.



Adding it up, there are multiple layers of proposed requirements in the rule that address the potential for chronic fatigue. In our view, some of the most burdensome of these should be removed. The effect of these revisions would be to significantly reduce the impact on the industry without reducing the reasonable assurance needed to protect public health and safety. There is no need for both break requirements and collective work hour controls. One of the two should be eliminated from the proposed rule. The industry proposes eliminating the collective work hour controls and providing a more flexible set of break requirements.

If rule provisions are followed, it would be very difficult to assign teams in a manner that provides for 24-hour coverage to complete critical maintenance or restore inoperable safety equipment. Thus, the addition of breaks as proposed in the rule will likely result in longer outage times, which results in a significant financial impact to the industry with no benefit to safety.

The artificial limits placed on outages are a direct consequence of the application of long term limits, whether there is a fatigue issue or not. During public discussions of the proposed rule, the industry attempted to emphasize the impact these limits will have on the ability to attract and retain supplemental workers needed during outages. We are concerned that the rule package does not acknowledge this

significant problem. It is difficult to understand how we can claim to be promoting safety with an approach that forces a high worker turnover rate and reduces the pool of experienced workers. Both provide a direct challenge to maintaining the high skill required by this industry.

The proposed rule break requirements will interfere with the "two super crew" concept for outage manning, in which individuals assigned to either day or night shift for the duration of the outage. A predictable work schedule of six-12 hour shifts per work week has some features that promote safety and reduce the potential for fatigue.

- Circadian rhythm issues are reduced by staying on one cycle for the duration. A variety of studies show the circadian factors far outweigh any cumulative fatigue variations that are being discussed in this rulemaking.
- The consistent cycle improves the effective use of the 12-hour rest break, so that it provides the opportunity for the 7 to 8 hours sleep that is needed.
- The elimination of a "cold" crew turnover (where all individuals have been away from the plant for several days) significantly reduces the potential for errors. About 80% of the relieving crew was present 12 hours before and only need to be updated on recent plant changes.
- Many reports from the field, indicate that a 2-day break during the night shift would generate more problems as people would have to readjust as they transition back onto the shift.

When all the layered provisions of this rule are considered, those workers on 8-hour shifts are at a significant disadvantage because credit is not given for the fact that there will be 16 hours between work periods. With fewer days off, even though the hours per week are the same, the layered provisions become unnecessarily restrictive and will tend to preclude 8-hour shift scheduling.

2.2 Plant Human Performance Data Review

Actual plant performance does not justify some of the rule provisions.

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 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."[10] In individual vote sheets on this rulemaking, Commissioners also recognized that there were few events in the industry.[11] The industry conducted a review of all significant events over an 8-year

[10] SECY-01-0113, Page 3 (June 22, 2001)
[11] SRM-SECY-01-0113 (January 8, 2002)

period and found that none of the events reviewed were attributed to fatigue as a cause.[12] These facts show that there is no need to significantly expand fatigue provisions beyond those contained in Generic Letter 82-12.

The results of the industry study were dismissed by some 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, working more than six days and 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.

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

- Human Performance Data (Index or Event)
- Industry 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 8 or 9 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.

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[12] INPO letter to NEI Ralph Beedle (January 27, 2000)

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 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 8 weeks.

2.3 10-hour break mitigates cumulative fatigue

The 10-hour rest period is the most important proposed improvement in the rule to address the potential for cumulative fatigue. It is widely accepted that cumulative fatigue will not build up if an individual gets the 7 to 8 hours of sleep that is needed each day. This amount of sleep is afforded by the 10-hour minimum break period.

During the NRC sponsored public meetings on this rulemaking, a number of professional sleep experts provided their perspective on the various rule provisions. There was agreement in only one area: that adequate sleep opportunity, not hours worked, is the key factor in chronic or cumulative fatigue. Exerts also agreed that a minimum 10-hour break was needed, not an 8-hour break, because of turnover time and travel.

The industry has fully supported the change from an 8-hour minimum break period to a 10-hour break period, to ensure that cumulative fatigue would not become an issue, even during the periods of an outage.

The rule package frequently refers to the 10-hour break as if it would be used on recurring days over some period of time. This is not possible. As a practical matter most breaks will be at least 12 hours. The individual limit of 26 hours in 48 hours will force a minimum of a 12-hour break the day before and the day after any 10-hour break. The 72-hour limit in 7 days also prevents long term use of 10-hour breaks.

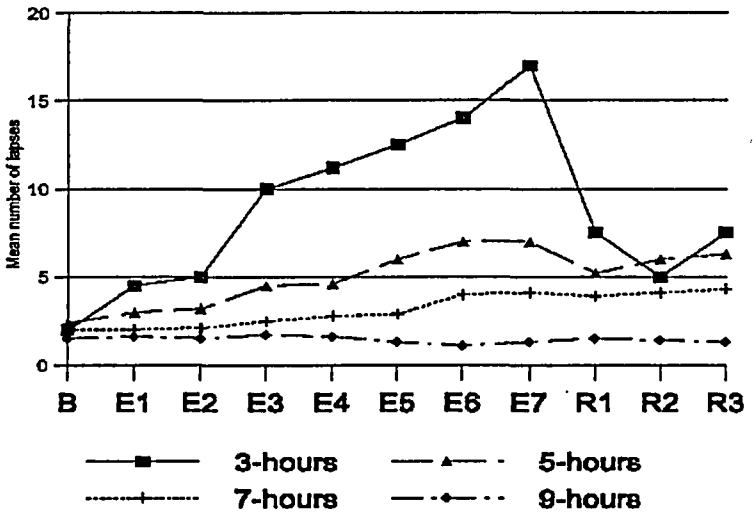
The scientific opinion on this matter has been summarized by Dr. Rosekind:

> "As previously discussed, this 10-hour break provides an 8 hr sleep opportunity and time for other personal needs ("daily living obligations"). This 8 hr sleep opportunity should be adequate for an individual to meet their daily sleep requirement and not create any acute sleep loss. *By definition, if there is no acute sleep loss, there will be no cumulative sleep debt...*
> "The proposed NRC rule also includes work hour limitations as follows: up to 16 hrs in any 24-hour period, 26 hours in a 48-hour period and 72 hours in a 7-day period [(26.199(d)(1)]. These work hour limits create further protection against acute sleep loss and cumulative sleep debt by creating scheduling scenarios that will both limit work hours and enforce sufficiently long break periods to obtain adequate sleep"[13]

The rule package, Attachment 4, Addendum 1, provides data from a Belenky study performed in 2003. The rule package states "...use of the Belenky study in this analysis is expected to be a reasonable estimate of the performance improvement of mitigated fatigue in the nuclear power industry." Figure 2-1(included below) from that study shows that individuals with a 9-hour rest remained at the baseline level of performance. The normal 12-hour break provides that rest opportunity.

[13] Rosekind

Figure 2-1
Sleepiness and Sleep Deprivation
(From Belenky, 2003)



The U. S. Department of Transportation (DOT) recently issued a work hour rule[14] based upon extensive research in the transportation industry. The rule provides for:

- A 14-hour work period, of which 11 hours may be driving.
- A 10-hour break between work periods.
- A limit of 60 hours in 7 days or 70 hours in 8 days.
- A break of 34-hours between 7 or 8 day periods.
- A 34-hour break resets the clock on hours worked.

The DOT rule package makes a strong case that the 10-hour break provides adequate rest to prevent the buildup of cumulative fatigue.[15] The 34-hour break was found to be adequate to provide rest and personal time. Note that during an outage in the nuclear industry, working six 12-hour shifts a plant worker gets a 36-hour break every seven days.

The industry has been concerned that transportation studies, based solely on hours of driving for long-haul truckers, may not have a direct correlation to power reactor workers. The industry belief that significantly different results would be achieved for individuals engaged in a variety of activities is supported in a DOT finding that, on a per-mile basis, long-haul trucks are almost 20 times more likely to be involved in a fatigue-related crash when compared to short-haul drivers. One study suggested that factor in this statistical imbalance is the variety of work short-haul drivers typically perform; variety seems to minimize fatigue.

[14] 70 Fed. Reg. 49,978 (Aug. 25, 2005)
[15] 70 Fed. Reg. 49,992 (Aug. 25, 2005)

In the NRC's Fitness for Duty rule package, much of the same background material is used as that for the DOT rule, yet much more conservative conclusions are drawn. For example, a trucker can drive more than 60 hours a week continuously, yet the NRC rule package cites examples of individuals who needed to work 60 hours a week for some period as fatigued, justification for the rule requirements.

2.4 Periodic Break Requirements

The need for intense levels of effort during on-line maintenance and outage at nuclear reactors has been a complicating factor in this rulemaking. Other sectors with work hour controls, such as the airline and transportation industries, do not need to address these issues. In referencing rule requirements from other sectors as justification for some restrictive measures, the NRC rule package fails to recognize the real world needs of the nuclear industry.

The resulting rule package break requirements have been assessed by Dr. Rosekind as follows: "...artificially requiring a 24 hr break every 7 days or a 48 hr break every 14 days is completely arbitrary and there is no scientific justification to support these specific numbers. In fact, they are contrary to scientific data, the schedules portrayed, the effectiveness of the 10 hr break and work hour limits included in the proposed NRC rule [26.199(d)(2)(i)]."

The industry recommends that the recovery concept is scientifically supported, and that some form of periodic recovery break requirements should be included as a defense-in-depth measure against cumulative fatigue. However, the approach should take into account existing work schedules and scheduling practices, and there is no scientific basis for linking recovery breaks to any particular number of days less than, say, 14 consecutive days.

There is no simple scheme of prescriptive limits that addresses the cyclical nature of the work load in this industry. An intense effort is required when equipment requires maintenance or during outage. There is a negative safety impact with longer out-of-service times when work is delayed because of work hour limits. The safest approach involves minimizing the out-of-service time.

Issue: There is a problem with the focus solely on days off when considering the 8-hour and 12-hour shift rotations.

A review of a typical Operations 12-hour and 8-hour rotation schedule demonstrates the industry's concerns.

1. **Basic parameters:**
    a. Operations crew schedule
    b. 24 hour per day coverage is required—either two 12-hour, or three 8-hour shifts
    c. 4 days of training per cycle—9 hour days
    d. 5 section rotation, results in the cycle repeating every 35 days
    e. Average weekly hours worked over cycle is between 40 and 41

2. **There are 10 days off for 8-hour rotation:**
    a. [35 (days in cycle) x 3 (shifts per day)]/5 sections = 21 (days per cycle)
    b. Days of training = 4 days per cycle
    c. Days off is 35 (days in cycle) -21 (days per cycle of watch)-4 (days of training) = 10 days off per cycle

3. **There are 17 days off for 12-hour rotation:**
    a. [35 (days in cycle) x 2 (shifts per day)]/5 sections = 14 (Days per cycle)
    b. Days of training = 4 days per cycle
    c. Days off is 35 (days in cycle) -14 (days per cycle of watch)-4 (days of training) = 17 days off per cycle

A single approach to break requirements that focuses only on days off will generate reduced flexibility for the 8-hour rotation when compared to the 12-hour rotation.

Regardless of how work shifts are split, there are not enough days off in an 8 hour cycle to allow rational application of the proposed limits in Subpart I. The 24/7 and 48/14 breaks require an individual to have at least three days off every 14 days. Thus, over the 35 day cycle the absolute minimum time would be 7.5 days off in a 35 day cycle (5 weeks). Actually, there would be eight days off in one cycle and seven days off in the next cycle. Both the 8-hour shift rotation schedule and the 12-hour shift rotation schedule allow for greater than seven days off during the 35 day cycle and thereby afford ample opportunities for rest.

Additionally, none of the 8-hour rotation schedules reviewed would meet the current 24/7 and 48/14 criteria. One option considered by the industry was averaging the requirements over a four week period. Even with that approach, schedules would provide no flexibility. One day of overtime at certain periods of the cycle would violate the break requirements.

With the industry's proposed break requirements of an average of one day off over a cycle for 8-hour shifts and two days off over a cycle for 12-hour shifts, the flexibility in the schedule is seven days on 12 hour shifts and five days on 8-hour shifts over a 5 week period:

1. **12-hour rotation.**
    a. Required breaks 2 (days per week) x 5 (weeks per cycle) = 10 Days per cycle.
    b. Actual scheduled days off = 17 days
    c. Flexibility 17 – 10 = 7 days.
2. **8-hour rotation.**
    a. Required breaks 1 (day per week) x 5 (weeks per cycle) = 5 Days per cycle.
    b. Actual scheduled days off = 10
    c. Flexibility 10 – 5 = 5 days.

A similar calculation for an 8-hour, 6 section crew rotation would provide 6 days flexibility in a 42 day cycle.

The actual schedule used by licensees also considers the goals of providing at least one long break during a rotation cycle and conduct of training during the Monday through Friday period.

The following examples show schedules that would be consistent with the industry's break recommendations.

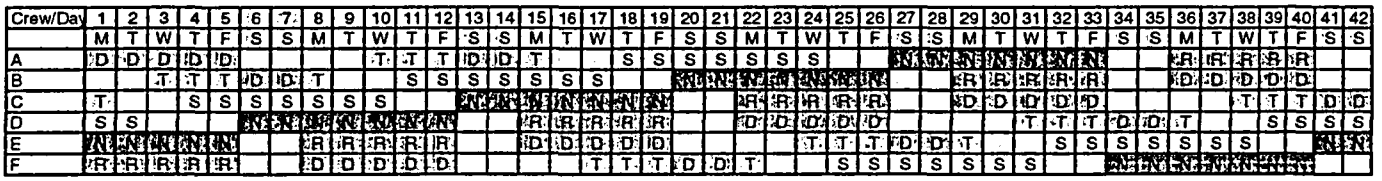
Operations Department—5 crew rotation, 12 hour shifts, 9 hour training

Crew/Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
A	T	T	T	T				D	D	D				N	N	N	N								D	D	D	D				N	N	N	
B	D	D	D				N	N	N	N								D	D	D	D				N	N	N		T	T	T	T			
C	N	N	N								D	D	D	D				N	N	N		T	T	T	T				D	D	D				N
D				D	D	D	D	D			N	N	N		T	T	T	T				D	D	D				N	N	N	N				
E				N	N	N		T	T	T	T				D	D	D				N	N	N	N								D	D	D	D

Operations Department—5 crew rotation, 8 hour shifts, 9 hour training

Crew/Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
A	D	D	D	D	D					T	T	T	D	D	T			S	S	S	S	S	S	S			N	N	N	N	N	N	N		
B			T	T	T	D	D	T			S	S	S	S	S	S	S	N	N	N	N	N	N	N	N	N			D	D	D	D	D		
C	T			S	S	S	S	S	S	S			N	N	N	N	N					D	D	D	D	D					T	T	T	T	D	D
D	S	S	S			N	N	N	N	N	N	N			D	D	D	D	D					T	T	T	D	D	T			S	S	S	S
E	N	N	N	N	N			D	D	D	D	D					T	T	T	D	D	T			S	S	S	S	S	S	S			N	N

Operations Department—6 crew rotation, 8 hour shifts, 9 hour training



Outage Manning—Super Crew, 12 hour shifts

Days	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28
	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
D1	D	D	D	D	D	D		D	D	D	D	D	D		D	D	D	D	D	D		D	D	D	D	D	D	
D2	D	D	D	D	D		D	D	D	D	D	D		D	D	D	D	D	D		D	D	D	D	D	D		D
D3	D	D	D	D		D	D	D	D	D	D		D	D	D	D	D	D		D	D	D	D	D	D		D	D
D4	D	D	D		D	D	D	D	D	D		D	D	D	D	D	D		D	D	D	D	D	D		D	D	D
D5	D	D		D	D	D	D	D	D		D	D	D	D	D	D		D	D	D	D	D	D		D	D	D	D
D6	D		D	D	D	D	D	D		D	D	D	D	D	D		D	D	D	D	D	D		D	D	D	D	D
D7		D	D	D	D	D	D		D	D	D	D	D	D		D	D	D	D	D	D		D	D	D	D	D	D
Night																												
N1	N	N	N	N	N	N		N	N	N	N	N	N		N	N	N	N	N	N		N	N	N	N	N	N	
N2	N	N	N	N	N		N	N	N	N	N	N		N	N	N	N	N	N		N	N	N	N	N	N		N
N3	N	N	N	N		N	N	N	N	N	N		N	N	N	N	N	N		N	N	N	N	N	N		N	N
N4	N	N	N		N	N	N	N	N	N		N	N	N	N	N	N		N	N	N	N	N	N		N	N	N
N5	N	N		N	N	N	N	N	N		N	N	N	N	N	N		N	N	N	N	N	N		N	N	N	N
N6	N		N	N	N	N	N	N		N	N	N	N	N	N		N	N	N	N	N	N		N	N	N	N	N
N7		N	N	N	N	N	N		N	N	N	N	N	N		N	N	N	N	N	N		N	N	N	N	N	N

In the super crew approach, there is maximum work continuity between shifts. In this approach, several crews are combined into two sections, one working 12-hour day shifts, and the other working 12-hour night shifts. Individuals are scheduled for 72 hours per week with each individual within the crew scheduled for a day off at least once every 7 days. The resulting 12 hour break between each shift allows adequate opportunity for sleep. Deviations from the schedule cannot be made without writing an waiver or providing time off before the individual works extra time. As shown below, the day off actually represents a 36 hour period that allows two sleep periods. An individual cannot be rotated from day to nights or nights to days after only a 24-hour break without violating the 72-hour per week limit.

Day	1		2		3		4	
Shift	Day	Night	Day	Night	Day	Night	Day	Night
Day Crew	Day		Day				Day	
Night Crew		Night		Night				Night

Issue: Maintenance Flexibility

In the nuclear industry, there is no standard schedule for maintenance personnel. Most maintenance personnel are scheduled for four 10-hour days or five 8-hour

days. However, a variety of schemes are used to provide needed coverage on backshifts and weekends.

Example 1: In the following example, the licensee schedules for 20 % maintenance coverage over each weekend. As a result, each individual would work one weekend in a five week period, while still getting two days off per week. This results in a 40 hour per week average.

Crew/Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
A	D	D	D	D	D	D	D			D	D	D			D	D	D	D	D			D	D	D	D	D			D	D	D	D	D		
B	D	D	D	D	D			D	D	D	D	D	D	D			D	D	D			D	D	D	D	D			D	D	D	D	D		
C	D	D	D	D	D			D	D	D	D	D			D	D	D	D	D	D	D			D	D	D			D	D	D	D	D		
D	D	D	D	D	D			D	D	D	D	D			D	D	D	D	D			D	D	D	D	D	D	D			D	D	D		
E			D	D	D			D	D	D	D	D			D	D	D	D	D			D	D	D	D	D			D	D	D	D	D	D	D

To meet the 24/7 and 48/14 requirements, the schedule would have to be changed. One approach would be to split the break around the weekend work period. The schedule would be as shown below.

Crew/Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
A	D	D	D	D		D	D		D	D	D	D			D	D	D	D	D			D	D	D	D	D			D	D	D	D	D		
B	D	D	D	D	D			D	D	D	D		D	D		D	D	D	D			D	D	D	D	D			D	D	D	D	D		
C	D	D	D	D	D			D	D	D	D	D			D	D	D	D		D	D		D	D	D	D			D	D	D	D	D		
D	D	D	D	D	D			D	D	D	D	D			D	D	D	D	D			D	D	D	D		D	D		D	D	D	D		
E		D	D	D	D			D	D	D	D	D			D	D	D	D	D			D	D	D	D	D			D	D	D	D		D	D

There are several possible concerns with this approach. The day off will generate turnover problems as a result of the Friday break since there will be no continuity between Friday and the weekend work. By splitting the break, the 48/14 limit becomes a problem the following weekend if there were any unplanned work. It is also unlikely that the work force would endorse this approach.

Another approach would be to only work each individual one day on a weekend. This would meet the 48/14 and 24/7 requirements but would require each individual to work some part of twice as many weekends, a much more disruptive schedule.

Crew/Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
A	D	D	D	D	D	D			D	D	D	D			D	D	D	D	D			D	D	D	D	D		D		D	D	D	D		
B		D	D	D	D		D		D	D	D	D			D	D	D	D	D			D	D	D	D	D			D	D	D	D	D	D	
C		D	D	D	D			D	D	D	D	D	D			D	D	D	D			D	D	D	D	D			D	D	D	D	D		D
D	D	D	D	D	D			D	D	D	D	D		D		D	D	D	D			D	D	D	D	D			D	D	D	D	D		
E	D	D	D	D	D			D	D	D	D	D			D	D	D	D	D	D			D	D	D	D			D	D	D	D	D		

From these examples, the industry concluded that compliance with the proposed 48/14 and 24/7 break requirements does not necessarily provide a better work schedule when all factors were considered.

Example 2:

The following schedule shows the complexity of the maintenance scheduling process. In this case, individuals are rotated through 12-hour day or night shifts to provide on-shift coverage, but spend most of their time working on a day shift routine.

MECHANICAL MAINTENANCE

A= 0700 TO 1730 D=0700 TO 1900

C=0700 TO 1530 P= PTO N=1900 TO 0700

CT= 8 HRS TRAINING H= HOLIDAY AT= 10 HRS TRAINING

REV. 1 12/15/04 DEC, 25, 2004 THRU JAN. 21, 2005

DAY	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F
DATE	25	26	27	28	29	30	31	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21
EMPLOYEE NAME /HPID																												
					N	N	N			A	A	A	A				A	A	A	A				A	T	T	T	
					N	N	N			A	A	A	A				T	T	T	T				A	A	A	A	
					D	D	D			A	A	A	A				T	T	T	T	T			A	A	A	A	
					D	D	D			A	A	A	A					T	T	T	T			A	T	T	T	
	D	D	D	D								N	N	N			A	A	A	A	A				T	T	T	A
	D	D	D	D								N	N	N			A	A	A	A	A				A	A	A	A
	N	N	N	N								D	D	D														
	N	N	N	N								D	D	D														
			H	C	C	C	H	D	D	D	D								N	N	N				A	A	A	A
			H	C	C	C	H	D	D	D	D								N	N	N			A	T	T	T	
			H	P	P	P	H	N	N	N	N								D	D	D			A	T	T	T	
			H	C	C	C	H	N	N	N	N								D	D	D			A	T	T	T	
			H	P	P	P	H			A	A	A	A		D	D	D	D								N	N	N
			H	P	P	P	H			A	A	A	A		D	D	D	D								N	N	N
			H	P	P	P	H			A	A	A	A		N	N	N	N								D	D	D
			H	P	P	P	H			A	A	A	A		N	N	N	N								D	D	D
			H	P	P	P	H			A	A	A	A				T	T	T	T		D	D	D	D			
			H	P	P	P	H				A	A	A	A			T	T	T	T		D	D	D	D			
																	T	T	T	T		N	N	N	N			
																	A	A	A	A		N	N	N	N			
			H	C	C	C	H			A	A	A	A				A	A	A	A				A	A	A	A	
			H	P	P	P	H			A	A	A	A				A	A	A	A				A	A	A	A	
			H	P	P	P	H				A	A	A	A			A	A	A	A	A				A	A	A	A
			H	C	C	C	H			A	A	A	A				T	T	T	T				A	A	A	A	
			H	P	P	P	H			A	A	A	A				T	T	T	T				A	A	A	A	
			H	P	P	P	H				A	A	A	A			T	T	T	T	T				T	T	T	A
			H	C	C	C	H			A	A	A	A				T	T	T	T				A	A	A	A	
			H	C	C	C	H			A	A	A	A				T	A	A	A				A	A	A	A	
			H	C	C	C	H			A	A	A	A				A	T	T	T				A	A	A	A	
			H	C	C	C	H			A	A	A	A				A	A	A	A				A	A	A	A	
			H	P	P	P	H			A	A	A	A				A	A	A	A				A	A	A	A	
			H	C	C	C	H			A	A	A	A				T	A	A	A				A	A	A	A	
			H	P	P	P	H			A	A	A	A				A	A	A	A				A	A	A	A	
			H	P	P	P	H			A	A	A	A				T	A	A	A				A	A	A	A	
			H	P	P	P	H			A	A	A	A				T	A	A	A				A	A	A	A	
			H	C	C	C	H			A	A	A	A				T	A	A	A				A	T	T	T	
			H	C	C	C	H			A	A	A	A				T	A	A	A				A	T	T	T	
			H	P	P	P	H			P	P	P	P					T	T	T	T			A	A	A	A	
			H	P	P	P	H			A*	A	A	A				A*	A	A	A				T	T	T	T	
			H	P	P	P	H			A	A	A	A				A	A	A	A				A	T	T	T	
			H	P	P	P	H				A	A	A	A			A	T	T	T					A	A	A	A
			H	C	C	C	H			A	A	A	A					A	A	A	A			A	A	A	A	

2.5 Long term limits are not needed

There are a number of diverse approaches to managing cumulative fatigue. As discussed in Section 7 of this letter, the combination of individual limits and modified break requirements proposed for this rule will fully address cumulative fatigue. There is no basis in the cumulative fatigue area for long-term limits

Despite years of effort, only two approaches have been identified to address long-term limits. The first, which is reflected in the current proposed rule, is the concept of a group work hour limit of 48-hour per week, averaged over a 13-week period, for each functional group. The second, which was in an earlier draft and rejected, provides an individual limit of 800 hours per quarter and 2600 hours per year. **We submit that neither approach is needed for cumulative fatigue management.**

Both approaches will result arbitrary work hour limits, with significant unintended consequences. Under the quarterly and annual individual limits, a company could be unprepared for an unplanned outage near the end of the year. As one licensee has commented, everyone will be competing for resources to support spring outages. Under the group work hour limits, the ability to complete a major equipment replacement outage will be unnecessarily disrupted.

The Commission frequently discusses the need for performance-based rulemaking. It provides an effective, flexible regulatory process that is focused on results. The work hour portion of the Fitness for Duty rule offers an opportunity to use the more effective performance-based approach.

NUREG/BR-0058, Rev. 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission (Sept. 2004) ("RA Guidelines") sets forth NRC policy for the preparation and contents of regulatory analyses. Section 4.2 (Identification and Preliminary Analysis of Alternative Approaches) of this NUREG states (p. 21) that: "requirements should be performance-based, and highly prescriptive rules and requirements should be avoided absent good cause to the contrary."[16] In our view, this policy has not been adhered to in proposing certain provisions of Subpart I of the proposed rule. These proposed new requirements are needlessly prescriptive, and the regulatory analysis fails to justify such an overly rigid approach.

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[16] This section of the RA Guidelines further states (p. 21): "If the objective or intended result of a proposed generic requirement or staff position can be achieved by setting a readily quantifiable standard that has an unambiguous relationship to a readily measurable quantity and is enforceable, the proposed requirement should merely specify the objective or result to be attained rather than prescribe to the licensee how the objective or result is to be attained." In our view, the NRC Staff has clearly failed to follow this policy in proposing Section

In discussion of the drug and alcohol portion of this rule, the industry asked for a prescriptive set of requirements that would not require any additional implementing guidance. Experience indicates the need for a rigorous process in drug and alcohol testing that protects the rights of the individual while, at the same time, standing up to legal scrutiny. Notably, the same issues do not apply to the work hour portion of the rule. The industry believes that a performance-based approach will best achieve many of the Commission goals for this part of the rule.

The draft Subpart I contains a series of performance-based requirements. For example, work scheduling must be conducted in a manner that addresses the potential for fatigue. Licensees are required to maintain records and conduct periodic reviews that assess the effectiveness of the program in ensuring individuals' ability to safely and competently perform their duties.

Considering the complexity of work scheduling in the nuclear reactor industry and the need for management flexibility, performance-based requirements provide the best tool for ensuring that hours worked do not generate a public health and safety issue. Adding prescriptive layers that attempt to address every conceivable situation will be ineffective and burdensome.

The draft work hour rule contains the following provision.

> "Section 26.199(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."

As the specific provisions of the rule developed, more and more layers of prescriptive limits have been added in the rule package. These layers were added in an attempt to address hypothetical examples of abuse of individual work hour limits could occur. The industry believes that additional prescriptive layers are not necessary since the hypothetical examples posed would clearly violate the intent of 10 CFR 26.199(c).

The example crew rotations provided under Section 2.4 of this letter would also meet the criteria of proposed rule 26.199(c). In these schedules the flexible break requirements are met, while providing breaks at reasonable intervals to prevent impairment from fatigue.

Generic Letter 82-12 provides that: "Enough plant operating personnel should be employed to maintain adequate shift coverage without routine heavy use of overtime. The objective is to have operating personnel work a normal 8-hour day, 40-hour week while the plant is operating." The generic letter also recognizes that

in the event of unforeseen problems and during outages, extensive overtime up to the individual limits would be used.

The provisions of Proposed Section 26.199(c) meet the scheduling intent of the generic letter and would provide the flexibility needed to address outages, planned maintenance, and unplanned maintenance. Codifying this requirement in the rule should resolve the concern that this provision of Generic Letter 82-12 was not included in licensees' Technical Specifications and could not be enforced. If implemented, this performance-based provision would provide equivalent guidance to the licensees to protect workers against fatigue induced by ineffective work hour schedules.

2.6 Unintended Consequences

A number of potential unintended consequences need to be considered in developing the final work hour rule. The industry is concerned that many of these consequences, which have not been considered in the rule analysis, will have a negative impact on safety. The changes recommended by the industry would prevent these unintended consequences.

Issue: 8-hour Shift Rotation.

The break requirements of proposed Section 26.199(d) focus on days off without considering the number of hours worked in a particular day and the actual breaks between work periods. The application of a single set of break criteria to both the 8-hour and 12-hour shift rotations cannot be implemented in an equitable manner. The loss of scheduling flexibility for the 8-hour shift rotation will result in most licensees shifting to a 12-hour rotation. The alternative approach proposed in this letter will put break requirements for 8-hour and 12-hour shifts on an equitable basis, resolving this concern.

Issue: Loss of Experienced Supplemental Workers

Supplemental workers are already in short supply. As a result, attracting qualified supplemental workers to support outages is challenging in the entire commercial reactor industry. Imposing additional work hour restrictions on these individuals through the break requirements in the proposed rule will make the problem significantly worse. Licensees report that they are in competition with many other industries for qualified local resources. For example, outages at coal fired power plants, petrochemical plants, and food processing facilities use many of the same skilled craft. The industry has already experienced cases where individuals have left during an outage to go to a job that offered more overtime. For many supplemental workers the availability of overtime is a key factor in where they decide to work.

Attracting the same individuals to work subsequent outages and retaining them for the duration of an outage, significantly improves the quality of the work process. If the industry were forced to place supplemental workers on a 48-hour week instead of a 72-hour week, we believe that there would be major attrition in the critical final phases of the outage. Even if replacement workers can be found, the lack of experience on the specific jobs will generate a higher potential for errors than any projected fatigue induced errors.

Issue: Second Jobs

Based on anecdotal information, one of the outcomes of the security work hour order has been an increase in the number of individuals who have taken second jobs to get total hours of work they desire. If work hour restrictions are too severe, the number of workers who have second jobs can be expected to increase in other areas.

Issue: Loss of Management Flexibility

The lack of management flexibility resulting from the layered requirements in this proposed rule is a major concern to the industry. Potential delays in work completion on safety-related equipment due to these restrictions could have significant adverse safety implications.

The break requirements of proposed Section 26.199(d) are the major source of this concern. If a safety-related component fails on a Friday, the licensee's ability to apply the appropriate resources to the job in a timely manner can be significantly restricted. Under the proposed rule, an individual cannot work both weekend days without an waiver from the break requirements. At the same time, the rule is written in a manner that discourages use of waivers. The result will be delays in completion of both planned and unplanned maintenance. Having safety related equipment unavailable unnecessarily has safety implications. When a maintenance crew has been working 40-hour weeks, it is difficult to show that there will be a fatigue issue working a job through a weekend.

Another example of the unintended safety consequences of Subpart I is in the conduct of planned maintenance on diesel generators. This nominal 10-day job will be extended to 11 or 12 days so the maintenance teams can take one or two days off. Assigning additional less qualified individuals to the job in an effort to get the job completed in 10 days will increase the potential for errors.

The industry's proposed alternative to the break limits will address the potential for cumulative fatigue in a rigorous manner, while providing the needed flexibility to conduct critical maintenance in a timely manner.

Issue: Operational Distraction

Trying to manage the nuclear plant workforce with all the proposed restrictions in Subpart I will require significant management attention. In making decisions on current work assignments, the loss of future flexibility must be considered. This effort will provide an added distraction from a focus on safe operation of the plant. If implemented in its current form, the proposed rule will add one more layer, mostly prescriptive, that will distract management attention from other areas that affect safety.

Issue: Unnecessary Extension of Outages

The extension of outages that is likely to result from this rule has safety implications that have not been considered. Increased time at reduced inventory and in altered electrical configurations has safety implications. Because no adverse trend in human performance indicators has been shown for outages between five and thirteen weeks, it is unclear that extending outages will show any improvements in performance under the proposed rule.

The loss of those supplemental workers unwilling to stay for the reduced hours after the eighth week of an outage, introduces a much higher potential for human errors than the stated concerns about fatigue in the rule package. New workers will lack experience, jobs will be delayed, and turnovers increased. Consider a steam generator outage with over 1000 supplemental workers involved. These individuals, having worked as part of a team during the first weeks of the outage, have an understanding of the job that cannot be easily conveyed to new workers. It is estimated that at least 20 percent of these workers will leave at the 8-week point. This will include the most experienced and skilled individuals, who are in high demand in other industries. While it is hard to quantify the impact of this phenomenon, it has significant potential safety implications.

For example, it could create increased pressure on management to complete these major equipment outages within the 8-week window. This will result in more jobs in parallel and increased pressure on the critical path activities. This artificial pressure is not needed when current outage experience does not show any increase in human performance issues for outages up to thirteen weeks in length.

Issue: Increased Turnovers

Each time a job is turned over to a new individual or team there is some potential for human errors associated with the turnover. A number of techniques have been employed by the industry to reduce the potential for this type of error. The lack of flexibility in the break requirements of the proposed rule will interfere with some of these good practices. When a job is complex and important enough to work around

the clock, having the same team members work each day maintains the continuity of the work and reduces turnover problems.

Stability of the work team on a job that takes several days is an important factor in maintaining the continuity of the work and returning a component to service promptly improves overall plant safety. For these two reasons a repair will frequently be worked to completion, even if it goes through a weekend. The proposed rule break requirements may force management to delay the work or bring in new people who are not familiar with the work in progress, which could be adverse to safety.

There are a number of examples where there appears to be a very low potential for fatigue. Consider a licensee where the maintenance department works 8-hour days, Monday through Friday and the work load has been stable with individuals averaging 40 hours per week for the last several months. A diesel generator is declared inoperative on Friday afternoon. Safety would dictate having the most qualified individuals working on the diesel, not taking the proposed rules mandated 24-hour break every 7 days.

Issue: Increased Difficulty Scheduling E-Plan and Security Drills

The E-plan and security drills require participation by a number of individuals from different shifts. Planning these evolutions is challenging. The break requirements of the proposed rule will make these drills even harder to plan. If an individual must participate during a day off, there could be an issue with the 48-hour in14-day or 24-hour in 7-day break requirements. The limitations on who could participate, as well as the potential need for waivers, present an unnecessary complication. Even if an individual were only scheduled to participate in a drill for several hours, a full day break would have to be provided.

These requirements could also interfere with NRC inspection activity. As demonstrated in the Security area, conduct of drills while meeting the individual limits and group work hour restrictions can challenge the schedule. An exception to the group work hour limits was provided in the security order. The break requirements will add a new challenge. For example, an individual who is on a required break will not be available for interview or to participate in a weapon proficiency demonstration if selected.

Issue: Schedule Disruption

The super-crew concept used during outages, working six shifts of 12-hour days with one day off per week, provides schedule stability. Individuals cannot be extended beyond their scheduled shift without a waiver. Crews stay on days or

nights for the duration of the outage, thereby reducing the impact of circadian issues. Individuals also receive a 36-hour break which offers two rest periods.

The requirement for a 48-hour break every 14 days results in a week in which the individual would be scheduled only five shifts, or 60 hours. This provides much more incentive to work beyond the 12-hour shift length. Adding two hours to the first, third and fifth day of the shift would be possible without exceeding individual limits. It would also be possible to rotate the individual from day shift to night shift with exactly a 48-hour break. Conversely, if the individual were to stay on day shift, the break would end up being 60 hours, with three rest opportunities, not the two discussed in the rule package.

A number of individuals have expressed concern with the 48-hour break requirement based on their experience working the night shift during outages. One day off provides an additional rest period and the individual would tend to stay in the same sleep cycle. With two days off there will be the potential to shift to a night sleep cycle for one day, then back. This would have a negative effect on workers' sleep cycle and require readjustment to the night shift again. Some individuals have stated that two days off would be worse than having no days off.

Issue: Worker Schedule Preference

Work hour schedules have been developed over time based on experience and worker preference. Many of the schedules are the result of collective bargaining agreements. Significant time, expense and effort will be needed for licensees to negotiate new rotations. Additionally, the industry is concerned that other factors that affect shift schedules have not been considered. The rule package discusses the issue of length of shift, days in a row and breaks. It is clear that individuals place importance on having a long break during a shift rotation cycle and prefer a rotation that provides for two days off during as many weekends as possible. The schedule also needs to accommodate training, where required, during the Monday to Friday time frame.

For individuals on an 8-hour shift rotation, there is no clear indication that for a well structured seven day shift rotation, a 6-day cycle would result in less potential for fatigue. The 16-hour break between work periods is more than adequate for the individual to get the needed rest. Discussions with shift workers indicate that the challenge is adjusting to the second day in a particular shift rotation, not the last day. Individuals adjust to the cycle that they are on. Over the long-term, worker satisfaction is a key element in the success of the rotation that is in use. Therefore, arbitrary changes will have a net negative effect.

Section 3
Industry Recommended Rule Language Changes

This section provides specific rule language changes in Subpart I recommended by the industry. The justification for each of the changes is provided below and is amplified in other sections of this letter. We request the NRC modify Subpart I to reflect these recommendations. By incorporating the recommended changes the rule will provide reasonable assurance that fatigue does not introduce performance errors that affect public health and safety. At the same time, these changes will preserve those work scheduling practices that have proven effective in the past and that provide the management flexibility needed to safely operate plants.

3.1 Proposed Section 26.197(e) Reporting:

Issue: The reporting requirements of 26.197(e)(1) and (3) are unnecessary to protect public health and safety, unnecessary to facilitate NRC oversight of the revised Fitness for Duty rule, unduly burdensome for NRC power reactor licensees, and inconsistent with provisions of the Paperwork Reduction Act.

Discussion: The requested information is not required for the NRC to ensure public health and safety. The nuclear industry has established an excellent performance record and complies with regulatory requirements. The rule package does not demonstrate that the industry would fail to comply with the requirements of the revised rule without the imposition of these reporting requirements. Additionally, the NRC has an effective oversight process that does not depend on extensive data collection from licensees. This is particularly the case with the new reporting provisions of proposed Section 26.197(e)(1) and (3) to which the industry objects. The NRC rule package fails to provide a convincing rationale as to why these new reporting provisions are needed to augment the NRC's established licensee oversight and inspection process.

The reported information, if collected, will not indicate licensee program strengths and weaknesses, and will be ineffective in focusing NRC inspection resources.

Specifically, proposed Section 26.197(e)(1) requires an annual summary report of the number of instances in which an NRC licensee waived work hour controls for individuals in each of the job duty groups covered by the new requirements. Proposed Section 26.197(e)(3) requires reporting the number of fatigue assessments conducted during the previous calendar year, the conditions under which each fatigue assessment was conducted, and the management actions that were taken. These reporting requirements are unnecessary, will not provide useful information to the NRC staff, and should be deleted from the final version of the Part 26 amendments.

The rule package states: "The primary reason for requiring licensees to submit this information annually would be that, as discussed in Section IV. D, certain nuclear power plant licensees have permitted individuals to work hours that are significantly in excess of those intended under the NRC's Policy on Worker Fatigue and abused the waiver provisions of the Policy by granting blanket waivers to large groups of plant personnel for extended periods of time."[17] This broad assertion fails to support the reporting obligations that NRC proposes to impose in proposed Section 26.197(e).

The premise underlying the rule package justification is flawed. The NRC policy statement is generally worded and provides broad guidance to licensees. The NRC has allowed this policy statement to be subject to a number of interpretations during the many years that it has been in effect. It is inaccurate for the rule package to characterize all of these various interpretations as industry-wide "abuse of the waiver provisions of the policy." More importantly, the industry has, by and large, complied with the broad policy guidance provided by the policy statement, and the NRC has not shown otherwise in the rule package.[18] In sum, regardless of the NRC's degree of satisfaction with its previous implementation of the policy statement, that matter does not, in itself, support the NRC's claim that licensees would violate NRC regulatory requirements if these reporting provisions were not imposed.

One of the stated reasons for the inclusion of work hour provisions in the Fitness for Duty rule is to provide clear, consistent requirements with the level of specificity needed for a common interpretation across the industry. A review of industry performance indicators and NRC inspection results show that NRC power reactor licensees currently do an excellent job of complying with regulatory requirements where such requirements are well-defined and clear. The NRC has provided no basis for assuming that licensees will not comply with the requirements of the work hour portions of the Fitness for Duty rule when issued.

The work hour control waiver and assessment data that would be provided to the NRC pursuant to proposed Section 26.197(e)(1) and (3) does not provide to the NRC a meaningful indicator of the overall quality of the licensee's management of work

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[17] *See* 70 Fed. Reg. 50,579 (Aug. 26, 2005). NRC asserts that the reporting requirements in question are needed "to ensure that such abuses do not recur under the proposed rule." The Staff further states that it lacks sufficient resources to collect the information in question through NRC inspection personnel. Thus, the proposed rule states that these reporting provisions are needed to make available data on which the NRC may evaluate whether licensees' fatigue management programs are meeting the objectives of the proposed revised Part 26.

[18] In implementing the policy, NRC licensees have submitted, and the NRC staff has approved, changes to nuclear power plant technical specifications relating to work hour controls. Thus, there are variations in the plant-specific requirements. NRC licensees have complied with the commitments made in these technical specifications.

hours. There are a number of valid conditions that may warrant waivers of work hour controls. For example, the series of hurricanes that occurred in 2004 and 2005 could have resulted in a number of waivers for licensees of nuclear power plants located in Florida and along the Gulf Coast.

As a result of the way that Fitness For Duty work hour waivers are counted and maintained under NRC regulations, the data requested in these reports would not provide an accurate picture. As an example, data from a plant's 48-day outage was reviewed. During that period, a total of 61 waivers of the 72 hour per week limit would have been reported. This fact does not provide meaningful information. The waivers represented a total of 139 hours worked beyond 72 hours in a seven-day period. Of these hours, 13 waivers for 122 hours were the direct result of the crew rotation needed to get out of the outage manning alignment. One crew was on shift for a seventh day, immediately followed by at least three days off. The alternative was to continue the outage manning for several more days, providing individual breaks before going back to normal crew rotation. The other 48 waivers, each for one hour or less, resulted in a total of only 17 hours. These waivers were needed to complete evolutions or turnover that could not be completed as part of the routine crew change process.

The rule package states: "In addition, the proposed reports would permit the NRC to more efficiently focus its inspection resources on those licensees' fatigue management programs that do not appear to be meeting the objectives of this proposed subpart, and thereby maximize the efficiency of the inspection process."[19] This statement suggests that without the implementation of these new reporting requirements, the NRC staff would be unable to gauge the adequacy of reactor licensees' fatigue management programs. The industry does not believe that this will be the case. Additionally, the claim that the data to be reported under proposed Section 26.197(e) is needed to focus NRC inspection resources is inconsistent with the NRC's overall approach to monitoring licensee performance. At a September 21, 2005, public meeting the NRC staff stated that the Fitness for Duty inspection guide would be updated to include fatigue requirements in the proposed rule. With the NRC's baseline inspection program and resident inspectors assigned to each site, there is adequate attention to a broad range of performance indicators that would indicate any degradation in performance well in advance of a public health and safety issue.

The claim that the information to be reported under proposed Section 26.197(e) is needed to "focus" NRC inspection resources is inconsistent with the NRC staff's approach in other areas. For example, licensees are not required to submit an annual summary of activities under their corrective action program. The NRC has, as part of its initiative to reduce unnecessary burden, eliminated a number of

[19] *See* 70 Fed. Reg. at 50,579.

reports in the past. The addition of these new reporting requirements is inconsistent with the goal of eliminating unnecessary reporting requirements.

Further, the justification proposed for these new reporting requirements in proposed Section 26.197(e) is flawed because it ignores the significant duplication in licensee efforts that would be created. This duplication is apparent when one considers the "layering" of review, documentation, trending, and inspection activities that will be generated under proposed Section 26.197. For example, proposed Section 26.197(d) requires that licensees retain adequate records of waivers and assessments. Proposed Section 26.197(j) requires periodic reviews by licensees to assess the effectiveness of the work hour controls, including waivers and fatigue assessments. These reviews are documented and trended under the licensee's corrective action program. The corrective action program is periodically inspected by the NRC. Reporting data to the NRC on an annual basis is an unnecessary duplication of these requirements with no attendant increase in protection of public health and safety.

Recommendation: Change the draft rule language as follows.

(e) Reporting. Licensees shall include the following information in the annual FFD program performance report required under Sec. 26.217:

(1) ~~A summary of the number of instances during the previous calendar year in which the licensee waived any of the work hour controls specified in Sec. 26.199(d)(1) and (d)(2) for individuals within each job duty group in Sec. 26.199(a). The report must include–~~

~~(i) Only those waivers under which work was performed; and~~

~~(ii) Each work hour control that was waived in Sec. 26.199(d)(1) and (d)(2), including all of the work hour controls that were waived for any single extended work period for which it was necessary to waive more than one work hour control;~~

~~(2)~~ The collective work hours of ~~any~~ the security job duty group listed in Sec. 26.199(a)(5) that exceeded an average of 48 hours per person per week in any averaging period during the previous calendar year, in accordance with Sec. 26.199(f)(3) and (f)(5). The report must also include--

(i) The dates that defined the averaging period(s) during which collective work hours exceeded 48 hours per person per week;

(ii) The security job duty group that exceeded the collective work hours limit; and

(iii) The conditions that caused the security job duty group's collective work hours to exceed the collective work hours limit; and

~~(3) The number of fatigue assessments conducted during the previous calendar year, the conditions under which each fatigue assessment was conducted (i.e., self-declaration, for cause, post-event, followup), and the management actions, if any, resulting from each fatigue assessment.~~

3.2 Proposed Section 26.199(a) Individuals Subject to Work Hour Controls:

Issue: Clearly defining which individuals are subject to work hour controls is essential to successful implementation of Subpart I. The term "on-site directing" in proposed Section 26.199(a)(1) and (2) can be interpreted too broadly, and is already leading to divergent views on who is intended to be included in the "operations" and "maintenance" functional groups.

The industry is concerned that the rule package is now providing a significantly broader definition of "on-site directing" than was conveyed during public meetings to review proposed rule language. We are not aware of any rationale for making such a change.

Discussion: The Fitness for Duty rule requires that everyone with unescorted access within the protected area be fit to perform their assigned duties. Each individual receives training, is subject to behavioral observation, and is required to self-declare if he/she feels unfit-for-duty.

The work hour portion of the Fitness for Duty rule is intended to provide an extra level of assurance for those few individuals that have the most direct responsibility for maintaining reactor safety and site security, and who respond to mitigate the consequence of plant events. Proposed Sections 26.199(a)(3) and (4) clearly and appropriately focus on the emergency response functions for those performing health physics, chemistry and fire brigade leadership functions.

Regarding the operations functional group, the directing function can be defined with an example. The Senior Reactor Operator is "on-shift directing" and is responsible for the operations performed by a Reactor Operator. The Senior Reactor Operator may not, in many cases, operate systems but clearly has the responsibility for supervising the operations performed by other operators. The Operations functional group should consist of those individuals who operate risk significant systems as defined in 26.199(a)(1) and who are qualified to stand watch as licensed Reactor Operators, licensed Senior Reactor Operators, and Non-licensed Operators.

Defining the directing function for maintenance is more difficult. In NRC public meetings, the directing function was described as the maintenance supervisor working at the job-site and who is directly supervising the maintenance activity and who is able to detect and correct errors.

The confusion concerning the meaning of the term "directing" is not new . The industry has had a longstanding concern that the lack of clarity in this area would result in significant implementation issues. NEI Issue Paper 1 dated March 18,

2003, indicated the term maintaining or directing, used in the draft rule at the time, was confusing and recommended that the term clearly be defined as the first-line supervisor, foreman, or team leader for the maintenance or operational task. NEI Issue Paper 7, dated April 11, 2003, further pointed out that the directing function needed to be real-time and face-to-face by the person responsible for the proper and safe completion of the operation. Further discussion was provided in NEI Issue Paper 18, date August 29, 2003.

During the discussion of this issue, the clear focus during public meetings was on the maintenance department individual directly responsible for the proper completion of the job.

In proposed Section 26.5, Definitions, "directing" is defined as: "... the exercise of control over a work activity by an individual who is directly involved, capable of making technical decisions, and ultimately responsible for the correct performance of that work activity."

Recommendation: Change the rule language as follows.

(a) Individuals subject to work hour controls. Any individual who performs duties within the following job duty groups is subject to the requirements of this section:

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

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

3.3 Proposed Section 26.199(b)(1)(iii) Calculating Work Hours

Issue: The discussion in proposed Section 26.199(b)(1)(iii) are too restrictive on inclusion of all hours for an individual who joins the functional group at some point during the monitoring period.[20]

Discussion: Experience in the security functional group shows that the handling of individuals who join or leave the group is best addressed in several different ways. The details of this are best left to implementation guidance. Below are three examples, with different application.

1. An individual is part of the security department of a facility and qualified to perform duties as an armed responder. During the first four weeks of a 13-

[20] 70 Fed. Reg. 50587 (Aug. 26, 2005)

week calculation period, the individual is assigned to work that is not security related. The remaining nine weeks of this period, the individual performs the duties of an armed responder. In this case, the individual should be considered part of the functional group for the entire period and all hours counted.

2. An individual's assignment within an organization does not place him within a functional group. At some point, the individual is reassigned to the Security Department and starts to perform duties as a watchperson, for which he or she was previously qualified. In this case, the hours should only be calculated from the date that the individual became part of the functional group. The 75 percent exclusion criteria would determine whether this individual would be counted in the group for that period.
3. Similarly, if an individual who is in a functional group is at some point early in the calculation period reassigned to unrelated duties outside the functional group the individual should no longer be counted in the functional group.

The intent of proposed Section 26.199(b)(1)(iii) will be met without the additional qualification when considered in the context of other sections of the rule dealing with calculating group work hours. However, the individual should meet the short term individual limits when they start to perform activities within the functional group.

Recommendation: Change proposed Section 26.199(b)(1)(iii) to read:

> Licensees need not calculate the work hours of an individual who is qualified to perform the job duties listed in paragraph (a) of this section but has not performed such duties during the applicable calculation period. However, if the individual begins or resumes performing any of the job duties listed in paragraph (a) of this section, the licensee shall ~~include in the calculation of the individual's work hours all work hours worked, including hours worked performing duties that are not listed in paragraph (a) of this section, and~~ control the individual's work hours in accordance with the requirements of paragraph (d) of this section.

3.4 Proposed Section 26.199(d)(2)(ii) Breaks (Normal Operations)

Issue: The break requirements in the draft rule do not provide the flexibility needed during normal operations. As drafted, these provisions have the unintended consequence of favoring those on 12-hour watch rotations.

Discussion: The need for more flexible break requirements is discussed in Section 2 of this letter. The industry's proposed approach will provide the same degree of

flexibility for both 8-hour and 12-hour shift rotations to respond to unscheduled work that would require the use of overtime.

These changes proposed by the industry must be reviewed in light of the scheduling requirements of proposed Section 26.199(c), which requires scheduling in a manner that minimizes the potential for fatigue. It would be expected that breaks would be scheduled throughout the four to six week operating cycle. Scheduling an individual to work 30 continuous days of 8-hour watches during of a 5 week cycle would not meet the intent of this provision. More restrictive limits will not provide the needed flexibility.

In developing guidelines for outages, it has been recognized that an individual who has been working a normal schedule can handle an expanded work schedule for a short period of time. The requirement that the breaks be provided over a four to six week operating cycle provides adequate assurance against cumulative fatigue. Individuals working 8-hour shifts will have 16 hours between work periods, while individuals working 10-hour shifts will have 14 hours between work periods. This provides more than adequate opportunity to get the rest needed. The minimum average of 1 day break per week is adequate. Those on a 12-hour shift rotation have 12 hours off, again providing adequate rest opportunity. In this case, the minimum average of 2 days of break per week would be provided.

Recommendation: Delete proposed Section 26.199(d)(2)(ii) and replace it with:

(ii) During periods of normal operations:

(A) For a crew in a predominately 12-hour work schedule, an average of two 24-hour breaks per week over the nominal rotation cycle.

(B) For a crew in a predominately 8-hour or 10-hour work schedule, an average of one 24-hour break per week over the nominal rotation cycle.

(C) The nominal rotation cycle shall be between 4 and 6 weeks.

(D) Individuals are exempt from this requirement for the first 10 weeks of an outage in which the requirements of paragraph (d)(2)(iii) are applied.

~~A 24-hour break in any 7-day period; and~~

3.5 Proposed Section 26.199(d)(2)(ii) and (iii) Breaks (Outage)

Issue: During an outage, a 1-day break in any 7-day period is more than adequate, when combined with other rule provisions to address cumulative fatigue.

Discussion: A 1-day break in any 7-day period during an outages will provide more than adequate protection against cumulative fatigue. The rule package analysis significantly overstates the potential for fatigue by not considering the practical schedule employed by licensees. **The industry believes that the 48-**

hour break every 14 days is unnecessary and should be dropped from the rule.

During outages many facilities have found the two "super-crew" concept to be highly effective for managing the intense, short duration work seen in an outage. In this approach, several operating crews are combined into two sections, one working 12-hour day shifts, and the other working 12-hour night shifts. Each individual within the crew is scheduled for a day off at least once every seven days. As a result, individuals work up to 72 hours in any 7-day period, yet get adequate breaks to ensure that cumulative fatigue is not an issue.

Circadian factors are handled by rotating individuals into the assigned shift before or early in the outage and, in general, keeping the individual on the day or night shift for a number of weeks. This eliminates concerns for the need to adjust to a schedule that rotates between days and nights.

Turnovers during outages are particularly important because of the changes in plant conditions that occur. In the super crew concept, the two crews relieve each other. Thus, the crew coming on was the group that turned over just 12 hours ago. The turnover needs to only focus on the changes that have occurred in the last 12 hours. With breaks for individuals being rotated through the week, nominally only 20 percent of the crew would not be involved in the previous turnover. The potential for human performance errors that could result from the turnover of the job will be significantly reduced by eliminating the requirement to have a 48-hour break every 14 days.

The super crew approach also offers rest opportunities that have not been discussed in the rule package. Individuals receive a 12-hour break between work periods. Individuals receiving a 1-day break have two sleep opportunities in the 36 hours during the break period. Applying the principles discussed in the rule package for proposed Section 26.199(d), it can be seen that there is not a cumulative fatigue problem with this schedule.[21] First, "the 10-hour break would ensure that individuals would generally have seven hours available each day for sleep, which is close to the seven to eight hours of sleep needed by adults in the U.S." Using the same calculations, a 12-hour break would provide a 9-hour sleep opportunity, more than the various cited studies would recommend.

When the individual receives one day off, there are two sleep opportunities. The actual break time would be 36 hours. Using the same basic set of scientific information and a rigorous evaluation process, the DOT rulemaking makes a very strong case that a break of 34 hours allows an opportunity to eliminate any cumulative fatigue and that the "clock" should be reset at that point. The individual is rested and ready for another work cycle.

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[21] 70 Fed. Reg. 50591 (Aug. 26, 2005)

The industry finds the DOT conclusions compelling. They are related to 14-hour work days, not the 12 hours common in this industry. They are related to drivers who have a direct, single point of failure, connection to safety. They involve driving for 11-hour periods, an activity that requires constant attention and eye hand coordination in a very restricted physical environment.

The industry analysis concludes that a combination of one day off in any 7-day period, in conjunction with the work hour limits of 26.199(d)(1) and the minimum 10-hour break are fully protective. The individual will receive a 12-hour break with an opportunity for 9 hours of sleep. Further, at least once every seven days the individual will get a day off, nominally 36 hours, with two opportunities for rest. Under these conditions, cumulative fatigue is not an issue.

The layering of limits, as discussed in the industry's alternative proposal, results in a stable schedule. Any deviations would be highly disruptive and would, in most cases, require a waiver of one of the limits. For example, it would appear that an individual could work for 14 hours on one day and stay within the 26-hour in 48-hour limit and be provided the 10-hour break. However, during the first week of the outage the individual would have to work a 10-hour day to stay within the 72-hour limit. In the second week, or later, the individual could not work a 14-hour day without an waiver to the 72-hour requirement.

When an individual has worked 12-hour shifts for six days, the 1-day break will involve at least 36 hours to stay within the 72-hour per 7-day limit. For example, if at the end of the sixth day of day shift the individual was given exactly 24 hours off and returned on a night it would add up to 84-hours in a 7-day period resulting in the need for a waiver.

Recommendation: Delete 26.199(d)(2)(iii) and replace with.

(iii) <u>During outage periods, in which the requirements of (d)(2)(ii) above are not applied, a 24-hour break in any 7-day period.</u> ~~A 48-hour break in any 14-day period, except during the first 14 days of any plant outage if the individual is performing the job duties listed in paragraph (a)(1) through (a)(4) of this section.~~

3.6 Proposed Section 26.199(d)(3) Waivers

Issue: The restrictions on use of waivers do not provide the needed flexibility to address all situations that might arise. There is a need for management flexibility to address these situations.

Discussion: There will be cases where a waiver would allow the completion of important work in a timely manner and there is no safety or security impact. Facility management should have the flexibility to approve waivers in these infrequent cases.

The requirements for a supervisory evaluation of an individual before granting waivers provide needed assurance that there will not be fatigue-induced errors. The industry believes that the justification in the rule package for the restrictive approach does not adequately considered the evaluation that must be conducted to ensure that an individual working on a waiver will be fatigued.[22] For example, there will be cases where an individual will reach the limit of 26 hours in any 48-hour period where a review of the work history will show little potential for fatigue. There are a number of conditions that are important to the proper operation of the balance-of-plant that would not be defined as safety related.

As an example, consider the peak demand periods that occur in the summer where licensees are frequently asked to operate in a manner that provides high reliability in the delivery of electric power to the grid. During such a period a waiver may be warranted to maintain reliability even though public health and safety is not an issue.

The industry does not believe that there is any degradation in safety by providing plant management with this added flexibility.

Recommendation: Add language to allow for operational flexibility, as follows:

(3) Licensees may grant a waiver of the individual work hour controls in paragraphs (d)(1) and (d)(2) of this section, as follows:

(i) In order to grant a waiver, the licensee shall meet both of the following requirements:

(A) An operations shift manager determines that the waiver is necessary to mitigate or prevent a condition adverse to safety, or a security shift manager determines that the waiver is necessary to maintain the security of the facility, or a site senior-level manager with requisite signature authority makes either determination <u>or a determination that the waiver is necessary for plant operations</u>; and

(B) A supervisor, who is qualified to direct the work to be performed by the individual and trained in accordance with the requirements of Sec. Sec. 26.29 and 26.197(c), assesses the individual face to face and determines that there is reasonable assurance that the individual will be able to safely and competently perform his or her duties during the additional work period for which the waiver

[22] 70 Fed. Reg. 50594 (Aug. 26, 2005)

will be granted. At a minimum, the assessment must address the potential for acute and cumulative fatigue considering the individual's work history for at least the past 14 days, the potential for circadian degradations in alertness and performance considering the time of day for which the waiver will be granted, the potential for fatigue-related degradations in alertness and performance to affect risk-significant functions, and whether any controls and conditions must be established under which the individual will be permitted to perform work;

3.7 Proposed Section 26.199(f) Collective work hour limit applicability

Issues: When the other rule provisions are considered, there is no need for collective work hour limits for any functional group other than Security Officers.

Discussion: The potential for cumulative fatigue is adequately addressed by other provisions of the rule, obviating the need for the added requirements of collective work hour limits. Security Officers are recognized as a special case.

Control of work hours for security personnel must be more stringent than for other individuals who would be subject to the proposed work hour controls. First, security personnel are the only individuals at nuclear power plants who are entrusted with the authority to use deadly force. Decisions regarding the use of deadly force are not amenable to many of the work controls (e.g., peer checks, independent verification, post-maintenance testing) that are implemented for other personnel actions at a nuclear plant to ensure correct and reliable performance.

Second, unlike most other work groups, security personnel are typically deployed in a configuration such that some have very infrequent contact with other members of the security force, or other plant personnel. This lack of social contact can exacerbate the effects of fatigue on individuals' abilities to remain alert. Third, these deployment positions can be fixed posts where very little physical activity is required, further promoting an atmosphere in which fatigue could transition into sleep. Finally, unlike operators, security forces lack automated backup systems that can prevent or mitigate the consequences of an error caused by fatigue.

As discussed in Section 7 of this letter, detailed analysis conducted as part of the motor carrier hours of service rule shows that the combination of individual limits and break requirements in this rule will fully address cumulative fatigue.

The scheduling requirements of proposed Section 26.199(c) provides adequate assurance that long term work schedules do not lead to fatigue. It also meets the intent of Generic Letter 82-12 work scheduling requirements. The industry finds no reason for any long term limits on the other functional groups. The tracking and

management burden cannot be justified. There is no real improvement in public health and safety in these provisions.

During public meetings, the use of quarterly and annual limits on individuals was discussed as an approach to the perceived need for long term limits. It should be clear that the industry believes that this approach is not acceptable and would introduce even more serious implementation issues.

The other provisions in this rule will provide needed assurance that public health and safety are protected.

Recommendation:

26.199(b)(2) Collective work hours. For the purposes of this subpart, licensees shall calculate collective work hours as the average number of work hours worked among each group of ~~individuals~~ security personnel who perform the duties listed in paragraph (a)(5) of this section, within an averaging period that may not exceed 13 weeks, as follows:

(i) Licensees may define broad job duty groups comprised of ~~individuals~~ security personnel who perform the job duties listed in paragraph (a)(5) of this section, or may define smaller groups of ~~individuals~~ security personnel who perform similar duties. The groups must collectively include all ~~individuals~~ security personnel who perform the job duties listed in paragraph (a)(5) of this section;

(ii) Licensees shall include in the average for each job duty group the work hours of any ~~individuals~~ security personnel who performs the job duties of the group at the licensee's site, except if, during the averaging period the individual worked less than 75 percent of the group's normally scheduled hours;

...

26.199(f) Collective work hour limits. In addition to controlling individuals' work hours in accordance with paragraph (d) of this section, licensees shall control the collective work hours for job duty groups comprised of security personnel ~~of each group of individuals who are performing similar job duties, as listed in paragraph (a) of this section~~. Licensees shall ensure that the collective work hours of ~~each~~ the security job duty groups do not exceed an average of 48 hours per person per week in any averaging period, except as follows:

(1) The licensee need not impose the collective work hour controls required in this paragraph ~~on the job duty groups specified in paragraphs (a)(1) through (a)(4) of this section~~ during the first ~~8~~10 weeks of a plant outage or planned security system outage;

~~(2) For job duty groups comprised of security personnel –~~

(i) The group work hour average(s) may not exceed 60 hours per person per week during the first ~~8~~10 weeks of a plant outage or a planned security system outage;

(ii) The group work hour average(s) may not exceed 60 hours per person per week during the actual conduct of force-on-force tactical exercises (i.e., licensee exercises and NRC-observed exercises);

(iii) The licensee need not impose any collective work hour controls for the first ~~8~~10 weeks of an unplanned security system outage or an increased threat condition;

(iv) If an increase in threat condition occurs while the site is in any plant outage or a planned security system outage and the increased threat condition persists for a period of ~~8~~10 weeks or less, the licensee need not impose collective work hour controls on security personnel for the duration of the increased threat condition. However, if during any such outage, the threat condition returns to the least significant threat condition that was in effect at any time within the past ~~8~~10 weeks, then the licensee shall limit the collective work hours of security personnel to an average of 60 hours per person per week for the first ~~8~~10 weeks of the outage for the periods prior to and following the increased threat condition, and shall limit the collective work hours of security personnel to an average of 48 hours per person per week following the first ~~8~~10 weeks of the outage;

(v) If additional increases in threat condition occur during an unplanned security system outage or increased threat condition, the relaxation of the collective work hour limits that is permitted in paragraph (f)(2)(iii) of this section may be extended with each increase in the threat condition, but only for a period that is the shorter of either the duration of the increased threat condition or ~~8~~10 weeks;

(vi) If the threat condition decreases during an unplanned security system outage or increased threat condition, the applicability of the relaxation of the collective work hour limits that is permitted in paragraph (f)(2)(iii) of this section must be based upon the date upon which the current threat condition was last entered as a result of an increase;

(~~3~~2) The collective work hours of ~~any~~ the security job duty group listed in paragraph (a)(5) of this section may exceed an average of 48 hours per person per week in one averaging period if all of the following conditions are met:

(i) The circumstances that cause the group's collective work hours to exceed 48 hours per person per week cannot be reasonably controlled;

(ii) The group's collective work hours do not exceed 54 hours per person per week; and

(iii) The additional work hours that result in the group's collective work hours exceeding 48 hours per person per week are worked only to address the circumstances that the licensee could not have reasonably controlled.

(43) The collective work hours of ~~any~~ the security job duty group may not exceed 48 hours per person per week if the collective work hours for the job duty group exceeded 48 hours per person per week--

(i) In the previous averaging period; or

(ii) In any other averaging period that ended within the past 26 weeks.

(~~5~~4) Licensees may also exceed any collective work hour limits in this paragraph if the licensee has received prior approval from the NRC of a written request that includes, at a minimum,--

(i) A description of the specific circumstances that require the licensee to exceed the applicable collective work hour limit, the job duty group(s) affected, and the collective work hours limit(s) to be exceeded;

(ii) A statement of the period of time during which it will be necessary to exceed the collective work hour limit(s); and

(iii) A description of the fatigue mitigation strategies, including, but not limited to, rest break requirements and work hour limits, that the licensee will implement to ensure that the individuals affected will be fit to safely and competently perform their duties.

...

26.199(j)(1)(iii) Individuals who performed the job duties listed in paragraph (a)(5) of this section whose average work hours per week exceeded 54 hours during any averaging period for which the collective work hour limit is 48 hours in this section; and

3.8 Proposed Section 26.199(f) Eight Week Outage Exclusion

Issue: The outage exclusion should be increased to 10 weeks

Discussion: The NRC staff reviewed outage data from the 2000 to 2002 period and indicated that 89 percent of the outages were less than eight weeks in duration.[23] A review of more recent outages shows an increase in the number of outages that exceed eight weeks. Projected schedules for major equipment replacements shows a number of outages that will exceed eight weeks but could be adequately managed with a ten week exclusion.

The rule package states, "that decreasing the exclusion period by one or two weeks could decrease the potential for cumulative fatigue, but the magnitude of the decrease would be difficult to quantify and the benefit would not likely justify the costs."[24] An industry review of human performance data for a series of outages between five and 13 weeks shows that there is no negative human performance trend near the end of any outage reviewed. The industry, therefore; believes that increasing the outage waiver from eight to ten weeks would not represent any measurable increase in the potential for cumulative fatigue.

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[23] 70 Fed. Reg. 50469 (Aug. 26, 2005)

[24] 70 Fed. Reg. 50469 (Aug. 26, 2005)

More important, there will be clear unintended consequences in trying to comply with the group work hour limits in the final stages of the outage. The loss of supplemental workers and loss of workforce focus will represent a significant challenge in maintaining the quality achieved during current outages.

Supplemental workers are already in short supply. As a result, attracting qualified supplemental workers to support outages is challenging. Adding additional work hour restrictions on these individuals will make the problem significantly worse. Licensees report that they are in competition with companies for local resources. For example, outages at coal fired plants, petrochemical industry, and food processing plants use many of the same skilled craft. The industry has already experienced cases where individuals have left during an outage to go to a job that offered more overtime. For many supplemental workers the availability of overtime is a key factor in where they decide to work.

Attracting individuals for repeated outages and retaining them for the duration of the outage significantly improves the quality of the workforce. If the industry were forced to provide supplemental workers with added breaks or with a 48-hour week instead of a 72-hour week, there would be major attrition in the critical final phases of the outage. Even if replacement workers can be found, the lack of experience on the specific jobs will generate a higher potential for errors than any projected fatigue induced errors.

The extension of outages that is likely to result from this rule has safety implications that have not been considered. Increased time at reduced inventory and in altered electrical configurations has safety implications. Based on the fact that there is no adverse trend in human performance indicators for outages between five and thirteen weeks, it is unclear that extending outages will show any improvements in performance.

When all factors are considered, a ten week waiver period would be fully appropriate, providing needed flexibility without affecting safety.

Recommendation:

Change "first 8 weeks of a plant outage" to "first 10 weeks of a plant outage" throughout the rule package.

3.9 Proposed Section 26.199(g) Successive Plant Outages

Issue: During an extended outage, if a functional group returns to normal operations for a period in excess of two weeks, the elapsed period should be

recalculated based on when the functional group returned to an outage work schedule.

Discussion: of The industry reviewed manning practices during several extended outages where there were unexpected material issues that required analysis and development of a detailed repair procedure. In these cases, some functional groups were placed on a normal, non-outage schedule for an extended period of time during the outage.

The rule should provide the flexibility that if a security functional group is placed in a normal routine, the criteria for successive plant outages could be applied.

Recommendation:

(g) Successive plant outages. If two or more plant outages occur at the licensee's site and the interval(s) between successive outages is less than 2 weeks, the licensee shall apply the requirements in paragraphs (d)(2)(iii), (f)(1), (f)(21)(i), and (f)(21)(iv) of this section based upon the number of days that have elapsed since the first plant outage in the series began. If an outage is scheduled such that a functional group returns to a normal operational schedule for at least two weeks, the number of days may be restarted from the date outage manning is resumed.

Section 4
Comments on Federal Register Notice

In addition to the general comments and proposed rule change, there are specific issues in the rule package that warrant attention. In general, the package overstates the potential for fatigue induced errors and makes generalizations about a few isolated incidents as if they were general industry practices. The package does not appear to provide a balanced approach to the complex issues involved in this rulemaking and in some cases presents specific "facts" in support of a particular requirement without the providing the perspective of other science that would not support the conclusions.

4.1 Issue: The draft work hour provisions of Subpart I do not fulfill Goals Two, Three and Five.

Discussion: The Work Hour requirements in Subpart I are inconsistent with some of the stated goals of the rulemaking. Goal 3 calls for improved effectiveness and efficiency of FFD programs. Goal 5 is to improve Part 26 by eliminating or modifying unnecessary requirements. In applying these principles to the rest of the Fitness for Duty rule, it is unacceptable to incorporate new inefficiencies and unnecessary requirements in Subpart I. Such a result clearly suggests that the NRC is failing to meet its own goals in promulgating Subpart I of the proposed rule. Broader application of performance-based principles and fewer prescriptive limits would more effectively meet the Commissions intent in Generic Letter 82-12. These elements can be incorporated in the rule in a manner that is clear and enforceable, meeting the intent of Goals 2, 3, and 5.

Goal 2 states: "Strengthen the effectiveness of FFD programs at nuclear power plants in ensuring against worker fatigue adversely affecting public health and safety and the common defense and security by establishing clear and enforceable requirements for the management of worker fatigue."[25] Yet, the layering of requirements in the proposed rule goes well beyond reasonable measures needed to protect against fatigue induced errors. By contrast, the rule changes proposed by the industry will fully meet this goal by providing clarity and a set of enforceable requirements. Thus, we urge the NRC to incorporate NEI's recommendations in proposed Subpart I.

In discussion of this goal, the rule package claims to "substantially increase the protection of public health and safety..."[26] This claim is made throughout the rule package for each element, or layer, of the rule. However, this stated improvement in public health and safety is not justified in the rule package. In this regard, the

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[25] 70 Fed. Reg. 50446 (Aug. 26, 2005)
[26] 70 Fed. Reg. 50447 (Aug. 26, 2005)

Commission has stated that there have not been any significant events attributed to fatigue. The package also indicates that a majority of licensees have followed the policy statement in Generic Letter 82-12 and have adequate programs. Given these admissions, the NRC should meet its burden of showing that implementation of all provisions in Subpart I are in fact needed to protect public health and safety. As drafted, however, the rule package does not provide justification for the substantial layering of requirements that are proposed.

4.2 Issue: The broad assertions in Section IV.D of the rule package[27] do not justify the excessive layering of the regulatory requirements in Subpart I and the added burden on each facility of $1.3 million year.

Discussion: Section IV.D (1) and (2) of the rule package make sweeping generalizations concerning a number of alertness problems that may occur as a result of fatigue.[28] Much of the research alluded to in this discussion is not drawn from the nuclear industry. Further, the discussion does not establish the level of fatigue that would result in an unacceptable level of performance. A number of studies have clearly indicated that the nature of the task to be performed is a significant factor affecting alertness. For example, the Federal Motor Carrier Safety Administration (FMCSA) states that: "On a per-mile basis, long-haul truckers are almost 20 times more likely to be involved in a fatigue-related crash. One study suggested that a contributing factor to this statistical imbalance is the variety of work short-haul drivers typically perform; variety seems to minimize fatigue."[29]

The lack of correlation between the studies cited in the rule package and actual nuclear industry data is an area of significant concern about the validity of the conclusions reached. For example, the rule package states that it has "evaluated the research available on the degradation of worker abilities that are important to safe plant operation. The research supports the fatigue management provisions in Subpart I."[30] No further analysis is included. The rule package cites studies that indicate more than 4 consecutive 12-hour shifts is a problem;[31] however, industry review of outages between 5 and 13 weeks in length does not indicate any adverse trend in human performance indicators.

The industry believes that there are other factors, which have apparently not been considered, that reduce the potential for fatigue induced errors in the industry. The safety culture in the industry, training, work procedures, and attention to details

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[27] 70 Fed. Reg. 50,454.
[28] 70 Fed. Reg. 50455 (Aug. 26, 2005)
[29] 70 Fed. Reg. 49980 (Aug. 25, 2005)
[30] 70 Fed. Reg. 50,455.
[31] 70 Fed. Reg. 50456 (Aug. 26, 2005)

are all factors that make it difficult to directly apply conclusions from many studies conducted outside the industry.

A more realistic review would show that the more flexible approach recommended by the industry would protect public health and safety.

4.3 Issue: The rule package claims that licensees have violated the NRC Policy on worker fatigue in Generic Letter 82-12 while at the same time indicating these provisions are not enforceable.

Discussion: Throughout the rule package there are statements that licensees have violated NRC requirements in the policy statement. However, the package also notes that NRC "policy" or guidance documents do not prescribe requirements, and that the policy is only enforceable to the extent that it is included in individual licensee's Technical Specifications. [32]

The industry agrees that including the work hour requirements in rule language can provide the consistency and clarity needed in the rulemaking. This has been a consistent industry position initially provided to the Commission in August 2001.[33] The claimed violation of policy is not an appropriate basis for the reporting requirements contained in the proposed Subpart I.

4.4 Issue: The rule package makes assertions in two places about the abuse of overtime based on flawed analysis of industry provided data from the 1997 to 1999 time frame.[3435] Data collection surveys that ask for the amount of overtime paid do not accurately reflect hours worked. Hours paid do not accurately reflect hours actually worked.

Discussion: The rule package makes assertions about the abuse of overtime based on a flawed analysis of industry provided data from 1997 to 1999.[36] In these surveys conducted by NEI, reactor licensees were asked to provide data on the hours of overtime individuals were paid for. It is now recognized that direct use of overtime hours, based on pay records, does not accurately reflect the hour that an individual worked. NEI has pointed out the errors in the analysis of this data at several public meetings on the Fitness for Duty rule.

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[32] 70 Fed. Reg. 50458 (Aug. 26, 2005)
[33] NEI letter to Chairman Meserve (Aug. 17, 2001).
[34] 70 Fed. Reg. 50459 (Aug. 26, 2005)
[35] 70 Fed. Reg. 50582 (Aug. 26, 2005)
[36] 70 Fed. Reg. 50582 (Aug. 26, 2005)

At the heart of the issue is the fact that many individuals are paid overtime when they are working a normal shift schedule. For example, security officers working three 12-hour shifts one week, for 36 hours, and four 12-hour shifts the next week, for 48 hours will be paid 8 hours of overtime. While working an average of forty hours per week, these individuals documented 10 percent of their normal work hours as overtime.

In other cases, individuals are paid overtime for any hours worked beyond an 8-hour day. As a result, for individuals on a 12-hour shift rotation, 33% of their compensation would be listed as overtime. There are also cases where security officers are paid overtime to eat lunch because they have to remain on site in a response status.

In hindsight, the use of overtime from pay records was a significant flaw in the 1997 to 1999 data. It is now recognized that only a scheme that accounts for actual hours worked gives a true picture of how much time is being worked beyond the normal 2000 hours a year. It is estimated that the 1997 to 1999 data provided by the industry is in error, on average, by at least 200 to 300 hours of overtime paid as part of a normal work cycle. The data does not represent the hours worked in excess of the normal schedule of 2000 hours per year.

Therefore, the rule package conclusions based on this data are erroneous and do not reflect the hours actually worked by individuals.

4.5 Issue: The stress on reactor licensee security officers following the events of September 11, 2001 is poor justification for many of the fatigue rule provisions.

Discussion: The industry is concerned with the rule package statement that: "The inadequacy of the current regulatory framework for addressing cumulative fatigue became particularly apparent in the months following the terrorist attacks of September 11, 2001."[37] Any condition that unexpectedly requires security posture at the highest level of alert is beyond the normal bounds. First, if this rule had been in effect at that time, it is reasonable to assume that the NRC would have provided an immediate blanket waiver to the industry. Second, in at least two meetings with Commissioners, industry executives reported that remaining at the highest possible alert level was resulting in stress on their security departments. Finally, the invasion of Afghanistan resulted in the activation of many security officers, further extending the period needed to hire and train additional security personnel. By the time the Security Order was issued in April 2003, adequate additional security officers were in place or in training.

[37] 70 Fed. Reg. 50460 (Aug. 26, 2005)

4.6 Issue: The rule package states that current regulatory requirements, orders and the policy statement are adequate. Claims in other parts of the rule package of significant improvements in public health and safety for other new provisions are clearly overstated.

Discussion: The rule package states that the current regulatory framework provides adequate protection of public health and safety.[38] This position is based in part on credit for current work controls, behavioral observation programs, automatic reactor protection systems, and other administrative controls such as post-maintenance testing, peer checks, and independent verification.

The industry also agrees that the current regulatory framework does not provide the clarity and enforceability needed for effective regulation. Codifying the current work controls will, in fact, provide the assurance that public health and safety is protected. Again, it is clear from the rule package material that the addition of multiple layers of requirements is not warranted in this rule and inconsistent with the statements in this section of the package.

4.7 Issue: The stated rationale for the reporting requirements in proposed Section 26.197(e) does not justify the need for the requested information.

Discussion: One of the key reasons for this rulemaking is to provide clarity of requirements. In the past, different interpretations have been applied to the intent of Generic Letter 82-12. There have been, for example, different interpretations of the applicability of individual limits and the use of waivers during outage periods. But, the fact that there has been disagreement concerning the regulatory guidance in Generic Letter 82-12 does not justify a conclusion that licensees will violate NRC regulations.[39] Licensees must and do comply with clearly defined regulatory requirements.

Additionally, the reporting of waivers discussed in proposed Section 26.197(e)(1) does not provide meaningful information upon which to evaluate the effectiveness of a licensee's program. The convoluted example included in the rule package[40] reinforces the point that a summary of waivers does not in itself provide an accurate picture of the effectiveness of a licensees fatigue management program.

Further, the industry disagrees with the rule package assertion that waivers represent an "assumed risk" because of worker fatigue. An evaluation of the worker to assure that the individual is fit to perform the assigned task is required before

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[38] 70 Fed. Reg. 50460 (Aug. 26, 2005)
[39] 70 Fed. Reg. 50479 (Aug. 26, 2005)
[40] 70 Fed. Reg. 50480 (Aug. 26, 2005)

allowing one of the work hour limits to be exceeded. Therefore, the assumptions of fatigue and errors are not warranted.

In itself, the number of fatigue assessments does not provide relevant information on the quality of a licensee program. A large number of assessments will not indicate whether a program has problems or, alternatively, is aggressive in finding and addressing potential fatigue issues.

One of the key elements that the proposed reported data would not provide is the result of the licensee's evaluation and actions taken based on the reviews and assessments required by proposed Section 26.199(j). This evaluation and the licensee's effective use of the corrective action program can only be meaningfully examined at the plant site during routine inspection visits.

The NRC's current oversight program is adequate and the proposed reporting requirements are not needed for an effective rule.

4.8 Issue: The group work hour limits cannot be justified as needed to address cumulative fatigue.

Discussion: In public meetings on the proposed rule, there have been several challenges to the rationale for the group work hour limit of 48 hours per week. Broad, conclusion statements such as: "The proposed collective work hour controls, including the 48-hour per week group limit during normal plant operations, would address cumulative fatigue..."[41] have created significant confusion as to precisely what will be achieved by this limit. Moreover, the potential for cumulative fatigue is already being addressed by other provisions of the rule, such as the individual limits of 26-hours in a 48-hour period and 72 hours in any 7 day period, and the 10-hour minimum break requirements. Although a minimum rest break of 10 hours is required, individuals will receive at least a 12 hour break in a vast majority of cases. With these limits and proposed rest breaks during normal operations and outages, there is a low potential for cumulative fatigue.

The industry believes that the group work hour limits cannot be justified based solely on mitigating cumulative fatigue.

4.9 Issue: The limitation on outage exclusion from group work hour limits to only 8 weeks is arbitrary and unjustified.

Discussion: The outage exclusion should be extended to 10 weeks. NRC reviewed outage data from the 2000 to 2002 period and indicated that 89 percent of the

[41] 70 Fed. Reg. 50468 (Aug. 26, 2005)

outages were less than eight weeks in duration.[42] Review of more recent outages shows an increase in the number of outages that exceed 8 weeks. Projected schedules for major equipment replacements show a number of outages that will exceed eight weeks; these projects could be adequately managed with a 10-week exclusion.

The rule package states: "decreasing the exclusion period by 1 or 2 weeks could decrease the potential for cumulative fatigue, but the magnitude of the decrease would be difficult to quantify and the benefit would not likely justify the costs."[43] Industry review of human performance data for a series of outages between 5 and 13 weeks shows that there is no negative trend in human performance towards the end of any outage. The industry therefore believes that increasing the outage waiver from eight to ten weeks would not represent any measurable increase in the potential for cumulative fatigue.

More important, if this provision is not modified, licensees will face unintended consequences in trying to comply with the group work hour limits in the final stages of an outage. The loss of supplemental workers and loss of workforce focus will represent a significant challenge in maintaining the quality of work.

4.10 Issue: The justification for a 48-hour break every 14 days and a 24-hour break every 7 days is flawed.

Discussion: The rule package discusses the effects of cumulative fatigue without first establishing that cumulative fatigue could exist when other provisions of the rule were observed.[44] Research cited in the rule package includes a collection of evidence that does not represent the conditions at a power reactor site. The lack of industry specific evidence does not provide adequate justification for this significant backfit (a burden at each facility of over $500,000 per year).

The industry also disagrees with the rule package statement that these breaks are needed as a "key component of fatigue mitigation for the transient workforce."[45] This statement ignores the numerous other provisions included in this proposed rule that are designed to mitigate the impact of fatigue. There is serious concern about the impact of the proposed rule break provision on reactor licensee's ability to attract qualified supplemental workers to support outages. The lack of qualified supplemental workers could result in more human performance errors and potentially a number of unintended safety consequences.

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[42] 70 Fed. Reg. 50469 (Aug. 26, 2005)
[43] 70 Fed. Reg. 50469 (Aug. 26, 2005)
[44] 70 Fed. Reg. 50471 (Aug. 26, 2005)
[45] 70 Fed. Reg. 50471 (Aug. 26, 2005)

The alternative approach proposed by the industry will provide a stable schedule and adequate rest breaks for both assigned staff and supplemental workers during outage periods.

4.11 Issue: The industry supports the need for policies, procedures, training and records as discussed in proposed Section 26.197 (a) through (d)

Discussion: The lack of clarity in Generic Letter 82-12 and the different approaches used to implement its underlying policy have been cited as the primary justification for the work hour rulemaking. Establishing clear policies and procedures will be a significant step in ensuring clarity in work hour requirements. Since both the individual and the licensee have responsibility for preventing fatigue induced errors, the proposed training is an important step in meeting the overall goal of protecting public health and safety.

The industry believes that the added clarity in this proposed rule will fully address the concerns raised by the perception that a few licensee practices are inconsistent with the policy statement.[46] These steps will provide for the stated goal of effective management of worker fatigue.[47]

4.12 Issue: The rule package discussion significantly expands the operations and maintenance function groups and who would be included in the area of directing.[48]

Discussion: During public meetings, the industry expressed concerns with the lack of clarity in the "directing" in the Operations and Maintenance functional groups. For Operations this was understood to mean individuals with direct authority, such as the Senior Reactor Operator directing the activity of the Reactor Operator. In the Maintenance functional group, the NRC staff stated that it was the individual who was at the job site providing direct supervision throughout the job, who had the ability to detect errors and was ultimately responsible for the successful completion of the job.

Although we agree that the group should include management routinely assigned to a shift, the proposed addition of other individuals who provide periodic support, such as a special outage manager, is unwarranted. The licensed operator is directly responsible for the safe operation of the plant.

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[46] 70 Fed. Reg. 50576 (Aug. 26, 2005)
[47] 70 Fed. Reg. 50576 (Aug. 26, 2005)
[48] 70 Fed. Reg. 50584 (Aug. 26, 2005)

In the maintenance area, the application of the term "directing" to engineering personnel who provide technical advice is of particular concern. The rule package discussion clearly indicates there is now a different view from that provided by the NRC at pubic meetings on the scope of those to be included in the maintenance functional group.

It is important that the criteria for these functional groups be well defined. In the case of the Security functional group, the criteria have been carefully linked to the security plan and the definitions of various individuals, such as "armed security officer." Thus, under the security definition an individual who is qualified and carries a weapon at any point is in the functional group, even if a supervisor.

The term "directing" has added a significant degree of uncertainty to who should and should not be included in the functional group. Without better definition of the expectations in this area, there will repeatedly be disagreement regarding implementation requirements.

Another potential unintended consequence is the distancing of engineering staff from the maintenance and operations staff. Wherever possible, licensees will define an engineer as an advisor, not a director, of the operations or maintenance groups. In some cases an engineer may not go into the field to give technical advice or participate in troubleshooting for fear that someone will decide he or she is part of a functional group and subject to work hour controls.

4.13 Issue: Inclusion in proposed Section 26.199(a)(4) of the fire brigade member who is responsible for understanding the effects of fire and fire suppressants on safe shutdown capability of is not warranted.

Discussion: Every individual inside the protected area is expected to be fit to perform his or her assigned duties. This is an overarching requirement of proposed Section 26. In deciding whether to include functional groups, the issue is not whether an individual should be fit for duty, but whether their duties are so critical that the additional work hour controls are needed. It is difficult to build a case for someone in an advisory capacity. Industry concerns were expressed in several public meetings on the scope of 26.199.

There are significant problems with applying the work hour controls to small groups of individuals, such as those covered by 26.199(a)(4). At many facilities this function is already performed by individuals in the operations functional group defined in 26.199(a)(1). At those facilities where this function is performed by a unique fire brigade member, the administrative burden associated with tracking this small functional group will, most likely, result in the responsibility being

assigned to the Operations Department. Section 26.199(a)(4) should be deleted from the draft rule.

4.14 Issue: The industry supports the exclusion of turnover time as discussed in the rule package.[49]

Discussion: The rule package discussion focuses on the importance of a proper turnover to safe plant operations and maintenance, stating: "the NRC believes that the benefit of including turnover for managing worker fatigue would be outweighed by the potential adverse consequences on the quality of shift turnover."[50] The industry agrees with this conclusion. There are several other factors that support excluding turnover time at the beginning and end of a work period.

Individuals on an 8-hour shift rotation have 50% more turnovers than individuals on a 12-hour shift rotation. Thus, inclusion of normal shift turnover in the calculated hours worked places the 8-hour shift rotation at a disadvantage. This could contribute to the industry moving to 12-hour shift rotations.

Some of the limits included in the proposed rule, particularly the limit of 26-hours in any 48-hour period were developed based on the exclusion of turnover time. These limits would have to be increased if turnover time were included in the calculation. The 26-hour time period was chosen recognizing that on a 12 hour shift rotation an individual will routinely work 24-hours in a 48-hour period. When an assigned relief is not available it could take up to 2 hours to find and call in a replacement. Thus, 26 hours was selected to avoid the need to use waivers.

Attempting to track turnover time would significantly increase the burden involved in this process.

4.15 Issue: The rule package contains a contradiction between the performance-based and the proposed prescriptive requirements.

The rule package states: "Although research provides clear evidence of the importance of these factors in developing schedules that support effective fatigue management, the NRC also recognizes that the complexity of effectively addressing and integrating each of these factors in work scheduling decisions precludes a prescriptive requirement. Therefore, proposed Section 26.199(c) would establish a non-prescriptive, performance-based requirement."[51]

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[49] 70 Fed. Reg. 50585 (Aug. 26, 2005)
[50] 70 Fed. Reg.50585 (Aug. 26, 2005)
[51] 70 Fed. Reg. 50589 (Aug. 26, 2005)

The break requirements of proposed Sections 26.199(d)(2)(ii) and (iii) provide a prescriptive requirement that will prevent developing an effective rotation schedule. A schedule must consider a number of factors including the advantage of a long break at some point in the rotation cycle and the need to conduct training during the Monday through Friday time frame. To allow effective scheduling that addresses all performance factors, the industry believes that the proposed alternative to the break requirements is essential.

Section 5
Regulatory and Backfit Analysis

5.1 Overview of Backfit Analysis

The NRC's draft Regulatory Analysis (RA) concerning the proposed amendments to 10 CFR Part 26, which includes a backfit discussion, is included in Attachment 4 to the SECY-05-0074 rule package.[52] In the rule package, the Staff took the position that no separate backfit analysis should be performed for the fatigue management provisions of the proposed rule.[53] However, the NRC did analyze the benefits associated with four selected work hour control provisions in Subpart I in Addendum 1, "Methodology and Estimated Benefits of Four Fatigue Management Provisions of the Proposed Fitness for Duty Rule." ("Addendum 1").[54]

The backfit analysis evaluates the aggregation of proposed provisions that constitute backfits under the NRC backfit rule. NRC's analysis estimates that:

> "[T]these provisions would result in a net cost to industry of $594.3 million (present value) assuming a 7-percent discount rate, or $927.1 million assuming a 3-percent discount rate. The provisions would cost industry about $20.7 million in initial costs and would generate about $42.2 million in annual costs. For the average program, this equates to about $660,300 in one-time costs, and about $1.4 million in annual costs. Nevertheless, the NRC concludes that these impacts would be justified by the substantial increase in the protection of public health and safety provided by this rule." (RA, p. 81).

The NRC also conducted a screening analysis in accordance with NRC's Regulatory Analysis Guidelines "to ensure that the aggregate analysis does not mask the inclusion of individual rule provisions that are (1) not cost-beneficial when considered individually and (2) not necessary to meet the goals of the rulemaking."

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[52] *See* SECY-05-0074, Proposed Rule to Amend the Fitness-for-Duty Requirements in 10 CFR Part 26 (Apr. 28, 2005), Attachment 4, "Draft Regulatory Analysis of the Proposed Rulemaking to Amend the Fitness-for-Duty Rule (10 CFR Part 26)" ("Regulatory Analysis" or "RA"). Subsequent citations to the RA refer to Attachment 4 of SECY-05-0074.

[53] SECY-05-0074, p. 8.

[54] In a December 2004 letter to the NRC Executive Director for Operations, Luis Reyes, NEI requested a separate backfit analysis of the proposed requirement for a 48-hour break every 14 days given its major cost implications. Because the Staff determined in its screening review for disaggregation that the proposed requirement for a 48-hour break every 14 days is "necessary to meet the objectives of the rule," it did not perform a separate backfit analysis for that requirement. SECY-05-0074, p. 9.

(RA, p. 81). This review concludes that "each of the individual backfit requirements are necessary to meet the goals of the rulemaking." (*Id.*)

In the industry's view, the Regulatory Analysis was prepared in a manner that does not allow comparison of the relative merits of the various portions of the draft rule and the interaction of the various requirements. When all fatigue mitigation aspects of the proposed rule are considered in the aggregate, including those outside Subpart I, they provide multiple "layers" of requirements that protect against fatigue induced errors. Some proposed fatigue requirements, if properly analyzed in light of the other requirements, would provide only negligible benefit to the overall rule and at the same time substantially increase the attendant burden on the industry. It appears that the regulatory analysis was performed on a section by section basis, which makes it difficult to compare the incremental impact of each section.

Further, many sections of the Regulatory Analysis contain general statements to the effect that the requirement in question is important to prevent cumulative fatigue. But the bases for these conclusions are not quantified. For example, how important is each section of the proposed rule in preventing cumulative fatigue relative to the other provisions?[55] Thus, the RA does not effectively support an informed Commission decision on which parts of the proposed rule are warranted, based on the burden to be imposed on licensees. We therefore conclude that the requirements for backfit have not been met.

5.2 The Regulatory Analysis Does Not Justify the Cost and Burden Associated with Implementing Subpart I as Drafted

The NRC's backfit discussion claims "substantial" improvements in protection of public health and safety for each of the provisions in the work hour portion of the rule. [56] Although the RA includes extensive analysis of the cost of implementing Subpart I of the rule, the justification of the concomitant burden that will be

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[55] In discussing proposed Section 26.199(d)(2)(i), the NRC states: "By contrast, the 10-hour break would ensure that individuals would generally have 7 hours available each day for sleep, which is close to the 7-8 hours of sleep needed by adults in the U.S." *See* 70 Fed. Reg. 50,591. In discussing proposed Section 26.199(d)(2)(ii), the NRC states: "Therefore, the proposed provision for a 24-hour break in any rolling 7-day period would serve both to prevent and mitigate cumulative fatigue." *Id.* at 50,592. In discussing the 48-hour break requirement of proposed Section 26.199(d)(2)(ii), the NRC notes that the provision "would provide an important protection against cumulative fatigue for individuals who work consecutive outages and outages that are longer than two weeks." *Id.* at 50,594. None of these statements refers to the benefits claimed in the other statements, so the benefits of one provision should not be attributed to other provisions. The RA would have been more useful if it allowed comparison of the relative merits of each portion of the rule vis-a-vis other portions, relative to public health and safety.

[56] For example, see RA, p. 38.

imposed by implementation of Subpart I, based on broadly worded claims of improved protection of public health and safety, is deficient.

This is particularly the case given the disproportionately high cost of the proposed Subpart I provisions relative to the proposed rule as a whole. *See* RA Section 4.1.4.2 and Exhibit 4.6. That one-page section of the RA reflects the proportionate cost of the proposed Subpart I fatigue management provisions as compared to other provisions of the Part 26 amendments.[57] In it, the Staff states:

> As can be seen in Exhibit 4-6, *the substantial costs of Subpart I (Fatigue Management) dominate the cost results of the proposed rule as a whole.* When the other (non-fatigue) provisions are evaluated separately, the results show a considerable savings to industry." (RA, p. 41) (emphasis added).

Without additional discussion, the NRC concludes in this section that "the qualitative benefits of the fatigue management provisions are fully justified relative to the costs." (RA, p. 41). But given the associated costs (which are not insignificant), and the inherent imprecision in valuing "qualitative benefits," more specific justification should be provided.

A key issue that industry has reiterated during this rulemaking is the lack of objective evidence that fatigue is causing significant events at commercial nuclear power facilities. The rule package fails to establish any linkage to fatigue-induced errors, even where significant extended work hours have been used. The Commission itself has acknowledged the lack of significant fatigue related events. Through the many years the need for a work hour rule has been discussed, no attempt has been made to evaluate the proposed work hour requirements against actual plant performance. Instead, the rule package relies on studies conducted in other industries without demonstrating a direct applicability to conditions in this industry. We ask the NRC to give equal consideration to the results of the industry's own research in this area. (See Section 5.6, below)

In its 2002 rulemaking plan to incorporate worker fatigue into the Part 26 rulemaking (*see* SRM-SECY-01-0113), the Commission directed the NRC Staff to "resolve the backfit issues prior to expending significant resources on this rulemaking." In their vote sheets on the proposed FFD rule, several Commissioners explicitly recognized that no risk-significant events or performance trends attributed to fatigue have been identified. (See discussion in Section 2.2, above.) Against this background, it is difficult to conclude that a meaningful backfit has been conducted on a proposed rule with multiple and in some instances duplicative

[57] The NRC states that it is not required to present this disaggregated information but has done so "as a courtesy to stakeholders." (RA, p. 41.)

layers of regulatory requirements, whose implementation will cost $1.3 million a year for each facility.

5.3 The Regulatory Analysis Does Not Show that All of Subpart I Provides Substantial Benefits

The Staff states in the Regulatory Analysis that:

> "Many provisions of Subpart I are expected to lead to benefits that, while difficult or impossible to analyze quantitatively, are quite substantial in magnitude. Three such provisions, in particular, are the requirement that all workers be trained to recognize the factors contributing to worker fatigue and to identify symptoms of worker fatigue, the provision for worker self-declarations of fatigue, and the provision for for-cause fatigue assessments when workers exhibit symptoms of fatigue to managers or co-workers. These provisions will help ensure that individual variations in susceptibility to fatigue, arising from physiology, personal obligations, or life style, will be addressed in ways beyond the individual and collective work hour limits in the proposed rule. The training, self-declaration, and fatigue assessment provisions will help avoid potential adverse consequences caused by workers who, for whatever reason, are affected by fatigue irrespective of the other provisions of Subpart I. These provisions thus are primary contributors to safety."[58]

As stated in public meetings concerning proposed Subpart I, the industry agrees that the inclusion of provisions for training, self-declaration, and fatigue assessments will further reduce the potential for fatigue-induced errors as compared to the criteria of Generic Letter 82-12. Nor do we dispute the Staff's conclusion that these three elements, when compared to other provisions in Subpart I, are "primary contributor to safety." However, if these three Subpart I provisions are the primary contributors to improved safety, then the remaining work hour provisions in Subpart I must necessarily be less significant contributors, with less potential benefit. Moreover, we believe that several of the "other" Subpart I provisions (including collective work hour limits of proposed Section 26.199(f) and the break requirements of proposed Section 26.199(d)(2)(iii)) have a disproportionately higher cost than the provisions for training, self-declaration, and fatigue assessments. No convincing cost justification for these work hour controls has been provided in the Regulatory Analysis.

5.4 The Safety Goal Evaluation in the RA Is Deficient

With regard to Commission safety goals, RA Section 4.5 states:

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[58] RA, p. 38.

> "Safety goal evaluations are applicable only to regulatory initiatives considered to be generic safety enhancement backfits subject to the substantial additional protection standard at 10 CFR 50.109(a)(3). The current rulemaking would provide added assurance that individuals working at nuclear facilities are fit for duty and, consequently, the rule would reduce safety and security risks ranging from workplace safety incidents up to radiological damage to the reactor core. The proposed requirements may qualify, therefore, as generic safety enhancements because they may affect the likelihood of core damage, which generally is the focus of a quantitative safety goal evaluation. However, the magnitude of this change is not readily quantifiable due to uncertainties discussed in Section 3.2 of this analysis. A more dominant effect of the rule is to reduce the probability of other types of accidents and damages associated with a wide array of acts related to drug and alcohol abuse and fatigue, although this effect is equally difficult to quantify. *Because the change in safety associated with the rulemaking cannot be quantified, the proposed regulatory changes cannot be compared to the NRC's safety goals.*"[59]

NRC guidelines governing the preparation of regulatory analyses[60] provide that the safety goal evaluation included in a regulatory analysis is intended to answer "when a regulatory requirement should not be imposed generically on nuclear power plants because the residual risk is already acceptably low."[61] A regulatory analysis must include a safety goal evaluation where (as here, presumably) the regulatory initiative is considered a generic safety enhancement backfit subject to the "substantial additional protection" standard in Section 50.109(a)(3).

In our view, it is not clear that the cursory (less than one page) safety goal evaluation set forth in RA Section 4.5 fully satisfies the substantial standards for such evaluations found in the NRC's RA Guidelines. (*See* RA Guidelines, pp. 8-16.) Having included this section, the Staff should have prepared a safety goal evaluation that is more clearly consistent with the RA Guidelines; *see* Sections 3.2-3.3.4. Even in circumstances where it is not possible to develop adequate quantitative supporting information for the proposed new requirement, a "qualitative analysis and perspective" should be provided; these insights should be

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[59] RA, Section 4.5, p. 78 (internal footnote omitted) (emphasis supplied).

[60] NUREG/BR-0058, Rev. 4, "Regulatory Analysis Guidelines of the U.S. Nuclear Regulatory Commission (Sept. 2004) ("RA Guidelines").

[61] RA Guidelines, p. 8. This evaluation "is intended to eliminate some proposed requirements from further consideration independently of whether they could be justified by a regulatory analysis on their net value basis. The safety goal evaluation can also be used for determining whether the substantial added protection standard of 10 CFR 50.109(a)(3) is met." *Id.*

"related to the safety goal screening criteria." (RA Guidelines, p. 15.) In contrast, the Safety Goal Evaluation provided for this important rulemaking does not appear to address even these less rigid quantitative criteria.

Against this background, the Staff's finding that the proposed amendments "may qualify . . . as generic safety enhancements because they may affect the likelihood of core damage," and its statement that the rule will reduce the probability of accidents and damages, is conclusory and unsubstantiated.

More broadly, the Safety Goal Evaluation for the proposed rule highlights the overall lack of rigor and precision in the entire Regulatory Analysis. It is not disputed that Subpart I of the proposed amendments will, overall, contribute to the reduction of safety and security risks. For this reason, the industry supports most of the provisions of this rulemaking. However, the Staff's acknowledgement that its evaluation fails to quantify the "magnitude" of the claimed change in likelihood of core damage, or the claimed added assurance provided by the rule, is significant. The generality of the Staff's findings undermines the NRC's assertions in the rule package that implementation of Subpart I will "result in substantial non-quantified benefits related to safety and security." (RA, p. 81).

5.5 The Screening Review for Disaggregation is Deficient

The NRC's RA Guidelines recognize that in evaluating a proposed regulatory initiative, it is not always appropriate for the NRC to aggregate or "bundle" different requirements in a single analysis, because such an approach could potentially "mask the inclusion of an unnecessary individual requirement." For example, the net benefit from one requirement could potentially support another requirement that is not cost-justified. (RA Guidelines, p. 26.). Thus, when analyzing regulatory initiatives that consist of individual requirements, the NRC must determine the appropriateness of including each requirement. (Id.)

The RA Guidelines further recognize that in some instances, the inclusion of an individual requirement in the rulemaking will be necessary – for example, to resolve the problems and meet the stated objectives of the regulatory initiative. Even when this is the case, the analyst should obtain separate cost estimates for each requirement, to the extent practical, in deriving the total cost estimate presented for the aggregated requirements." (RA Guidelines, p. 26.) If a particular requirement is not a "necessary component" of the initiative, and the Staff has discretion regarding its inclusion, the NRC should include that requirement only if it determines that the overall effect is to make the bundled regulatory requirement more cost-beneficial. This would involve a quantitative and/or qualitative evaluation of the costs and benefits of the proposed initiative both with and without the individual requirement included, and a direct comparison of those results. (Id., pp. 26-27).

We believe that the screening review for disaggregation set forth in RA Section 4.4.2 is seriously flawed. As discussed elsewhere in these comments, industry is concerned that the layering of regulatory provisions in Subpart I generates a rule that will be overly prescriptive, that will unnecessarily restrict management options, and that will impose a burden not justified by a balanced approach to the regulatory analysis.

Of the fifteen rule provisions identified in the screening review, eleven are from Subpart I. (*See* RA, Section 4.4.2.) The analysis looked at each provision in isolation in an effort to show that the proposed requirement is needed to meet one of the seven stated rule objectives. NRC determined that all of the individual requirements identified in the first step of its screening review are "necessary to meet one or more goals of the rulemaking," and, therefore, that it did not have to evaluate any of the requirements independently to determine whether they are cost-justified on a stand-alone basis. (RA, p. 70). However, the screening review does not consider the relative impact and benefit of these provisions *in relation to other rule provisions.* This seems to be indicative of the way the proposed rule was developed: a number of independent requirements without fully considering the cumulative impact.

In our view, this discussion is also deficient because it fails to justify the claim that each section included is essential to the rule. For example, the justification provided in the analysis for proposed Sections 26.197(a)-(b), 26.197(c), 26.199(b), 26.199(c), 26.199(d)(2), 26.199(d)(3), 26.199(f)(1)-(2), 26.199(j), 26.201(a)-(d), and 26.201(e) is the same—that the new requirement is necessary to strengthen the effectiveness of FFD programs by establishing clear and enforceable requirements concerning the management of fatigue. Beyond the fact that this finding correlates to goal 2 of the rulemaking, it does little to explain why each provision is actually required.

Further, the industry believes that, when reviewed in the context of other rule provisions, several of the items discussed in this section do not support the stated rule objectives. The layering of provisions does not "Improve the effectiveness and efficiency of FFD programs. For example, the combination of the short term individual limits and the prescriptive break requirements make it difficult to develop a workable 8-hour shift rotation schedule. Additionally, long term limits are not needed to address cumulative fatigue, which has been fully addressed by the combination of other work hour limits and break requirements. When other rule provisions, such as the 10-hour break, can be shown to be adequate to prevent cumulative fatigue, the claimed improvement for some of the provisions is minimal at best.

Additionally, the analysis does not consider any of the potential negative effects of the rule or potential unintended consequences that could negatively affect public health and safety. The rule package analysis does not address a number of issues raised by stakeholders during public meetings on this rule.

As a result, the analysis of Subpart I does not meet the intent of the guidance on review for disaggregating. In its current form, this regulatory analysis will not provide the Commission with a truly accurate assessment of merits of the various provisions of Subpart I.

5.6 Findings of Industry Review of Human Performance Information

In response to concerns expressed by the NRC that the industry was not looking for indications of worker fatigue at nuclear power plants, the industry has reviewed a broad range of human performance indicators.[62] The results of this industry review were shared with the NRC staff. During a one year period, specific "hours of service" data was collected on all human performance events with a detailed supplemental fatigue evaluation. This study found no human performance events attributable to hours worked beyond the short term individual limits in the proposed rule. Setting aside the question of whether fatigue was a factor, there were no human performance events during the one year period that would have been prevented by the implementation of Subpart I. We believe the findings of this industry study are significant. These findings are not consistent with the approach taken in certain sections of proposed Subpart I.

The commercial nuclear industry has conducted a focused review of two contentions in the rule package: (1) the claim that working more than 6 days in a row increases errors and (2) the claim that performance degrades during outages longer than 8 weeks.

In the first part of the study, the industry reviewed human performance data related to working more than 6 days in a row during normal operations. This review, which sought to identify any human performance data that could confirm the adverse trend projected in the rule package, reviewed all indicators independent of the cause.

Some operating crew normal shift rotations have schedules that include 7 days on a particular shift cycle. In some cases, with the addition of training days at the

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[62] The analysis included human performance measures routinely available at a nuclear reactor facility, including human performance data (index or event), industry 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, and schedule adherence.

beginning of the cycle, a particular shift would work 8 or 9 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. 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 proper comparison.

Significantly, this study found *no adverse trend in crew performance beyond the sixth day* in any of the data reviewed. Contrary to the rule package contention that increased fatigue after the 6th day of work will affect human performance,[63] actual industry data shows no adverse trend in performance beyond the sixth day of work.

The industry also reviewed human performance data related to working outages longer than 8 weeks, in an effort to identify any human performance data that could indicate the adverse trend projected in the rule package. This review looked at all indicators independent of the cause. As with the other aspect of the study, the review included the same human performance measures discussed above.

The data was analyzed for outages from 5 to 15 weeks in length and the human performance indicators were evaluated on a week-by-week basis. In each outage evaluated, there was a clear decrease in the number of human performance indicators 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. This normalized data still showed a decrease in human performance indicators as the outage progressed.

Significantly, human performance indicators did not show a negative trend during any outage evaluated. Contrary to the contention in the rule package that fatigue is an issue for outages in which individuals work up to 72 hours per week for periods in excess of 8 weeks, actual data from power reactor outages shows no negative trend during long outages.

From this review, the industry concludes that the more flexible break requirements that industry proposes as an alternative to certain aspects of proposed Subpart I (discussed in Section 3 above) will adequately protect public health and safety. This will be achieved without many of the unintended consequences (discussed in Section 2 above) or cost of the more prescriptive requirements of the proposed Subpart I.

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[63] See 70 Fed. Reg. 50,456.

5.7 The Methodology of Addendum 1 to Attachment 4 Is Deficient and the Findings in Addendum 1 Are Not Supported

The Staff prepared a qualitative evaluation of the benefits associated with selective fatigue management provisions in Addendum 1 to the Regulatory Analysis.[64] The NRC states that this evaluation "is not necessary for full justification of the proposed rule, but provides further support for those specific provisions." (SECY-05-0074, p. 9). By making this additional analysis available and by citing to Addendum 1 throughout the Regulatory Analysis, the Staff is necessarily relying upon Addendum 1 to support the conclusions of the overall RA. Thus, public comments concerning Addendum 1 are appropriate.

As a preliminary matter, we note that the information in Addendum 1 is presented in a manner that is difficult to understand, and the process used in the analysis is not well explained. Facts and assumptions are mixed in a manner that tends to mask significant lack of certainty in the process applied. A perception of accuracy is generated when numbers are presented as 0.34% or 0.38%; however, that perception is undermined by the inaccuracy of the underlying science and the many assumptions.

Further, the industry has serious concerns with the analysis and the methodology followed in Addendum 1. The conclusions reached in this abstract study are not consistent with actual plant performance and a number of readily available human performance indicators. If a truly objective study on this topic were conducted in the nuclear industry, it would not result in the same conclusions reached in this study. In this regard, the Commission has acknowledged that there are no significant human performance events caused by fatigue.[65] Moreover, an industry review of human performance events also shows no events attributed to fatigue over the eight year period reviewed.[66] If fatigue has been an issue in the past, it has not been a major contributor as is suggested in the Addendum 1 methodology.

The industry does not know exactly why the methodology does not work, but the most likely problem is in the questionable "assumptions" made in Addendum 1, Section 2. We note that the U.S. Department of Transportation (DOT) rulemaking cited elsewhere in these comments (*see* section 7),[67] which used a defined preview process, took the same general data and came up with different results and conclusions. Applying the DOT's review process to the NRC's analysis would significantly reduce the improvements in safety and productivity that the NRC

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[64] SECY-05-0074, Attachment 4, Addendum 1(April 28, 2005).

[65] SECY-01-0113, Commission Vote sheets (Jan. 8, 2002).

[66] Jan. 27, 2000 letter from the Institute for Nuclear Power Operations (INPO) Ralph Beedle, NEI.

[67] 70 Fed. Reg. 49,978.

claims. For example, are the differences between the 7-hour and 9-hour rest breaks in the Belenky study statistically significant? Is the Psychomotor Vigilance Test a true indicator of job performance in all situations? DOT found that there was not always a direct correlation between these tests and actual task performance. Also, on what basis does the NRC study assume that individuals with a 12-hour break will only sleep 7-hours? Isn't it likely that an individual would adjust his/her schedule to get the sleep that they, individually, need?

Of particular concern in the Addendum 1 analysis is the assumption that an individual who works six 12-hour shifts in a week will need a 48-hour rest break. Most important, there is discussion of providing two recovery periods. In the discussion of the approach to outages, the two super crew concept, each individual will get a one day break that is actually 36 hours in length. This provides the two rest periods that are discussed in the package.

The DOT rulemaking contains a discussion of a 34-hour break and its elimination of the potential for cumulative fatigue with the two rest periods.[68] The industry proposal of one day off in any 7-day period during an outage, when combined with the short term individual limits, effectively provides a 36 hour rest break with two sleep periods. Any combination of work periods that would cut into this 36-hour period would require extra time off somewhere else in the near term schedule.

Addendum 1's attempt to extrapolate accidents to hours worked is highly dependent on the nature of the work being performed. At some point, fatigue will result in an increase in error rate. What is not clear, however, is at what point in the work cycle that increase occurs, and what the effect of other workplace factors may be. The DOT rulemaking package finds very little change in accident rate between the 10th and 11th hour of for a long haul trucker, a conclusion that would not be intuitive. Additionally, DOT points out that a variety of activity makes a significant difference in the real world. For example, short haul truckers had accident rates 20 times less than long haul truckers on a per mile basis.

Additionally, it appears that there is some error in the methodology applied with respect to the importance of vigilant response.[69] (RA, p. 18.) The Belenky study was focused on truck drivers who have to maintain constant vigilance to remain in the proper lane and react to traffic conditions. There is the need for constant eye hand coordination and a single point of failure. If the driver is not vigilant, the truck goes out of the lane. Nuclear power plant operators are involved in a variety of tasks and work in a significantly different environment and are not subject to the constant need for eye hand coordination.

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[68] 70 Fed. Reg. 49,995.

We also question some of the various assumptions made in Addendum 1 regarding the relationship between plant trips and vigilance. The rule package states: "25 trips occurred at the same time as the alarm indicating the condition which caused to the trip. Therefore, alarms cannot be substituted for properly vigilant operators." We would expect a more rigorous analysis to show that in most of these trips the cause, trip and alarms were simultaneous and there was little or no opportunity for operator intervention that could have prevented the trip. Thus, the assumed linkage is in error.

Moreover, productivity projections that appear in Addendum 1, which are based on a 1989 study of electrical workers, are seriously flawed. (Addendum 1, p. 21). Contrary to the assertions in this section, the conditions assumed do not replicate the work conditions experienced by a majority of nuclear power plant workers. Additionally, this study does not take into account a variety of management techniques that are applied to meet production schedules and maintain quality. For example, the results would be significantly different for a group paid an hourly wage compared to those paid on the basis of feet of cable installed. Additionally, if the work included variety, productivity would have been higher.

In summary, the failure of this analysis to show any correlation between its findings and actual performance and conditions in the commercial power reactor industry makes the rest of the seemingly precise calculations meaningless. (See Addendum 1, section 2.) The results are not meaningful. Therefore, the methodology is not a quantitative analysis as purported. It is highly subjective and does not support the rule provisions any better than the "qualitative" assumptions that there will be substantial improvements in public health and safety.

Addendum 1's conclusion on the reduced rework (p.176) is incorrect because it ignores the many measures in place in the industry, such as use of detailed procedures, supervision and quality assurance measures. Actual equipment reliability statistics demonstrate that these existing measures are effective.

Section 6
Response to Issues for Public Comment

On pages 50,616 to 50,617 of the proposed rule package, the NRC requests public comment on a number of specific issues. NEI's response to each of these questions with particular relevance to Subpart I is set forth below.

6.1 Question 8.a (Break requirements)

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

The inflexibility of these proposed break requirements will create unreasonable burden for licensees endeavoring to manage fatigue at power reactor facilities. The requirement to have one 24-hour rest break in any 7-day period will drive many licensees who currently employ an 8-hour shift rotation to adopt a 12-hour shift rotation in order to maintain needed flexibility. While this appears to be an unintended consequence of the proposed rule, it is unwarranted.

Maintenance crews that work a normal five day work week, Monday to Friday, with an 8-hour work period will also be at a significant disadvantage. There is inadequate flexibility in the proposed rule to cover weekend work and move break periods around. This provision will force licensees to consider a four-day work week, with 10-hour work periods, to provide one extra break day per week, restoring some flexibility. Ultimately, some licensees will consider placing maintenance personnel on 12-hour days to achieve even greater flexibility to respond to the unplanned maintenance.

In our view, an alternative approach to these break requirements is justified. Such an alternative is proposed in Sections 2 and 3 of this letter.

6.2 Question 8.b (Waivers)

> "Proposed Sec. 26.199(d)(3) would permit licensees to waive individual work hour limits and rest break requirements only in circumstances in which it is necessary to mitigate or prevent a condition adverse to safety, or to maintain the security of the facility. Proposed Sec. 26.197(e)(1) would require licensees to report the number of waivers granted in a year."

As noted above, the work hour limits and rest break requirements set forth in the rule package lack sufficient flexibility. In our view, the staff should recognize that situations will arise where a waiver is appropriate for the situation even though safety is not challenged. Licensee senior management should have the ability to grant waivers in these situations. The documentation of waivers and review requirements would prevent any long term abuse of this relaxation.

Requiring licensees to report the number of waivers granted in a year will not provide useful information to the NRC and is an unnecessary administrative burden to the industry. The NRC has an established inspection process that can accomplish the desired review.

Section 3 of this letter proposes wording to provide this flexibility.

6.3 Question 8.c (Collective Work Hour Limit)

> "Proposed Sec. 26.199(f) would prohibit job duty groups that are subject to work hour controls from working more than a maximum collective average of 48 hours per person per week, except during the first 8 weeks of any outage, as well as certain other circumstances for security force personnel."

It has been generally recognized that the individual limits of Generic Letter 82-12, where applied, have been effective in mitigating fatigue. Also, the 10-hour rest period is the most important improvement of the rule that addresses the potential for cumulative fatigue. As discussed in Section 2 of this response, there have been very few events with fatigue as a contributing cause and no significant events attributed to fatigue. It is, therefore, difficult to justify the need for group work hour limits, except for the security job duty group, as an added layer beyond other requirements in the draft rule. Group work hour limits are discussed in Section 3 of this letter.

The provisions of proposed Section 26.199(c) meet the scheduling intent of the Generic Letter 82-12 and will provide the flexibility needed to address outages, planned maintenance, and unplanned maintenance. Codifying this requirement in the rule will address the concern that this provision of the generic letter was not included in Technical Specifications and could not be enforced.

6.4 Question 9 (Schedules That Meet Rule Requirements)

> "As a means of determining the flexibility of the proposed rule work hour controls in Sec. 26.199, the NRC is seeking public comment on work-scheduling examples that meet the requirements of the proposed rule and

whether such schedules afford a reasonable degree of flexibility to licensee management."

A schedule that meets the requirements of the rule could be developed if the only factors considered are the break requirements. However, other factors need to be considered in developing a schedule such as providing one long break, scheduling training between Monday and Friday and providing the maximum number of weekend days off. A 12-hour shift rotation meeting these break requirements would be achievable. However, for 8-hour shift rotations, it is significantly more difficult.

An alternative proposal that would allow much more flexibility in work schedules is provided in Section 3 of this letter and would not put the 8-hour shift rotation at a disadvantage.

A schedule that provides the break requirements of the proposed rule will not be any more successful in reducing the potential for fatigue than the current schedules in use by the industry. The industry schedules (8-hour and 12-hour rotations) have been developed and tested over time and are supported by the workers involved.

One of the key concerns with the break requirements set fourth in the proposed rule is their inflexibility, which will make it difficult to address the periodic need for overtime for emerging issues or provide relief for individuals who are sick or otherwise unexpectedly unavailable. There needs to be adequate flexibility to provide needed breaks while allowing the work schedules to be fit around a maintenance schedule.

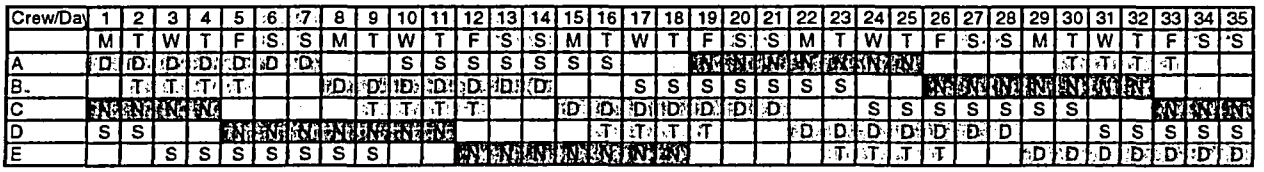
A maintenance crew working 8-hour day shifts from Monday to Friday would meet the break requirements of this rule if there were never equipment failures that required attention on the weekend. However, experience clearly shows that flexibility is needed to address emergent work as it develops. Safety considerations dictate restoring inoperable risk significant equipment to service in a timely manner. Safety considerations may also dictate restoring non-risk significant equipment for various reasons, including increased power production. The proposed break requirements will interfere with the timely completion of work in cases where fatigue is not an issue.

Adequate scheduling flexibility is critical to plant management's ability to provide needed breaks for affected employees as well as maintain adequate staffing levels for normal operations, maintenance schedules, and emergent work.

The following example shows that developing an 8-hour shift rotation that meets the technical requirements of the rule is possible. However, it is not a practical schedule as seen in the second half of the schedule.

Typical 8-hour shift rotation—7 day cycles:

The following schedule provides a five crew rotation for a typical operating crew with four days of training in each cycle.



Crew/Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35
	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S
A	D	D	D	D	D	D	D			S	S	S	S	S	S	S			N	N	N	N	N	N	N					T	T	T	T			
B		T	T	T	T			D	D	D	D	D	D	D			S	S	S	S	S	S	S			N	N	N	N	N	N	N			
C	N	N	N	N					T	T	T	T			D	D	D	D	D	D	D			S	S	S	S	S	S	S			N	N	N
D	S	S			N	N	N	N	N	N	N					T	T	T	T			D	D	D	D	D	D	D			S	S	S	S	S
E			S	S	S	S	S	S	S			N	N	N	N	N	N	N					T	T	T	T			D	D	D	D	D	D	D

The features of this rotation are:

- Training is not conducted over weekends
- One long break per cycle of 4 days.
- Two days between work periods
- Two full weekends off.
- Each shift starts on the same day of the week—Days always on Monday, Swings always on Wednesday, Nights always on Friday.
- Cycle repeats every 5 weeks.

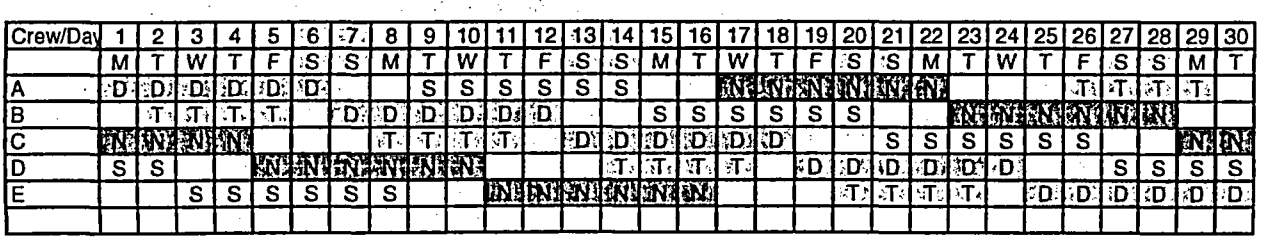
On this schedule individuals are:

- On watch or training 71% of the days (25 of 35)
- Have a break 29% of the days (10 of 35)
- Average 40 hours per week over the 5 week cycle.
- Have 42 days of training a year.

However, this practical 8-hour rotation cycle violates the proposed Subpart I break requirements and would need to be modified.

8-hour shift rotation—6 day cycle.

The following schedule was developed by making the minimum modifications to the above schedule to allow comparison. For example, Crew A day shift starts on Day 1, a Monday, in both cases and training is shown at the end of the cycle. Where possible the two days between work periods has been preserved.



Crew/Day	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30
	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T	W	T	F	S	S	M	T
A	D	D	D	D	D	D			S	S	S	S	S	S			N	N	N	N	N	N				T	T	T	T	
B		T	T	T	T		D	D	D	D	D	D			S	S	S	S	S	S			N	N	N	N	N	N	N	
C	N	N	N	N				T	T	T	T		D	D	D	D	D	D			S	S	S	S	S	S			N	N
D	S	S			N	N	N	N	N	N	N				T	T	T	T	D	D	D	D	D	D			S	S	S	S
E			S	S	S	S	S	S			N	N	N	N	N	N				T	T	T	T			D	D	D	D	D

The negative impacts of this schedule are:

- Training must be scheduled on the weekends
- Very few contiguous weekend days off.

- Shift days do not start on the same day of the week
- The cycle only repeats once every 30 weeks.
- A long break is three, instead of four days, has been achieved by reducing the break between training and day shift to one day. This will still meet the 48 hour in 14 day requirement.

On this schedule individuals the averages are essentially the same as above:

- On watch or training 72% of the days (22 of 30)
- Have a break 28% of the days (8 of 30)
- Average 41 hours per week over the 30 week cycle.
- Have 48 days of training a year.

The industry concludes that the negative impacts of a shift from a 7 day cycle to a 6 day cycle outweighs any potential fatigue mitigation by working fewer days in a row. We conclude that a plant would be more inclined to go to a 12 hour shift rotation to achieve a reasonable schedule.

Although, technically, an 8-hour shift rotation can be developed that meets the requirements of the draft rule, it is not a practical schedule for other reasons.

6.5 Question 10 (Exclusion During Outages)

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

The outage exclusion should be increased from 8 weeks to 10 weeks. A review of planned outage schedules for the next several years indicates that approximately 15% of the outages are scheduled for greater than 8 weeks to allow major equipment replacements. The industry proposed change to 10 weeks will provide adequate time to complete these extended outages. With the individual limits and break requirements proposed by the industry, there is little potential for the buildup of cumulative fatigue. Individuals who are working at the maximum limit of 72 hours per week would have a one day break every 7 days. This break day is actually a 36 hour period providing two rest periods. There is a compelling case that this schedule, with the break, will prevent the buildup of any cumulative fatigue. This is discussed further in Section 7 of this letter.

Additional support for the 10 week exclusion is provided in the review of human performance data related to working outages longer than 8 weeks. This review

looked for any human performance data that could indicate the adverse trend projected in the rule package. This review did not focus on the cause of the performance issue but trended all indicators. Thus, fatigue related errors were counted even if not attributed as a cause.

The analysis included human performance measures routinely maintained by the facility. The areas reviewed included:

- Human Performance Data (Index or Event)
- Industry Safety Data (Lost time, OSHA reportable, number of reports, and 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

The data was analyzed for outages from 5 to 13 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. Human performance indicators did not show a negative trend during any outage evaluated.

Thus, actual data from power reactor outages does not support the rule package contention that fatigue is an issue for individuals working up to 72 hours per week for periods in excess of 8 weeks.

6.6 Question 11 (Alternatives to Group Work Hours)

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

The industry has conducted extensive reviews of the implementation issues associated with the alternative approach proposed in public meetings for long term limits on work hours.

The alternative proposal to use of an 800 hour per quarter and 2600 hour per year limit for individuals, would result in simpler rule language. However, the implementation of this requirement would be very difficult and could result in violations of other labor laws. The principle concern is accounting for the hours worked by a contract individual who has worked for another company during the

quarter or year. Companies generally will not provide this information unless compelled by law. Putting the burden on a licensee to get this information generates a requirement that likely cannot be met.

This approach will also have significant unintended consequences. Plants with Fall outages will be at a disadvantage when using individuals who also worked a Spring outage. The requirements also make little sense at a dual unit facility that may have two outages in one year and no outage the following year. The long term individual limits are inconsistent with actual plant outage practices.

Group work hour limits are clearly preferred where there is a demonstrated requirement for the added burden. The use of group work hour limits for a relatively stable group, such as security, can be reasonably applied. The group is clearly defined with the same definitions used in this rule and other security regulations. Thus, when the rule discusses armed security force officers or response team leaders, there is no room for misinterpretation. With unique, site specific, training requirements the security force is relatively stable.

Applying group work hour limits to poorly defined groups, such as maintenance, will significantly increase the burden, decrease the benefit, and generate implementation issues. Maintenance personnel only work on risk significant equipment part of the time and supplemental workers are frequently used for short periods of time. Although maintenance personnel should meet the individual limits when they perform risk significant work, the burden of managing group work hour limits for these individuals is not warranted.

In summary, the industry strongly opposes long term limits. While group work hour limits may be implementable, they represent an unnecessary and indefensible layer of regulatory requirements.

6.7 Question 12a (Adding Shift Technical Advisor to Functional Group)

> "Proposed Sec. 26.199(a) would require any individual who performs duties within specified job duty groups to be subject to the work hour control provisions in Sec. 26.199. Other individuals, beyond those specified within the scope of Sec. 26.199(a), might substantially impact the outcome of risk-significant work, such as certain engineers (e.g., Shift Technical Advisors). The NRC requests comment on the inclusion of other individuals in the scope of Sec. 26.199(a)."

The industry strongly disagrees with the inclusion of other individuals such as engineers within the scope of the work hour restrictions. Most individuals who have unescorted access to the protected area perform a job function that has some

relationship to the safe operation and security of the facility. Their responsibilities are part of a layer of measures providing defense-in-depth to the protection of public health and safety.

The remainder of the Fitness for Duty rule provides for a robust set of requirements for all individuals within the protected area to ensure each individual is fit to perform assigned duties. The rule contains the following provisions that, as a minimum, address the potential for fatigue:

- Well defined policies and procedures that set expectations and processes.
- Training of all individuals with plant access on key techniques for recognizing and managing the potential for fatigue.
- A behavioral observation program that goes beyond just drug and alcohol issues and addresses fatigue.
- Self-reporting, which, when combined with behavioral observation provides protection against fatigue affected performance from any cause.

In early public meetings on the rule there was discussion of the scope of applicability of the additional work hour restrictions. There was no clear set of criteria developed for who needs the extra controls and who does not. Instead, the stated goal became one of justifying those functional groups that had been included in Generic Letter 82-12. Over time this has expanded to include other groups, such as the fire brigade team leader.

From the discussion of the fire brigade team leader functional group it became clear that a rationale could be developed for applying work hour limits to any set of individuals.

In public discussions it was clear that the NRC staffs intent was to include only those individuals who had a direct, hands-on, responsibility for operations and maintenance. This issue was discussed extensively concerning the term "directing." Industry expressed frequent concern that this could be misinterpreted as personnel outside the hands-on maintenance team or plant operators. The NRC staff provided assurance that this was not the intent of this requirement. However, the rule package has been expanded to include some engineers, an area that was outside the scope presented in the public discussion.

The industry has proposed a change to narrow the definition of those that are "directing" to restore the original understood intent of the term "directing."

6.8 Question 12.b (Defined Attributes)

> "The NRC is also seeking comments on an alternative approach for identifying the specific job functions that would be subject to these requirements. Specifically, the NRC is interested in whether, as an alternative, the scope should instead be structured to define attributes of the job functions (e.g., time-critical nature of decisions needed to ensure public health and safety, operational control of risk-important equipment) that would fall within the scope of the proposed work hour control provisions in Sec. 26.199. Under such an alternative, the licensee would then be required to identify the specific job functions that fit the defined attributes."

The industry would welcome a clear set of job functions that would be used as a basis for deciding those individuals who warrant added work hour restrictions. However, based on the years of discussions involved in development of the proposed rule, there appears to be little chance for success in achieving agreement on this type of performance-based criteria. There has been a clear focus on detailed deterministic limits with little flexibility.

In early work hour rulemaking discussions, there was discussion of criteria that would be appropriate for work hour controls. There was also discussion of the intent to codify Generic Letter 82-12 policies in the rule. Ultimately it became clear that any set of criteria that would be acceptable to the NRC staff would be broad enough to include maintenance personnel, because they were covered in the Generic Letter.

When the NRC staff proposed adding the fire brigade team leader to the scope for work hour controls, the industry expressed strong objections based on the failure to meet an objective set of criteria for inclusion. It was also an expansion beyond the stated intent of using the same groups listed in the generic letter. The written justification provided at the next public meeting clearly showed that meaningful criteria for defining functional groups would not be established.

If the Commission withdraws Subpart I and directs a performance-based approach the industry would willingly support the discussions. However, any rational set of criteria would not involve maintenance personnel or the engineers as discussed in response to question 12.a.

Realistic criteria could include factors such as:

- Need to make rapid decisions
- Last line of defense against plant upsets
- Armed individuals who must make decisions to fire
- Individuals stationed in remote posts with little activity or human interaction

The industry concludes that maintenance personnel and engineers would not meet these criteria because of a variety of defense in depth measures already in place in the commercial reactor industry. Maintenance activity involves the use of procedures, quality assurance checks, frequent breaks, and varied activities. The inclusion of maintenance personnel in the draft rule has led to unnecessary complexity of this rule in trying to address the variety of work arrangements that occur.

6.9 Question 15 (Administrative Burden of Reporting.)

> "The NRC is seeking comment regarding the administrative reporting burden that the proposed rule provisions would create. Provide any comments as described in Section XIII, Paperwork Reduction Act Statement, of this notice."

The industry has previously submitted comments to the Office of Management and Budget on the unnecessary reporting requirements contained in proposed 10 CFR 26.197(e).[70] As discussed in detail in those recent OMB comments, the industry believes that this proposed reporting requirement will not provide information that is useful in making a determination on the adequacy of a facility's fatigue management program. The requested report will not be suitable for assigning inspection resources.

The industry finds that the reporting requirements associated with the drug and alcohol portion of the rule to be appropriate.

[70] See NEI letter to OMB (Sept. 26, 2005)

Section 7
Motor Carriers Act

On August 25, 2005, the Department of Transportation, Federal Motor Carrier Safety Administration (FMCSA) issued a final rule governing hours of service for commercial motor vehicle drivers.[71] That new rule discusses many of the same issues relating to hours of service and the potential for fatigue as are dealt with in the NRC's Fitness for Duty rule package. However, a number of conclusions in the FMCSA rule package contradict the regulatory analysis for the proposed Part 26 amendments.

The FMCSA regulatory analysis, in recognizing the complex physiological, historical, social, and economic influences on the safety outcome, resulted in an enforceable regulation that can be implemented. It also integrates well with the affected industry's established practices for managing fitness for duty and ensuring adequate safety. In contrast, the NRC's proposed Part 26 rule package imposes a significantly more restrictive approach that is piecemeal, prescriptive, and impractical. The Commission should consider the precedent established by the FMCSA, which is based on sound science, and fits with an integrated approach to managing both acute and cumulative fatigue.

7.1 Comparative Rigor of DOT and NRC Analysis

The rigor with which the scientific research data was reviewed in the FMCSA package is missing from the NRC draft Fitness for Duty rule package. In developing Hours of Services for Drivers, the FMCSA pursued a research program to identify relevant, scientifically valid studies on the hours of service issue.[72] A review of 530,000 citations resulted in only 26 studies that FMCSA considered to be relevant and scientifically valid.[73] The low relevance is significant since the transportation industry is fairly easy to study and reflect actual driving conditions in a simulator or testing environment.

The industry is concerned that the NRC rule package does not indicate the same rigor in review and application of studies conducted outside the power reactor industry to form the "basis" for this rule package. Alertness is a complex issue and conclusions should not be drawn without careful review of all the contributing factors in a particular study. A number of studies presented during public meetings had marginal applicability to the nuclear industry, and the regulatory analysis often extrapolated narrow research findings into overly broad assertions.

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[71] 70 Fed. Reg. 49978 (Aug. 25, 2005)
[72] 70 Fed. Reg. 49980 (Aug. 25, 2005)
[73] 70 Fed. Reg. 49982 (Aug. 25, 2005)

The FMCSA study also takes into account the historical, social and economic influences on regulating work hours as a means of improving safety. Such factors as motivation of the workers, historical precedent and self-selection of individuals to particular work schedules, and collective bargaining agreements must be taken into account for the regulation of work hours to have a chance of success. The industry believes that a key to attracting the best qualified supplemental workers is the ability to provide an opportunity for reasonable amounts of overtime. As an example of the impact of motivation the FMCSA study notes that "...high pressure to work overtime in combination with low rewards was associated with a three-fold increase in the odds for somatic complaints as compared with a reference category of low overtime pressure in combination with high rewards. Alternatively, high pressure in combination with high rewards did not differ from the reference category."[74] "This research suggests that if workers are adequately compensated for their time, they are less likely to have health complaints. This is an important variable that can play a significant factor in conducting subjective types of research on the effects of long work hours and health. It also raises concerns regarding most subjective data regarding the health consequences of long hours that do not look at compensation as a factor." Similar conclusions would be applicable to outage schedules and the compensation of supplemental workers for long hours.

The FMCSA analysis was guarded in its extrapolation of narrow research findings into broad regulatory assertions. For example, in many of the studies a psychomotor vigilance test is used to monitor for fatigue. However, as pointed by FMCSA this does not necessarily equate to actual performance of assigned tasks.[75] Truckers performed well during driving simulation even though a psychomotor vigilance test did not show they had returned to the baseline value.

7.2 An Important Scientific Consensus: The 10-Hour Break

The FMCSA rule includes a break period of 10-hours, an increase from the 8-hour requirement before the 2003 rulemaking. "This is enough time to enable drivers to get the 7 to 8 hours of sleep most people need to maintain alertness and prevent the onset of cumulative fatigue. Throughout the rule package there are frequent references to the improvements achieved in going from an 8-hour to 10-hour break period.

The NRC rule package does not give proper credit to the same change, an increase from a minimum 8-hour to 10-hour break between work periods. It should be noted that the normal break period at a power reactor site is at least 12 hours. The proposed 10-hour break, in conjunction with the requirement to work no more than

[74] 70 Fed. Reg. 49990 (Aug. 25, 2005)
[75] 70 Fed. Reg. 49994 (Aug. 25, 2005)

26 hours in any 48-hour period, provides robust protection against both acute and cumulative fatigue that is apparently not credited in the rule package.

The 10-hour break requirement is the most significant change from Generic Letter 82-12. This is the one area where all sleep experts agreed that change was necessary. During NRC public meetings the statement was made that getting adequate rest was more important than the hours worked. A 10-hour break insures this rest period, while an 8-hour break did not.

Further, Alertness Solutions provided expensive comments on the FMCSA rule and found that, "The daily 10-hour off-duty period is intended to minimize or eliminate any acute sleep loss, so any cumulative sleep debt that might exist under the HOS rule should be minimal or none."[76]

The Commission should question why a 10-hour break is so effective in the trucking industry to prevent cumulative fatigue, yet is considered inadequate in the NRC rule package.

7.3 No Need for Long Term Limits

The FMCSA rule discusses the significant impact of one day off (in their case, 34-hours) and the ability to reset the potential for cumulative fatigue based on this one day break. The FMSA rule also states that, on average, drivers work slightly more than 60 hours per week[77]. Under the Hours of Service rules, a trucker could work up to 84 hours in one week based on 5-14 hour days, a one day break, followed by another 14-hour day. However, even under these extreme conditions, FMCSA concludes that there is no buildup of fatigue if the individual has a one day break. In commenting, Alertness Solutions stated, "that once any cumulative sleep debt has been erased through recovery sleep, an individual should be considered rested and without any acute sleep loss or sleep debt. From a physiological perspective, after a 34-hour restart period, a driver would be considered to have zero sleep loss, acute or cumulative and be appropriately rested for duty." This reasoning is clear and is based on scientific consensus, that the 34-hour break period provides two complete sleep cycles, which is sufficient to recover from even severe sleep deprivation.

Alertness Solutions suggested, "...that any subsequent duty hours accrued would be accrued for a reset or 'zeroed' sleep loss calculation and added to the following total of work hours." Further, "while the total hours can be calculated to be higher in a

[76] 70 Fed. Reg. 50018 (Aug. 25, 2005)
[77] 70 Fed. Reg. 49989 (Aug. 25, 2005)

"week" by adding retroactively, this ignores the physiological status of a driver who should be rested and ready for duty."[78]

This discussion has a key parallel in the power reactor industry during outage. Individuals who are working 6-12 hour shifts are getting routine breaks that exceed 10 hours, and thus are nowhere near being at risk of sleep deprivation. One day off in any seven day period, a break of 36 hours (since in practice, outage schedules do not rapidly rotate individuals between night shifts and day shifts), would result in the individual having two full sleep opportunities, being fully rested, and achieving a "zero" sleep loss, acute or cumulative and so being appropriately rested for duty.

The industry has also maintained that the variety of activities that nuclear reactor Operations and Maintenance personnel are involved in significantly reduces the potential for alertness issues. Support for this can be seen in the FMCSA rule statements that: "On a per-mile basis, long-haul truckers are almost 20 times more likely to be involved in a fatigue-related crash. One study suggested that a contributing factor to this statistical imbalance is the variety of work short-haul drivers typically perform; variety seems to minimize fatigue."[79]

7.4 Parallels in Short Term Limits

Under the FMCSA rules, a driver may, following a 10-hour rest break, have an on duty period of 14 hours of which 11 hours may be driving.[80] The individual may operate for 60 hours in a 7 day period if the company operates 5 days a week or 70 hours in an 8 day period, if the company operates on a 7-day a week. These periods may be reset by a break of 34 hours.[81] There are significant parallels between these the limits and the NRC's draft Fitness for Duty rule. First, the minimum 10-hour break is the same under both rules. Under the FMCSA an individual may be in an on duty status for up to 14-hours a day for long periods. Under the NRC's draft rule, a maximum work period is 16 hours. However, the added restriction that an individual not work more than 26-hours in any 48-hour period effectively limits normal scheduling to 12-hour shifts. The limit of 70 hours in 8 days closely parallels the industry limit of 72 hours in any 7-day period.

What is different is that FMCSA concludes that individuals can work for long periods of time in the 60 to 80 hour range without suffering from cumulative fatigue. Under the FMCSA rules there are no long term quarterly, annual or group work hour limits. Further, significant research data is cited to support that conclusion.

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[78] 70 Fed. Reg. 50019 (Aug. 25, 2005)
[79] 70 Fed. Reg. 49980 (Aug. 25, 2005)
[80] 49 CFR Part 395.3
[81] 49 CFR Part 395.3