

ATTACHMENT 3

**RULEMAKING PLAN
NUCLEAR POWER PLANT PERSONNEL
FATIGUE AND WORKING HOURS REGULATIONS**

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REGULATORY ISSUE

In 1982 the NRC issued the “Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors.” Through this policy statement the Commission highlighted the importance of establishing “controls to prevent situations where fatigue could reduce the ability of operating personnel to keep the reactor in a safe condition.” The policy specifically stated that “the controls should focus on shift staffing and the use of overtime--key job-related factors that influence fatigue.” The staff has since found that the NRC’s regulatory efforts to address personnel fatigue, principally through guidance, have not been wholly effective. The basis for this conclusion, which includes findings concerning the frequency of deviations from the policy guidelines and the use of overtime for personnel who perform safety-related functions, are detailed in the “Assessment of the NRC’s Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors” (Policy Assessment).

The staff has also identified several concerns with the current policy guidance and the requirements of the associated plant technical specifications (TSs). These concerns include the following: (1) certain policy guidelines allow more hours and less rest than the staff believes can be technically justified for ensuring that personnel are not impaired by work-related fatigue, (2) general policy guidance for the control of work hours during outages does not appear to be consistent with insights concerning shutdown risk, (3) insufficient policy guidance to ensure an appropriate focus on risk when scheduling personnel for extended work hours, and (4) guidance for a periodic review of work hours that does not ensure appropriate corrective actions are initiated. Since licensees developed plant TSs in accordance with the NRC’s policy guidance, these concerns are also generally applicable to the requirements of the associated plant TSs. In addition, plant TSs include broad terms that have not been defined and, as a result, plant TSs limiting working hours have been inconsistently interpreted and are difficult to effectively and efficiently enforce. Although Part 26, “Fitness for Duty Programs,” provides broad requirements concerning personnel impairment from any cause, it includes non-mandatory language when referring specifically to fatigue and is similarly difficult to efficiently and effectively enforce in matters pertaining to working hours and fatigue.

The staff has considered alternatives to rulemaking but does not currently believe that this regulatory issue can be effectively resolved through such alternatives. For example, the Commission could revise the policy to clarify its intent or update guidance, but the policy revision would not be enforceable and would not resolve concerns with plant technical specifications concerning working hours or Part 26 as it pertains to fatigue. As a result, the staff is proposing to establish requirements that resolve these concerns, better support the NRC’s performance goals for nuclear reactor safety, and ensure that personnel impairments from fatigue do not compromise public health and safety.

EXISTING REGULATORY FRAMEWORK

The principal components of the current regulatory framework for matters pertaining to working hours and fatigue are (1) the NRC’s “Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors,” as disseminated via Generic Letter (GL) 82-12, “Nuclear Power Plant Staff Working Hours,” (2) plant TSs related to this policy, and (3) certain requirements of 10 CFR Part 26, “Fitness for Duty Programs.”

Policy Statement - The "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors" (policy) was originally adopted by the Commission on February 11, 1982 (47 FR 7532, February 18, 1982) and forwarded to nuclear power plant licensees by GL 82-02 (February 8, 1982). Thereafter, the policy was revised slightly (47 FR 23836, June 1, 1982), and reissued to licensees in GL 82-12 (June 15, 1982) (see Table 1 of the Policy Assessment).

The objective of the policy is to ensure to the extent practicable that personnel are not assigned to shift duties while in a fatigued condition that could significantly reduce their mental alertness or their decisionmaking ability. The policy, in effect, provides a three-category approach to work hours. The first category is normal operation, where licensees should employ "enough plant personnel . . . to maintain adequate shift coverage without routine heavy use of overtime," with the objective of having a "normal 8-hour day, 40-hour week while the plant is operating."¹ The second category consists of times when there are "unforeseen problems," or "during extended periods of shutdown for refueling, major maintenance or major plant modifications." In such cases, and "on a temporary basis," the policy sets forth four guidelines for work schedules, including a 16-hour-per-shift limit. Finally, the policy states that there may be "very unusual circumstances requiring deviation" from the four guidelines. However, the deviations "shall be authorized by the plant manager or his deputy or higher levels of management," and the "paramount consideration" in determining whether to authorize deviations from the guidelines "shall be that significant reductions in the effectiveness of operating personnel would be highly unlikely."

It is well established that NRC guidance documents, such as the NRC's policy on fatigue, cannot prescribe requirements but merely set forth policy pronouncements or advice on a possible method of meeting a regulatory requirement. Thus, unless a policy has been imposed by regulation, license condition, TS, or order, such guidance is unenforceable. When the NRC disseminated the policy via GL 82-12, the agency requested licensees to take action as necessary to revise the administrative section of their TS to ensure that plant administrative procedures were consistent with the revised working-hour guidelines.

Technical Specifications - The policy has been incorporated, directly or by reference, into the TSs at all but three nuclear power plant units.² The staff's review of the implementation of the policy found variation among sites in the wording and details of the TSs (see Policy Assessment, Section 4.0) and in licensee control of working hours in accordance with the TS guidelines (see Policy Assessment, Section 6.0). Control of working hours in accordance with these TSs was monitored through routine periodic inspections. Routine inspections were discontinued with the implementation of the revised reactor oversight process (RROP). This change was consistent with the general design of the RROP which is intended to identify indications of plant performance problems and cause licensees and the NRC to initiate more focused analyses and inspections when program performance thresholds are exceeded.

¹ The NRC has since approved technical specification amendments, on a case-by-case basis, to allow the use of 12-hour shifts.

² The three units that do not have TSs concerning working hours have administrative procedures that are largely consistent with the policy. Unlike many other Three Mile Island action items, the amendment of TSs to ensure the consistency of licensee administrative procedures with the Commission's policy was not imposed by orders.

Since licensees developed plant TSs in accordance with the NRC's policy guidance, the staff's concerns regarding the policy guidance are also generally applicable to the requirements of the associated plant TSs. As a result, the staff does not believe that current TSs limiting working hours are wholly effective for ensuring that licensees meet the intent of the policy statement or to ensure that the NRC can effectively and efficiently enforce the TS requirements. Key terms of the policy have not been defined, resulting in inconsistent interpretation and implementation of the TSs by licensees and difficulty for NRC staff pursuing enforcement. Specifically, many TS prohibit "routine heavy use of overtime" and provide guidance for "unforeseen problems" that can be used on a "temporary basis." The NRC has not defined these terms and has not consistently pursued enforcement on the basis of the amount or frequency of overtime authorized.

Code of Federal Regulations - On June 7, 1989, the NRC published in the *Federal Register* 10 CFR Part 26, "Fitness for Duty (FFD) Programs" (54 FR 24468). The rule became effective on July 7, 1989. The vast majority of the specific requirements of Part 26 concern the prevention and detection of personnel impairment from drugs and alcohol. However, in the staff requirements memorandum (SRM), "SECY-88-129, Proposed Rulemaking — Fitness for Duty Programs," dated July 18, 1988, the Commission directed the staff to develop a rule requiring comprehensive fitness for duty (FFD) programs "to detect a broad range of possible impairments to the ability of personnel to perform their duties." Accordingly, Section 26.10, "General performance objectives," states that FFD programs must —

(a) Provide reasonable assurance that nuclear power plant personnel . . . will perform their tasks in a reliable and trustworthy manner and are not under the influence of any substance, legal or illegal, or *mentally or physically impaired from any cause*, which in any way adversely affects their ability to safely and competently perform their duties. [Emphasis added.]

[and]

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

Section 26.20, "Written policy and procedures," states that each licensee "shall establish and implement written policies and procedures designed to meet the general performance objectives and specific requirements of this part." Paragraph (a) of this section continues by stating —

Licensee policy *should* also address other factors that could affect fitness for duty such as mental stress, *fatigue* and illness. [Emphasis added.]

Part 26 contains specific requirements only for handling alcohol and drug usage and is not prescriptive regarding licensee efforts to address fatigue. The issue of fatigue is identified as a request, that is, the use of "should" instead of mandatory terms such as "shall" or "must." As a result, it is more difficult to sustain a violation of the regulation based upon a licensee's failure to limit overtime hours. In addition, without a numerical limit on overtime hours, or a provision

limiting overtime, it is likely that a range of overtime practices could be viewed as “reasonable” and in compliance with the regulation. In enforcing this regulation, the staff must use a case-by-case approach that considers the reasonableness or soundness of licensee measures in the circumstances presented. Enforcement may not be clear cut or “efficient” given that the staff may have differing views of what is reasonable or sound in such cases.

RULEMAKING OPTIONS

In response to a petition for rulemaking (PRM) requesting the NRC amend Part 26 and Part 55 to establish enforceable work hour limits (PRM-26-2), the staff has considered several regulatory approaches that the NRC could take to provide assurance that personnel performing safety-related duties are not impaired by fatigue. Appendix 1 is a table summarizing the high-level requirements of these options. Each option was evaluated with respect to the following criteria: (1) maintaining safety by ensuring personnel are not impaired, (2) maintaining safety by being responsive to plant risk and the likelihood of personnel impairment, (3) reducing unnecessary regulatory burden, (4) increasing regulatory efficiency and effectiveness by establishing clear expectations, and (5) increasing public confidence. The staff believes that these criteria are effectively tailored to this regulatory issue while remaining appropriately aligned with the NRC’s performance goals for nuclear reactor safety.

OPTION 1: Implement the proposals in PRM-26-2

In general, the petitioner proposes to —

- Amend Part 26 to (1) add enforceable work hour limits, (2) establish explicit limits and conditions on exceptions to the work hour limits, and (3) require training for the mitigation and monitoring of fatigue.
- Amend Part 55 to require evaluation and self-disclosure of sleep disorders.

The specific requirements proposed by the petitioner are provided in the petition. The principal elements of the proposed requirements are as follows:

Work hour limits - The petitioner proposes limits on the number of hours an individual may work in any 48-hour period, and specific restrictions on the use of 16-hour shifts. The petitioner proposed weekly and biweekly limits on work hours, with the limits dependent on whether a plant is in an outage or non-outage period. The petitioner proposes annual limits on work hours. The proposed annual limits vary, based on whether an individual is a shiftworker, non-shiftworker, or part of a roving crew.

Exceptions to work hour limits - The petitioner proposes to allow exceptions to the work hour limits, in limited circumstances, provided that the licensee takes action to minimize the effects of fatigue on human performance. These circumstances include (a) activation of the Emergency Plan under 10 CFR 50.47, (b) shutdown for severe weather, (c) transition to Daylight Savings time, (d) plant transients or initiation of major engineered safety features, and (e) extended shutdowns. For extended shutdowns, the biweekly limit increases provided (i) before restart or fuel load that a plan is in place to ensure adequate rest for personnel performing critical tasks and (ii) the role of fatigue is specifically and promptly evaluated for specific events and conditions enumerated by the petitioner. These events and conditions

include certain conditions adverse to quality, reportable events of 10 CFR Part 50 and 10 CFR Part 20, Occupational Safety and Health Administration (OSHA) recordable injuries, and traffic accidents involving employees on their way home from work.

Training for mitigation and monitoring of fatigue - The petitioner proposes requirements for a) initial and continuing fatigue mitigation training to personnel performing safety-related work, their supervisors and managers, and (b) training for supervisors of personnel performing safety-related work in the monitoring and detection of fatigue.

Sleep disorder screening - The petitioner proposes revision to 10 CFR Part 55 and NRC Form 396 to require self-disclosure and evaluation of known sleep disorders. The intent is for NRC to issue conditional licenses with the appropriate compensatory actions.

ASSESSMENT OF OPTION 1

A. Ensures personnel are not impaired: The proposed work hour limits address some of the weaknesses in the current policy guidelines for limiting working hours and consequently would provide greater assurance than the current regulatory framework that personnel are not impaired. Specifically, the PRM addresses chronic scheduling effects by establishing 2-week and annual limits. The PRM also addresses the repetitive use of 16-hour shifts, which present a significant risk of impairment. The proposals in the PRM allows only limited circumstances for deviation from the established limits and consequently provides substantially greater assurance than the policy that personnel will not be impaired as a result of excessive use of overtime. The PRM also addresses fatigue from causes not currently addressed in the policy and through methods for which the policy currently provides no guidance. Specifically, the proposals in the PRM would require training of personnel on other factors that can cause fatigue and ways for maximizing rest. Personnel afflicted by sleep disorders would be identified to ensure appropriate mitigative actions. Supervisors would receive mandatory training in monitoring and detection of fatigue. The PRM also would establish requirements to ensure that fatigue is evaluated as a potential causal factor for certain events. These measures provide increased assurance that fatigue-induced impairments that are not prevented through schedule limits or other measures are effectively identified for corrective action.

B. Responsive to plant risk and the likelihood of personnel impairment: In absolute terms, the proposals in the PRM are not very responsive to plant risk, although they are more responsive than the current policy. The proposals of the PRM would be applicable regardless of the state of the plant, with limited exceptions (e.g., plant shutdown, activation of the emergency plan). In these instances, increased use of overtime is allowed based upon need and practical considerations rather than risk insights, which may not support a blanket relaxation in work hour limits for plant outages. However, the proposed requirements are limited to personnel who perform safety-related work, focusing the requirements on personnel who have the most direct influence on plant risk. The PRM also addresses plant risk by proposing a requirement for licensees to have a plan that ensures adequate rest for personnel engaged in critical tasks during startup following an extended outage. The PRM also addresses risk on an individual worker basis to a limited extent by restricting the use of 16-hour shifts between 11 p.m. and 7 a.m., a high-risk period for extended work hours. The proposals of the PRM would also allow higher annual limits on overtime for personnel who are not shift workers recognizing that these individuals are at lower risk of fatigue from working at night and trying to sleep during the day,

contrary to their circadian cycle of alertness. The proposals of the PRM also would require training that addresses individual differences in response to fatigue-inducing factors.

C. Regulatory burden: The PRM would increase burden on the licensees by establishing working hour limits that would cause, for example, some licensees to either increase staffing to minimize outage durations or to adopt less aggressive outage scheduling practices. The PRM would also impose a small increase in administrative burden to track working hour limits over a rolling 2-week period (versus the current 1-week period). The proposals of the PRM also would impose additional initial and continuing training requirements. The petitioner did not address the extent of this training, but the staff anticipates that the continuing training burden would likely be limited to approximately 1 hour per person per year. A rule, as proposed in the PRM, would supersede current plant TS concerning working hours. As a result, rulemaking would result in a one time burden on licensees and NRC staff to process associated technical specification amendments.

D. Establishes clear expectations: In general, the proposals of the PRM would establish clear expectations through well-defined requirements and quantitative limits. An exception is the requirement for a plan to ensure adequate rest for personnel performing critical tasks during plant startup. Relative to the policy, the PRM proposals establish significantly clearer expectations.

E. Increases public confidence: The Commission received a large number of comments from individual citizens and citizen action groups. The overwhelming majority of the comments were in favor of rulemaking to limit working hours. The comments on the petition indicate that the Commission's approach to personnel fatigue is a matter of public interest and confidence. The staff believes that granting the petition would increase public confidence.

OPTION 2: Amend Part 26 to establish thresholds for work hour controls. Provide flexibility and ensure focus on safety through a risk-informed deviation process. Amend Part 26 and RG 1.134 to ensure that fatigue from any cause is addressed through existing licensee programs.

The staff believes that the petitioner's proposal, if implemented, would provide significantly greater assurance than the current regulatory framework that personnel are not impaired by fatigue. However, the staff believes that Option 2 would be equally effective while affording the added benefits of increased scheduling flexibility, better focus on risk, and better alignment and integration with existing programs, including the use of licensee corrective action programs to support a performance-based approach.

The general approach would be to establish requirements that parallel current policy guidelines but correct identified deficiencies in the policy. Option 2 would establish base limits on personnel work hours that are consistent with human capabilities and physiological need for rest. These base limits would provide a high level of assurance that personnel working within these limits are not impaired by working excessive hours. Licensees would be able to authorize individual deviations from these limits, should operational demands necessitate such deviations. However, the ability to authorize a deviation would be contingent upon a licensee assessment that impairments in personnel performance would not present an undue risk. To ensure that use of deviations does not become excessive, licensees would be required to monitor the use of deviations and establish thresholds and criteria for initiating corrective action.

Work Hour Limits - The staff would propose to amend Part 26 to establish a uniform threshold for controlling work hours. The staff's review of the policy indicates that the current policy limits allow too many hours of work and insufficient time for rest to ensure that personnel working within the limits are not impaired by fatigue from working excessive hours. Specifically, the limit of no more than 16 hours in any 24-hour period is too high to ensure that personnel are not impaired by acute fatigue. Studies have shown marked increases in risk of accidents with increasing time since awakening. Other research has shown that individuals awake for 17 to 18 hours, as might be anticipated with a 16-hour shift, have performance impairments comparable to individuals with a blood alcohol content (BAC) of 0.05.³ Similarly, the limit of 72 hours in a 7-day period does not appear adequate to prevent cumulative fatigue. The staff has also found that the current requirement of at least an 8-hour break between work periods does not ensure that personnel have the opportunity for the 8 hours of sleep most people need to ensure adequate recovery. In addition, the staff has learned through interactions with stakeholders that the limit of 24 hours in any 48-hour period requires an authorized deviation for personnel on 12-hours shifts when, in many cases, only small amounts of overtime are worked. The staff proposes to work with stakeholders throughout the rulemaking process to develop work hour limits that are technically sound and compatible with practical work scheduling constraints.

Exceptions to Work Hour Limits - The staff proposes to allow licensees to authorize individual deviations from the limits contingent upon a licensee finding of no undue risk. This approach is similar to that of 10 CFR 50.65(a)(4) for managing the risk associated with maintenance activities. The staff believes that such assessments could be achieved through a relatively simple assessment tool (e.g., a check sheet or matrix) that structures a review of (1) the risk significance of the work to be performed, (2) the sensitivity of the work to degradations in human performance, and (3) the ability to mitigate (e.g., through independent verification) the effect of potential personnel impairments on plant operational safety.⁴ The staff would propose the development of a regulatory guide to define an acceptable method and criteria for conducting this assessment and initiating corrective action to ensure that the frequency of deviations do not present an undue risk.

Since these proposed requirements are similar to the current policy guidance, they would not impose a significant burden by requiring substantial changes in the processes currently used to control overtime. In addition, Option 2 would correct deficiencies in the current regulatory approach by establishing thresholds for the control of working hours that are more technically sound, ensure that the use of deviations are controlled consistent with risk, and that corrective actions are initiated upon indication that use of deviations was excessive.

Other Causes of Fatigue - The staff acknowledges that work hours are only one of many causes of fatigue and that, by itself, the control of work schedules does not ensure personnel are not impaired by fatigue. Accordingly, the petitioner has proposed requirements to address fatigue from causes other than work scheduling. Similarly, the staff believes that addressing fatigue from any cause through methods that support the early detection and prevention of

³ For purposes of comparison, 10 CFR Part 26, "Fitness for Duty Programs," establishes a BAC limit of 0.04.

⁴ Integrated approaches for managing risk and personnel fitness for duty are currently being used in several industries in Australia, including power production facilities.

fatigue would be (1) a substantial enhancement to the level of assurance that personnel are fit for duty, and (2) consistent with the Commission's directive provided in its SRM, "SECY-88-129, Proposed Rulemaking — Fitness for Duty Programs," dated July 18, 1988. This SRM directed the staff to develop Part 26 requirements for licensees to establish "a fitness for duty program to detect a broad range of possible impairments to the ability of personnel to perform their duties."

Option 2 would be responsive to the Commission's directive and the current objective of Part 26. Option 2 would accomplish this goal through incremental changes in Part 26 that would broaden the focus of existing requirements so that the measures licensees currently use to ensure personnel FFD effectively address the prevention and detection of fatigue. Specifically,

- Section 26.21 establishes FFD policy communications and awareness training requirements, but the specific requirements only address drugs, alcohol, and dietary conditions. Option 2 would amend the current FFD training requirements of 10 CFR 26.21 to include training to understand the performance effects of fatigue, effective strategies and personal responsibility for obtaining adequate rest, and recognizing indications of sleep disorders.
- Section 26.22 establishes requirements for the training of supervisors and escorts. Option 2 would amend 10 CFR 26.22 to ensure that training of supervisors and escorts include (1) behavioral observation methods appropriate for the detection of personnel impaired by fatigue and (2) practical measures to identify and mitigate task and environmental factors that induce decreased alertness.
- Section 26.24(a)(3) requires "for-cause" chemical testing following any observed behavior indicating substance abuse. Approximately 80 percent of all for-cause FFD tests conducted annually produce negative results for drugs and alcohol. Many of the symptoms that would lead to for-cause testing for the presence of drugs and alcohol can also result from excessive fatigue. Option 2 would amend the requirements of 10 CFR 26.24(a)(3) to require, in addition to chemical testing for substance abuse, an assessment of fatigue for personnel determined to require for-cause testing. Such an assessment could be accomplished through questionnaire screening tools regarding the individual's recent work-sleep history. This approach is performance based and would facilitate the identification of appropriate corrective action in the large number of instances that for-cause testing provides no indication of substance abuse and no additional insight concerning the cause of the apparent impairment. Effective identification and corrective action for impairment from fatigue are particularly important because personnel fatigue can be the result of programmatic deficiencies in scheduling that could widely affect the FFD of plant staff.
- Section 55.21 requires a medical examination for operator license applicants to determine that their medical condition and general health will not adversely affect their ability to perform their assigned duties. A licensed operator is required to have a medical examination every 2 years. Sleep disorders, such as sleep apnea, are medical conditions that can (1) significantly reduce the quantity and quality of sleep that individuals are able to obtain, (2) affect an individual's ability to remain alert, and (3) ultimately degrade an individual's FFD. Such conditions are not uncommon, but are

frequently undiagnosed.⁵ The petitioner has proposed amending Part 55 and revising NRC Form 396 to require evaluation and self-disclosure of sleep disorders. The staff believes that the existing regulatory requirements of 10 CFR Part Part 55 are adequate to address sleep disorders for license applicants and holders but proposes to clarify the expectation that sleep disorders are addressed through the initial and periodic medical examinations. This objective would be met by revising NRC Regulatory Guide (RG) 1.134, Medical Evaluation of Licensed Personnel at Nuclear Power Plants,” to add an exception to Section C, “Regulatory Position,” to reference sleeping disorders. Since RG 1.134 applies only to licensed operators, the staff will consider the means to address other covered positions.

ASSESSMENT OF OPTION 2

A. Ensures personnel are not impaired: Option 2 would provide greater assurance than the current regulatory framework that personnel are not impaired by fatigue. This goal would be accomplished, in part, by establishing base limits on work hours that are more consistent than the current policy guidelines with human capabilities and physiological need for rest. Deviations from these work hour limits would cause a higher risk of personnel impairment. Option 2 would allow deviations, but such deviations would be (1) contingent upon a licensee assessment of no undue risk to plant operational safety and (2) subject to controls that ensure that the frequency of deviations would not be excessive and that appropriate corrective actions are initiated when needed. In comparison to Option 1, Option 2 would allow more “deviations.” Option 1 allows exceptions from the limits only in prescribed circumstances. However, under Option 1, the staff notes that the proposed limits for outages and extended outages could present a greater risk of impairment (without deviations) than the staff would anticipate with the uniform work hour limits of Option 2.

Similar to Option 1, Option 2 addresses fatigue from causes not currently addressed in the policy. The proposed requirements are largely comparable. However, Option 2 would require the assessment of fatigue whenever an individual does not appear fit for duty and is tested for-cause. In contrast, the petitioner has proposed the evaluation of fatigue only for specific events or conditions that occur when a licensee is using the higher work hour limits allowed for extended shutdowns. The staff believes that Option 2 provides a more comprehensive and performance-based approach.

B. Responsive to plant risk and the likelihood of personnel impairment: In general, Option 2 would be responsive to risk by focusing the requirements on personnel who may directly affect plant operational safety through the performance of their assigned duties. In addition, Option 2 would address the likelihood of personnel impairment by revising the work hour guidelines of the current policy when insights concerning the potential for fatigue indicate that such revisions can be justified. The objective of proposed work hour limits would be to attain a high level of assurance that individuals working within the limits are at a minimum potential for impairment from fatigue caused by excessive work hours or inadequate opportunity for rest.

⁵ The prevalence of sleep apnea is estimated to be 4 percent for adult males and 2 percent for adult females (Young et al., 1993; 1997).

In contrast to the current policy and Option 1, Option 2 would establish uniform controls on work hours, regardless of plant state (e.g., operating or in outage).⁶ However, Option 2 would be responsive to plant risk by allowing individual deviations from the work hour limits contingent upon a licensee finding, using a structured assessment process that considers the tasks to be performed and the plant configuration, that the deviation did not present an undue risk. Such a process would be more responsive to plant risk than global categorizations of plant state such as operating or shutdown. In addition, this approach would ensure that personnel likely to be impaired by fatigue are not assigned to tasks that could affect plant operational safety yet allow licensees to effectively use these personnel resources for other activities for which they are fit.

C. Regulatory burden: Similar to Option 1, Option 2 could increase burden on some licensees by establishing working hour limits that would cause them to either increase staffing or adopt less aggressive outage scheduling practices. However, on the basis of a review of deviations from the current policy (see Attachment 1), the staff anticipates that this burden would be minimal for roughly two-thirds of the plants. In addition, the risk-informed approach for authorizing deviations proposed in Option 2 would likely allow greater scheduling flexibility and have a lesser impact on staffing needs than Option 1, which prescribes limited circumstances in which deviations can be authorized. In fact, the requirements of Option 2 would not cause any licensee to increase staffing unless the licensee's corrective action program found that their use of deviations from the work hour thresholds was indicative of a staffing shortage that could not be resolved through alternative work or personnel scheduling practices.

Option 2 would impose an initial burden to establish a risk-informed deviation process. As in Option 1, licensees would also have the increased burden of enhancing behavioral observation training for supervisors to detect fatigue impaired personnel and fitness-for-duty training for personnel concerning the effects of fatigue and mitigation strategies. The staff notes that the overall burden of Option 2 would not be substantial in that the proposed requirements would cause licensees to effect small changes in existing programs but would not require the development of entirely new programs or procedures.

D. Establishes clear expectations: Option 2 would address identified ambiguities in the current policy and, consequently, would establish significantly clearer expectations concerning the control of working hours. The deviation process proposed in Option 2 would likely be based on a qualitative risk assessment conducted in a manner consistent with guidance provided in a regulatory guide. Whereas the staff would anticipate that this process would provide a more well-defined process than currently used under the policy, it is reasonable to anticipate that this process would involve more subjectivity than the approach of Option 1 that defines the circumstances in which exemptions from the work hour limits are allowed.

E. Increases public confidence: As noted previously, the petition comments indicate that the Commission's approach to personnel fatigue is a matter of public interest and confidence. The

⁶ Risk insights concerning low-power and shutdown operations (NUREG-1449, "Shutdown and Low-Power Operation at Commercial Nuclear Power Plants in the United States") indicate that under certain conditions, plant risk during shutdown can be comparable to power operations. In addition, outages can present increased challenges to reliable human performance. As a result, the current policy guidelines for the control of working hours during outages may not be appropriately responsive to plant risk.

staff believes that rulemaking to address personnel fatigue, as defined in Option 2, would increase public confidence. The staff anticipates, however, that a risk-informed process for deviating from the work hour limits would be a matter of public interest that would require clear communication concerning how the process is consistent with maintaining public health and safety.

OPTION 3: Amend Part 26 to establish thresholds for work hour controls and a defined process for controlling exceptions

Option 3 would amend Part 26 to establish only the work hour controls described in Option 2 and a process for deviating from the limits.

Work Hour Limits - The staff would amend Part 26 to establish controls on work hours consistent with the proposal of Option 2.

Exceptions to Work Hour Limits - In addition to establishing thresholds for the control of working hours, the staff would amend Part 26 to define an acceptable method for licensees to authorize exceptions to meet operational demands and constraints while ensuring that licensees continue to meet the objective of the work hour limits. The staff would anticipate considering two approaches for controlling deviations from the limits on working hours. As described in Option 2, one approach would be to define a process for authorizing deviations based on risk and to require a process for monitoring the use of deviations to ensure that the use of deviations does not become excessive and that appropriate corrective actions can be initiated. An alternative approach would be, as in Option 1, to define the circumstances in which exceeding the limits would be acceptable. Such circumstances would likely include (1) activation of the Emergency Plan under 10 CFR 50.47, (2) unavailability of personnel because of severe weather or natural disaster, or (3) plant transients or initiation of an engineered safety feature.

ASSESSMENT OF OPTION 3

A. Ensures personnel are not impaired: Option 3 would provide greater assurance than the current regulatory framework that personnel are not impaired. Option 3 would accomplish this goal in the same manner as Option 2 by addressing identified weaknesses in the current policy guidelines. As in Option 2, Option 3 would allow deviations from the work hour limits. Such deviations would cause a higher risk of personnel impairment. The cumulative risk of impairment would vary, depending on the approach used to limit deviations. Following the approach proposed in Option 1 (i.e., limiting deviations to prescribed circumstances) would substantially limit the occurrence of deviations and the associated risk of personnel impairment. Following the approach proposed in Option 2 would potentially allow significantly more deviations, and risk of impairment, but such deviations would be (1) contingent upon a licensee assessment of no undue risk to plant operational safety and (2) subject to controls that ensure that the frequency of deviations did not become excessive.

Unlike Option 2, Option 3 would (1) not require training of personnel in fatigue mitigation, (2) not require training of supervisors in behavioral observation for fatigue, (3) not require the assessment of fatigue for personnel identified to be tested for cause, and (4) would not provide guidance for the screening of sleep disorders and implementation of appropriate compensatory measures. Rather, Option 3 would provide no measures that directly address fatigue from

causes other than working hours and would consequently be less effective than either Options 1 or 2 in ensuring that personnel are not impaired by fatigue.

B. Responsive to plant risk and the likelihood of personnel impairment: Option 3 would be responsive to the likelihood of personnel impairment from work scheduling factors as described for Option 2. Specifically, the work hour limits of Option 3 would have the objective of minimizing the potential for personnel impairment from fatigue caused by work scheduling. Regarding responsiveness to plant risk, Option 3 would establish a uniform limit on work hours, regardless of whether a plant was in outage or operating. Consequently, the responsiveness of this option to plant risk would be dependent on whether deviations were controlled using a risk-informed process for authorizing deviations or limited to pre-defined circumstances.

C. Regulatory burden: The burden for Option 3 would be less than Options 2 and 3 because licensees would not have the increased burden of enhancing behavioral observation training for supervisors, enhancing FFD training for workers to address fatigue, or evaluating fatigue as a cause when individuals have for-cause FFD testing. Although, as described for Option 2, the use of a risk-informed process for authorizing deviations would impose an initial burden of developing the process, this risk-informed approach would impose less burden than prescribing limited circumstances in which deviations can be authorized, as proposed in Option 1. The latter approach has the potential to be significantly more restrictive for licensee shift scheduling practices and to have greater impact on staffing needs.

D. Establishes clear expectations: Like Options 1 and 2, Option 3 would address identified ambiguities in the current policy and consequently would establish significantly clearer expectations concerning the control of working hours. Prescribing the circumstances in which limit deviations would be allowed would likely provide greater clarity of expectations than a risk-informed deviation process.

E. Increases public confidence: The staff believes that rulemaking to address personnel fatigue, as defined in Option 3, would increase public confidence. As described for Option 2, the staff anticipates that a risk-informed process for deviating from the work hour limits would be a matter of public interest, given the perception expressed in public comment on the PRM that, although permitted, licensees have deviated excessively from the current policy guidelines.

OPTION 4: Amend Part 26 to establish requirements for assessing and managing the risks associated with schedules and conditions that cause fatigue and impaired alertness. Amend Part 26 and RG 1.134 to ensure that fatigue from any cause is addressed through existing licensee programs.

Option 4 would amend Part 26 to establish a general requirement that licensees assess and manage risks associated with fatigue and impaired alertness of nuclear power plant personnel. As a consequence, Option 4 would not establish specific work hour limits. Rather the regulation would define the necessary factors that must be addressed in assessing a schedule or known condition (e.g., presence of a sleep disorder or use of a medication that may cause drowsiness) for the potential to induce fatigue or impaired alertness. Licensees would determine the actions necessary to manage any associated risk based on the assessment of the potential for personnel fatigue and the risk significance of the work to be performed. Management of the assessed risks could be accomplished through various methods including: (1) redesign of a schedule to reduce the frequency or duration of work periods with high potential for fatigue,

(2) work control measures that ensure the highest risk activities are performed during periods when personnel are least likely to be fatigued, (3) reassignment of tasks among personnel to ensure that the highest risk activities are performed by the personnel who are least likely to be fatigued, and (4) compensatory measures (e.g., independent verification) that reduce the likelihood of degraded personnel performance resulting in adverse consequences. Licensees would be required to monitor their performance in managing these risks to ensure that they are limited to the extent practicable.

Work Hour Limits - None. Rather than specify limits on work hours, as proposed in Option 1, or specify thresholds for implementing work schedule controls as proposed in Options 2 and 3, Option 4 would require licensees to assess and manage the risks associated with the potential for fatigue and impaired alertness. As a consequence, licensees would assess work schedules and conditions for the potential for fatigue to degrade personnel performance and determine the appropriate risk management actions that may be necessary based upon consideration of the risk significance of the activities to be performed and safety responsibilities of the individuals on the work schedule. Although a licensee may elect to limit work hours in response to this assessment, the licensee could use other methods, as described previously, to manage any associated risk.

Exceptions to Work Hour Limits - Not applicable. Because Option 4 does not establish work hour limits, no process is prescribed for limit exceptions. However, licensee assessments of work schedules and conditions for their potential to induce fatigue or impaired alertness would be required to encompass the actual schedule and conditions. Work hours that are not encompassed by an assessment (e.g., unscheduled overtime) would require an assessment that addresses the specific circumstances. As a consequence, this process would be similar to that proposed under Option 2 for schedule exceptions. However, the staff notes that this approach focuses on the specific circumstances that may contribute to fatigue rather than the size of a deviation from a routine or baseline schedule. As a result, a deviation of a given magnitude (e.g., 8 hours) may be found to have negligible effects on the potential for fatigue induced impairment at one point in a schedule and appreciable effects at some other point in a schedule. It would follow that the actions deemed appropriate for risk management could be markedly different in these two circumstances.

Assessments: Licensees would be required to assess (1) work schedules and conditions for the potential for fatigue to degrade personnel performance, in conjunction with (2) the nature of the work and safety responsibilities (e.g., emergency response, worker radiological safety, plant security) of the personnel on the work schedule.⁷ The criteria for assessing work schedule for the potential for fatigue to degrade the ability of plant personnel to perform their duties, would include as a minimum: (1) acute fatigue, including consideration of the total duration of work period and nature of the work, (2) cumulative fatigue, including consideration of a relevant history of preceding work periods and sleep opportunities; and (3) circadian variations in human alertness and performance. The staff would anticipate that schedule assessments would be conducted using a quantitative fatigue index that summarized the combined influence of these

⁷ The staff anticipates that a screening process could be used to preclude the need for assessment of schedules or conditions for personnel who perform work, or who have responsibilities, that are not substantively related to maintaining plant operational safety.

factors.⁸ The criteria for assessing the nature of the individual's planned activities and emergency response duties would include: (1) the risk significance of the work that is performed (e.g., whether the individuals operate or maintain systems, structures, or components that a risk-informed evaluation process⁹ has shown to be significant to public health and safety) and (2) the sensitivity of the work to degradations in human performance, and (3) the ability to mitigate through compensatory measures (e.g., independent verification) the effect of potential personnel impairments on plant operational safety.

Performance Monitoring: Licensees would be required to monitor their effectiveness in limiting the risks associated with the use of personnel whose abilities are potentially impaired by fatigue or impaired alertness. As a minimum, licensees would be required to monitor the incidence of significant conditions adverse to quality involving personnel that the licensee found to be at increased potential for fatigue-related impairment.

Other Causes of Fatigue: Option 4 would require licensees to manage the risk associated with known conditions, in addition to work schedules, that cause fatigue or impaired alertness and thereby substantively impair performance. These conditions would include sleep disorders and use of medications that may cause drowsiness. Licensees would be required to consider these conditions in conjunction with personnel work assignments and safety responsibilities and manage any associated risk accordingly.

Option 4 would also establish the same requirements proposed in Option 2 to address fatigue from causes other than work scheduling. Because such causes may be difficult to detect or address directly, the proposed measures are in addition to those described above for "known" conditions and use a defense-in-depth approach to prevent fatigue, detect fatigue-induced impairments, and mitigate the effects of fatigue on personnel performance and plant operational safety. Briefly, these are incremental changes in current Part 26 requirements to ensure: (1) training of personnel in the performance effects of fatigue, effective strategies for obtaining adequate rest, and recognizing indications of sleep disorders, (2) training of supervisors in behavioral observation of fatigue and practical fatigue mitigation strategies, and (3) assessment of fatigue for personnel determined to require for-cause testing for drugs and alcohol. In addition, the staff would revise RG 1.134 to clarify the expectation that sleep disorders are addressed through initial and periodic medical examinations.

ASSESSMENT OF OPTION 4

A. Ensures personnel are not impaired: Option 4 does not establish specific limits on work schedules and does not preclude the use of schedules that could result in personnel

⁸ For example, the United States Air Force has developed a metric to guide the scheduling of flights for pilots. In the United Kingdom, the Health and Safety Executive is working with the Defence Evaluation and Research Agency to develop a fatigue index for risk assessment of safety-critical work, including work at nuclear power plants.

⁹ The staff anticipates that the "risk-informed evaluation process" would be the same or equivalent to those used by licensees to meet the requirements of Section a(4) of 10 CFR 50.65, "Requirements for monitoring the effectiveness of maintenance at nuclear power plants."

impairment. However, Option 4 requires licensees to limit and manage the risks associated with the potential for fatigue or impaired alertness to degrade the ability of personnel to perform their duties. Licensees may meet this objective through work schedules that minimize the potential for fatigue-induced impairment, controls that reduce the potential consequences of performance degraded by fatigue, or a combination of these approaches. Option 4 would establish the same requirements as Option 2 to ensure that licensees establish specific measures to address fatigue from causes other than work scheduling. However, Option 4 would also require licensees to manage the risk associated with conditions, in addition to work schedules, that could cause fatigue or impaired alertness. These conditions would include sleep disorders and use of medications that may cause drowsiness.

B. Responsive to plant risk and the likelihood of personnel impairment: Option 4 would be responsive to plant risk and the likelihood of personnel impairment. Licensees would be required to limit the risks associated with work schedules and known conditions that can cause fatigue or impaired alertness consistent with their assessment of the risk significance of the work to be performed.

C. Regulatory burden: Relative to Options 1 through 3, Option 4 would likely impose the most burden for the development and implementation of the controls but would also provide the most flexibility of the four rulemaking options with respect to the scheduling of personnel. Option 4 would impose a burden on licensees to develop the methods for assessing the risks associated with personnel fatigue and impaired alertness and the processes to be used to manage these risks. Although metrics for assessing work schedules with respect to the potential for fatigue and degraded alertness have been developed and used in other industries, these approaches are relatively new and the staff is not aware of widespread use in the nuclear power industry. As a result, the staff anticipates that licensees would have to develop a metric or adopt an existing metric and validate it for use with nuclear power plant workers and the staff would need to develop appropriate review and inspection guidance. Similarly, licensees would need to develop a protocol for assessing the nature of the work and safety responsibilities of workers. Although broad qualitative risk categories could be adequate in this circumstance for assessing the risk significance of particular activities (e.g., a category could be whether the individuals operate or maintain systems, structures, or components that a risk-informed evaluation process has shown to be significant to public health and safety), licensees would need to establish such a system and integrate it with the fatigue metric to provide a tool or process that would support effective decisions concerning work scheduling and management of the associated risks.

D. Establishes clear expectations: Option 4 would establish general requirements limiting and managing the risks associated with the potential for fatigue-related impairments of personnel. Absent an endorsed standard and thresholds defining acceptable and unacceptable performance, Option 4 would not provide the clarity of expectations provided by Options 1 through 3 and would not likely provide clearer expectations than afforded by the current policy. Linking the implementation of Option 4 to an endorsed standard could address these concerns in part, and reduce the potential for (1) considerable variation in licensee practices, (2) the need to assess licensee practices on a case-by-case basis, and (3) difficulty in NRC enforcement of the requirements.

E. Increases public confidence: Option 4 would likely enhance public confidence relative to the status quo. However, the staff does not believe that Option 4 would increase public confidence

to the extent anticipated for Options 1, 2 and 3. Option 4 would not provide the clarity of expectations afforded by Options 1 through 3.

ALTERNATIVE APPROACHES

The staff considered the implications of addressing this regulatory issue, in part, through an industry initiative or maintaining the status quo.

To date, the industry has not set forth a proposal to address personnel fatigue in any manner not currently required under the existing regulatory framework. If the industry were to develop an initiative, the staff believes that beneficial industry activities would include developing (1) a standardized approach for controlling deviations from base work hour limits (as proposed in Options 2 and 3) and (2) methods for implementing fatigue management concepts that more broadly address the fundamental issue of personnel fatigue (as proposed in Options 1, 2 and 4). The staff believes that initiatives or involvement by the nuclear industry, in either or both of these areas, would be consistent with current initiatives by labor and trade organizations in the transportation industry to establish fatigue management programs. The staff notes, however, that such programs are adjuncts to existing Department of Transportation hours of service requirements. More importantly, industry initiatives described above could serve to ensure that controls on working hours are both technically sound and practical, and that FFD programs address fatigue broadly to ensure that personnel are not impaired by fatigue from any cause. The actual benefits obtained would be largely dependent on the specific guidance developed and success achieved in gaining broad and sustained implementation.

The Commission could opt to deny the petition for rulemaking. In this instance, the staff would propose revising the policy statement. Such an approach could be used to clarify the Commission's expectations concerning the control of work hours for personnel performing safety-related functions. However, since policy guidelines are not enforceable, the revised guidelines could not be used to limit the number of deviations that licensees authorize from the guidelines nor would it address concerns regarding the ability of the NRC to efficiently and effectively enforce the current technical specification and Part 26 requirements concerning working hours and fatigue. In addition, denying the petition would not effectively address concerns with the technical adequacy of plant technical specifications limiting working hours. The staff also notes that in 1993, an NRC regulatory review group (RRG) found that "Although the Commission clearly intended that this [fatigue] policy statement become a de facto requirement by its incorporation in plants' technical specifications, such is not the case for policy statements in general." The RRG recommended "the elevation of non-requirements, such as policy statements, into requirements and the regulatory status of policy statements in general be given further consideration" (Regulatory Review Group, Volume 3, Operating Licences, August 1993).

RECOMMENDED APPROACH

The staff recommends Option 2. This option would amend Part 26 to establish thresholds for work hour controls and require that hours worked in excess of these thresholds be controlled using a risk-informed process. This option would also ensure that fatigue from any cause is addressed through minor adjustments to existing licensee programs, particularly those focused on performance, and that excessive deviations from the work hour thresholds would be addressed in a timely manner through the licensee's corrective action program. As a result, the

staff believes that Option 2 provides a graded approach that is flexible, comprehensive, and appropriately focused on risk. Any increased burden on licensees to comply with the requirements of this option would largely be associated with licensee actions initiated through their corrective action program to reduce the incidence of personnel working excessive hours while performing safety-related functions. The staff proposes to develop Option 2 considering the guidelines for risk-informed regulation described in SECY-00-0213, "Risk-Informed Regulation Implementation Plan."

SCOPE OF REQUIREMENTS

The prospect of rulemaking to address personnel fatigue raises the question of the appropriate scope of facilities and personnel to whom the requirements should apply. The staff believes that the following information is relevant to this decision.

The current policy states that the controls on working hours shall apply to "personnel who perform safety-related functions (e.g., senior reactor operators, reactor operators, health physicists, auxiliary operators, and key maintenance personnel)." In GL 83-14, "Definition of 'Key Maintenance Personnel' (Clarification of Generic Letter 82-12)," dated March 7, 1983, the NRC stated —

Key maintenance personnel are those personnel who are responsible for the correct performance of maintenance, repair, modification or calibration of safety-related structures, systems, or components, and who are personnel performing or immediately supervising the performance of such activities.

Licensees have individually determined the particular individuals or job categories that meet these criteria. As described in the policy assessment, the staff has found variation among nuclear plant sites in the number and type of personnel for whom licensees have controlled work hours in accordance with this guidance.

In PRM-26-2, the petitioner has proposed limits on working hours for personnel who perform safety-related work. The petitioner does not further define this scope of personnel except to note that the proposed limits "apply to an individual regardless of work location or employer." However, the information and discussion presented by the petitioner appear to apply only to nuclear power plant workers. The staff notes that the principal amendments proposed in PRM-26-2 would be to Part 26, "Fitness for Duty Programs," which specifies requirements for a broader scope of personnel than the petitioner has proposed for requirements pertaining to fatigue. In general, Part 26 requirements apply to —

. . . licensees authorized to operate a nuclear power reactor, to possess or use formula quantities of SSNM [special strategic nuclear material], or to transport formula quantities of SSNM. Each licensee shall implement a fitness-for-duty program which complies with this part. The provisions of the fitness-for-duty program must apply to all persons granted unescorted access to nuclear power plant protected areas, to licensee, vendor, or contractor personnel required to physically report to a licensee's Technical Support Center (TSC) or Emergency Operations Facility (EOF) in accordance with licensee emergency plans and procedures, and to SSNM licensee and transporter personnel who [meet specific criteria defined in 10 CFR 26.20].

Upon consideration of the current scope of NRC requirements concerning working hours and fatigue, and the information presented by the petitioner, the staff proposes the following:

Any rulemaking to develop work schedule limits should only apply to licensees authorized to operate nuclear power reactors, and that materials licensees otherwise subject to Part 26 pursuant to Section 26.2(a) should be excluded from the scope of this rulemaking. This determination is based upon the following considerations: (1) the current NRC policy statement on personnel fatigue applies only to nuclear power plants and does not currently cover materials licensees subject to Part 26; (2) unlike the information available for overtime usage at nuclear power reactors, there is no data or anecdotal evidence regarding excessive overtime use by materials licensees subject to Part 26 and based on the staff's understanding of current operating practices at the two licensed materials facilities that are within the scope of Part 26, it is the staff's belief that those facilities are not using extensive overtime; and (3) the staff does not expect that a fatigue induced error at a materials facility subject to Part 26 would result in significant offsite radiation consequences. Consequently, the staff believes that for materials licensees subject to Part 26, the proposed rulemaking would result in higher costs to establish controls to meet the requirements without a corresponding substantial safety benefit.

With respect to nuclear power plants, the staff notes that it is currently implementing a separate rulemaking plan described in SECY-00-0022, dated February 1, 2000, that could result in a change in scope of personnel at nuclear power plants subject to certain requirements of Part 26, specifically the unannounced (random) drug and alcohol tests required by 10 CFR 26.24. The proposed change would result in graded requirements, with fewer controls on personnel whose duties are not likely to have a direct impact on plant operational safety. The staff believes that such a model may be appropriate for controls concerning fatigue and proposes to develop requirements concerning scope of personnel subject to controls concerning fatigue consistent with this approach.

With respect to decommissioning facilities, the staff is currently re-evaluating the need to address Part 26 in the proposed integrated rulemaking plan for power plant decommissioning. The staff will develop the scope of the proposed rulemaking concerning personnel fatigue consistent with this evaluation and the integrated rulemaking plan for power plant decommissioning.

BACKFIT CONSIDERATIONS

The staff believes that the proposed rulemaking would have backfit implications and would require a backfit analysis under 10 CFR 50.109(a)(4). The staff will prepare a backfit analysis as part of the rulemaking process to determine whether the recommended regulatory changes in this rulemaking plan would result in a substantial increase in protection to public health and safety, and whether the costs of the proposed rule would be justified.

THE OFFICE OF THE GENERAL COUNSEL (OGC) LEGAL ANALYSIS

The overall purpose of this rulemaking, as we understand it, is to establish clear, enforceable requirements for addressing fatigue at nuclear power plants, primarily through some form of control of work schedules. Although the NRC staff (staff) has had ongoing efforts to evaluate the impact of fatigue on nuclear power plant operations, this proposed rulemaking was

instigated by the submission of a petition for rulemaking (PRM). The staff developed four regulatory options that would be implemented by rulemaking to address worker fatigue at nuclear power plants:

- Option 1 Work hour limits and exceptions to those limits, as proposed by petitioner, specified in rule; training of personnel, supervisors and managers on fatigue mitigation required in rule; licensed operators under 10 CFR Part 55 required by rule to self-disclose sleeping disorders.
- Option 2 Work hour limits and exceptions to those limits, as developed by NRC staff, specified in rule, but exceptions to work hour limits would be based upon consideration of risk; fatigue from causes other than work schedules to be addressed by rule and regulatory guide, through extension of existing FFD programs and activities.
- Option 3 Work hour limits and exceptions to those limits, as developed by NRC staff, specified in a rule; fatigue from other causes, and FFD activities to manage fatigue such as training, self-disclosure and other activities for managing fatigue would *not* be addressed in the rule.
- Option 4 Require licensees to assess and manage risks associated with fatigue of workers, and monitor their “effectiveness in limiting the risks associated with the use of personnel who are potentially impaired.” Similar to Option 2, fatigue from causes other than work schedules to be addressed by rule and regulatory guide, through extension of existing FFD programs and activities.

After review of the Atomic Energy Act of 1954, as amended (AEA), we conclude that Sections 103, 104, 161, and 182 of the AEA provide the Commission with sufficient authority to promulgate any of the four rulemaking options being contemplated by the staff. We have not identified any legal basis for objecting to any of the four rulemaking options. Nonetheless, the proposed rulemaking is likely to be controversial, inasmuch as the Nuclear Energy Institute has expressed opposition to regulatory action in this area. We offer the following observations with respect to the proposed rulemaking.

NEI has argued (in written comments submitted on the petition for rulemaking as well as in oral presentations at a public meeting) that there is no information showing either a pattern of excessive use of overtime, or that worker fatigue was the cause of, or significantly contributed to, an accident or significant non-compliance with NRC requirements. In light of NEI’s arguments and data presented on overtime use at nuclear power plants, we believe that the staff will have to address the industry data and develop appropriate bases for proceeding with rulemaking in this area.

As currently envisioned by the staff, the proposed fatigue requirements would apply only to nuclear power plant licensees, and not to materials licensees who are otherwise subject to the general FFD requirements in Part 26. We believe that the staff has identified legally-defensible grounds for limiting the applicability of the rule to nuclear power plant licensees and excluding material licensees who are otherwise subject to the current FFD requirements in Part 26.

Options 2 and 4 rely in part upon regulatory guides to address fatigue from causes other than work scheduling. Regulatory guides are not legally-binding requirements and do not provide a basis for NRC enforcement action. In the absence of an overall industry commitment to implement the regulatory guides, the Commission's goals for the management of fatigue may not be achieved at all nuclear power plant licensees.

Option 4 does not set forth specific work schedule limits or factors for evaluating deviations from the limits, nor does it require licensees to adhere to the schedules and to explain deviations from the schedules. Moreover, unlike a true performance-based regulatory approach, this option does not set forth a clear performance threshold. Finally, since we understand (based upon discussions with the staff) that it is difficult to identify fatigue as a root cause of either adverse conditions at a nuclear power plant or adverse worker performance, we believe it will be difficult to take any enforcement action under this option. The regulatory approach embodied in Option 4 will share some of the enforcement difficulties present in the existing regulatory approach.

The proposed rule will require preparation of an environmental assessment, as it appears that there are no categorical exclusions in 10 CFR 50.51(c) that would apply to the proposed rule.

We believe that all four rulemaking options would constitute a backfit as defined in 10 CFR 50.109(a)(1). We believe that it would be difficult to successfully assert that any of the exceptions set forth in 10 CFR 50.109(a)(4)(i) through (iii) apply to any of the four rulemaking options for the proposed rulemaking. Accordingly, we believe that a backfit analysis should be prepared for the proposed rulemaking to determine whether the proposed rule constitutes a substantial increase to protection of public health and safety, and whether the direct and indirect costs of the proposed rule are justified in view of this increased protection.

The rulemaking plan reflects the staff's position that the proposed rule would not constitute a "major rule" under the Small Business Regulatory Enforcement Fairness Act. However, the rulemaking plan does not contain sufficient information to determine whether any of the four rulemaking options is likely to result in a \$100 million impact upon nuclear power plant licensees and their contractors. It is possible that nuclear power plant licensees would argue that reduced flexibility in scheduling of workers during outages and maintenance from any of the four rulemaking options could lead to longer outages and a consequent need for replacement power purchases that could exceed \$100 million annually when totaled across the entire nuclear power industry. If the proposed rule is a major rule, there is a statutorily mandated 60-day period to allow for Congressional review before the final rule becomes effective.

All of the options for the proposed rule will require licensees to change their existing operating procedures to reflect the new requirements on fatigue. In addition, licensees will have to keep new records to demonstrate their compliance with the requirements under any of the four rulemaking alternatives. Therefore, the proposed rulemaking will likely require Office of Management and Budget (OMB) review and approval under the Paperwork Reduction Act.

In accordance with the National Technology Transfer and Advancement Act of 1995, P.L. 104-113, the staff should determine whether there are any consensus codes and standards with respect to work hour limitations that could be endorsed in rulemaking as an alternative to NRC development of requirements addressing worker fatigue. We note that if an industry group such as the Nuclear Energy Institute (NEI) were to develop guidance on work hour limitations

and/or the management of fatigue from all sources, that guidance would not *per se* constitute a “voluntary consensus standard” within the meaning of the NTTAA and implementing guidance in OMB Circular A-119¹⁰; the process by which the industry guidance was developed would have to be assessed against the four attributes of a “voluntary, private sector, consensus standard” as set forth in Circular A-119.

In conclusion, we have determined that there are no known bases for legal objection to any of the four options for the contemplated rulemaking.

COMPATIBILITY OF AGREEMENT STATE REGULATIONS

Under the “Policy Statement on Adequacy and Compatibility of Agreement State Programs” approved by the Commission on June 30, 1997, and published in the *Federal Register* on September 3, 1997 (62 FR 46517), Part 26 is classified as compatibility category “NRC.” The NRC program elements in this category are those that relate directly to areas of regulation reserved to the NRC by the AEA or provisions of Title 10 of the *Code of Federal Regulations*.

SUPPORTING DOCUMENTS

This rulemaking will require a detailed regulatory analysis, which the staff believes would show a substantial increase in protection to public health and safety, and anticipates that the costs of the proposed rule will be justified in view of that substantial increase in safety. Because there are no categorical exclusions that would apply to a proposed rule in this area, an environmental assessment prepared in accordance with 10 CFR 51.22 will be necessary to demonstrate that there are no significant impacts on the environment and public health and safety. If the Commission selects Options 2, 3, or 4 the staff will likely need to develop a regulatory guide that describes an acceptable method for controlling deviations from the work hour limits. OMB review is required and a clearance package will be forwarded to OMB no later than the date the proposed rule is submitted to the Office of the Federal Register for publication.

SMALL BUSINESS REGULATORY ENFORCEMENT FAIRNESS ACT

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC believes that this action is not a “major rule” and, before issuing the final rule, will verify this fact with the Office of Information and Regulatory Affairs, OMB.

RESOURCES

The total resource estimate for the staff to complete this rulemaking is approximately 3.2 full-time-equivalent (FTE), which is available within the current budget. FTE usage is estimated to be 1.3 FTE for Fiscal Year (FY) 2002, 1.1 FTE in FY 2003, and 0.8 FTE in FY 2004. Contractor technical assistance would include: (1) development of a regulatory guide supporting a rule, (2) development of a regulatory analysis, and (3) development of a backfit analysis. It is estimated that these items will cost \$300,000. The staff would anticipate initiating a technical assistance contract in FY 2002 with the majority of the expenditures in FY 2002 and

¹⁰63 FR 8546 (February 19, 1998).

FY 2003. Upon Commission approval of rulemaking, NRR will address needed contract funding in their internal budgeting and planning process.

LEAD OFFICE STAFF AND STAFF FROM SUPPORTING OFFICES

Lead Office - NRR: David Desaulniers

Support Offices: ADM - Alzonia Shepard
NRR/DRIP/RGEB - Melinda Malloy
OGC- Geary Mizuno
RES - Julius Persensky

INTEROFFICE MANAGEMENT STEERING GROUP

None. This rulemaking effort would not be expected to benefit from an interoffice management steering group.

ENHANCED PUBLIC PARTICIPATION

This rulemaking plan and any subsequent published proposed rule will be placed on the NRC's rulemaking Web site. This Web site allows users to submit comments electronically and review comments submitted by others. The staff plans to hold stakeholder workshops during development of the proposed rule.

EDO OR COMMISSION ISSUANCE

This rulemaking will be issued by the Commission.

SCHEDULE

Proposed Rule to the Executive Director for Operations (EDO)	18 months from date of SRM
Final Rule to the EDO	12 months from date of SRM following Commission review of proposed rule

