

RULEMAKING ISSUE
(Notation Vote)

June 22, 2001

SECY-01-0113

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: FATIGUE OF WORKERS AT NUCLEAR POWER PLANTS

PURPOSE:

To inform the Commission of the staff's findings from the assessment of the NRC's "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors."

To inform the Commission of the staff's proposed resolution of a petition for rulemaking concerning fatigue of workers at nuclear power plants.

To request Commission approval for the staff to proceed in accordance with the recommendations detailed in the attached rulemaking plan to develop a rule that addresses the regulatory issue of fatigue of workers at nuclear power plants.

BACKGROUND:

On February 18, 1982, the Nuclear Regulatory Commission (NRC) published the "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors" (policy). The objective of the policy was to ensure, to the extent practicable, that personnel were not assigned to shift duties while in a fatigued condition that could significantly reduce their mental alertness or their decisionmaking ability. The NRC subsequently revised the policy to incorporate minor changes and clarifications and disseminated the policy via Generic Letter (GL) 82-12, "Nuclear Power Plant Staff Working Hours," dated June 15, 1982. In GL 82-12, the NRC requested that licensees take action as necessary to revise the administrative section of their technical specifications to ensure that plant administrative procedures were consistent with the revised working hours guidelines. The policy has been incorporated, directly or by reference, into the

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technical specifications at all but three nuclear power plant units.¹ The control of working hours in accordance with these technical specifications was monitored through routine periodic inspections but was discontinued with the implementation of the revised reactor oversight process (RROP). This change continues to be considered appropriate and consistent with the general design of the RROP which is to identify indications of plant performance problems and initiate more focused licensee analyses and NRC inspections when program performance thresholds are exceeded.

In a letter dated February 25, 1999, Congressmen Dingell, Klink, and Markey expressed concerns to former NRC Chairman Shirley Ann Jackson that low staffing levels and excessive overtime may present a serious safety hazard at some commercial nuclear power plants. Similar concerns were expressed in a letter dated March 18, 1999, from David Lochbaum of the Union of Concerned Scientists (UCS) to Chairman Jackson, and in the UCS report "Overtime and Staffing Problems in the Commercial Nuclear Power Industry." The NRC staff conducted a preliminary review of inspection reports and licensee event reports from 1994 through April 1999. In conducting this review, the staff found that few events at nuclear power plants had been attributed to fatigue, and in all instances, automated safety systems or other barriers were available to prevent events that may have had safety consequences. However, the staff acknowledged that the number of events attributable to fatigue could not be reported with certainty, given the difficulty of making such determinations, and that NRC inspectors had identified several instances each year in which licensee use of overtime appeared to be inconsistent with the general objectives or specific guidelines of the NRC's policy statement. In a letter dated May 18, 1999, the Chairman informed the Congressmen of the staff's findings and stated that the staff would assess the need to revise the policy.

While the staff was beginning to reassess the policy, the Commission received a petition for rulemaking (PRM-26-2), dated September 28, 1999, from Barry Quigley. The petition requests that the NRC amend 10 CFR Parts 26 and 55 to establish clear and enforceable work hour limits to mitigate the effects of fatigue for nuclear power plant personnel performing safety-related work. The PRM was published in the *Federal Register* for public comment on December 1, 1999 (64 FR 67202). The staff subsequently formed a working group to concurrently assess the policy and respond to PRM-26-2. The assessment of the policy is provided as Attachment 1.

DISCUSSION:

The staff reviewed PRM-26-2 and considered the public comments received in response to the petition. A summary of the comments and the staff's analysis are provided in Attachment 2. The NRC received 176 comment letters in response to the petition. The majority of the comments (157) were in favor of a rule. These comments were principally from individuals and public interest groups. Comments received from licensees, the Nuclear Energy Institute (NEI) and Winston and Strawn, a law firm representing several utilities, were opposed to PRM-26-2.

Although the staff received many comments concerning the specific requirements proposed in PRM-26-2, in general, letters in support of the rulemaking (1) cited the importance of ensuring that personnel who perform safety-related functions are not impaired by fatigue, (2) expressed concern that the NRC did not have a regulation limiting working hours and the perception that

¹The three units that do not have technical specifications concerning work hours have administrative procedures that are largely consistent with the policy.

the NRC lacked the authority to enforce the policy guidelines, (3) asserted that the guidelines were ambiguous and interpreted as not applicable when the plant is in an outage, (4) asserted that “the NRC appears to look the other way” when licensee work scheduling practices appear inconsistent with the guidelines, and (5) expressed the concern that utility restructuring and cost competition will cause reductions in staffing levels and increased working hours and fatigue. Several commenters noted that the Federal Government had established work hour limits for personnel in other industries and suggested that similar limits should apply to nuclear power plant workers.

In general, comments that opposed the petition expressed the opinion that existing regulatory requirements (i.e., technical specifications and Part 26, “Fitness for Duty Programs”) were adequate to ensure that personnel were not impaired by fatigue, that the proposed requirements would impose unnecessary and excessive burden that could not be justified through a backfit analysis, and that industry performance data refute the petitioner’s argument that a rule is necessary to prevent fatigued personnel from performing safety-related work.

In evaluating the merits of the comments concerning PRM-26-2, the staff considered the findings from the staff’s assessment of the policy statement. The staff’s assessment included (1) an assessment of the technical adequacy of the guidelines for ensuring that personnel are not impaired, (2) a review of the implementation of the policy through technical specifications, (3) an assessment of the adequacy of plant technical specifications and Part 26 fitness for duty requirements for enforcement actions related to plant personnel working hours and fatigue, (4) a comparison of work scheduling practices at nuclear power plants relative to the policy guidelines, (5) an assessment of the incidence of events attributed to fatigue at nuclear power plants, (6) a preliminary assessment of the sensitivity of plant core damage frequencies to fatigue-induced impairment of plant personnel, and (7) a survey of limits and controls for addressing fatigue in other regulated industries and for nuclear plant personnel in other countries. In addition, the staff held public meetings on February 23 and September 14, 2000, to discuss concerns with the implementation of the policy and to solicit stakeholder input to the assessment process. The staff’s principal findings from the policy assessment are as follows:

- a. There are only a limited number of events at U.S. nuclear 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. However, several factors limit the ability of the staff and licensees to come to a finding that fatigue is a cause of an event, including the level of detail provided in event reports and the depth of the event analysis conducted. More importantly, whereas the effects of fatigue can be observed and documented (e.g., inattention to detail, non-conservative decisionmaking), fatigue cannot be objectively proven as the underlying cause. Given these considerations, the staff concludes that the number of events attributed to fatigue should be interpreted with caution and can not be reported with certainty.
- b. The policy provides for authorized deviations from the NRC’s work and rest guidelines in “very unusual circumstances.” NEI conducted a survey during June – July, 2000, concerning guideline deviations. Approximately one-third of the survey respondents are authorizing more than a thousand, to as many as 7,500, approvals in a year to exceed the policy guidelines. The frequency of deviations does not appear to be consistent with either the specific guidelines or the general objective of the policy. NEI has presented calculated averages to the staff that suggest that, on average, the number of deviations per person is quite small. However, neither the NRC nor, to the

staff's knowledge, NEI has data to indicate whether the calculated averages are representative of actual individual use of deviations. In addition, the staff believes that an analysis of deviations based on averages is not technically sound, given the fact that fatigue is experienced on an individual basis, not a group basis, and at a specific time, not averaged over time.

- c. The policy states that "enough plant operating personnel should be employed to maintain adequate shift coverage without routine heavy use of overtime." The staff has reviewed the data collected by NEI concerning overtime and found that 8 of 36 sites providing data had more than 20 percent of the personnel covered by the policy working in excess of 600 hours of overtime per year. Considering all plants that provided data, the percentage of personnel working in excess of 600 hours of overtime increased from 7 percent in 1997 to 11 percent in 1999. The percentage of licensed operators working in excess of 600 hours increased from 13 percent in 1997 to more than 16 percent in 1999.
- d. There is variation in plant technical specifications that implement the policy. Three nuclear plant units have no technical specifications to implement the policy. The policy applies to personnel who perform safety-related functions. The staff found variation in the numbers and types of personnel covered by individual plant administrative controls. A limited number of sites may not be applying work hour controls to all personnel performing safety-related functions, including at least two nuclear plant sites that do not apply the work hour controls to any maintenance personnel. Although the observed variability in the controls does not by itself present a safety concern, the staff believes that such variability is inconsistent with establishing a uniform level of assurance that personnel are not in a fatigued condition that could significantly reduce their mental alertness and decisionmaking capability.
- e. The language in plant technical specifications and Part 26 is largely advisory with respect to limiting working hours and addressing fatigue and includes terms that may be broadly interpreted. As a result, the NRC's current regulatory framework does not support efficient and effective enforcement on matters concerning excessive working hours and personnel fatigue.
- f. The staff reviewed the current and proposed Federal limits on work hours for personnel in six other industries in the United States and Canada, as well as nuclear plant workers in eight other countries. Although many factors influence specific regulatory limits, and requirements for other industries should be considered in context, the staff found that the NRC's guidelines were collectively the least restrictive.
- g. Studies in both laboratory and diverse work settings concerning work scheduling, extended work hours, human circadian physiology, and human performance indicate that scheduling of personnel at or near the NRC policy limits for controlling work hours during outages (e.g., no more than 16 hours of work in any 24-hour period) can result in degraded human performance from work-related fatigue. The research also suggests that when personnel exceed the policy guidelines (e.g., when guideline deviations are authorized), they are more likely to exhibit degraded alertness and decisionmaking and are more susceptible to committing fatigue-induced errors. Studies have shown that the incidence of errors by nuclear power plant personnel varies as a function of their daily variations in alertness. In addition, studies

concerning extended work hours (e.g., more than 12 hours) suggest that in a broad range of industries fatigue-induced personnel impairment can increase human error probabilities by a factor of more than 2 to 3 times baseline human error probabilities. Although a more detailed analysis would be necessary to characterize the amount of time such fatigue effects would be operative and the types of tasks affected in nuclear plant operations, preliminary sensitivity studies indicate that if increased levels of fatigue can be shown to increase human error probabilities applied in nuclear plant PRAs by factors of this magnitude, substantial increases in core damage frequency may be predicted.

Having considered these findings, the staff recommends rulemaking to address specific issues with the NRC's regulatory framework and industry control of work hours as they relate to personnel fatigue. The staff's objective is to achieve a uniform level of assurance across the U.S. commercial nuclear power industry that personnel whose duties may affect nuclear power plant operational safety are not in a fatigued condition that could significantly reduce their alertness or decisionmaking ability.

Many of the public comments concerning PRM-26-2 addressed specific requirements proposed by the petitioner, including their potential effectiveness, burden, and consequences. After reviewing the requirements proposed in PRM-26-2, and following consideration of public comment, the staff developed three additional rulemaking options and two alternatives to rulemaking. The requirements proposed by the petitioner, the rulemaking options and alternative approaches developed by the staff, and the evaluation of these options are described in detail in the rulemaking plan presented in Attachment 3. The rulemaking options are also summarized in a table to provide an overview of their major elements and facilitate their comparison (see Attachment 3, Appendix 1). The staff evaluated these options in accordance with 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.

On the basis of its evaluation, the staff has concluded that the petitioner has proposed a comprehensive set of requirements that could reasonably be expected to effectively address fatigue from individual and programmatic causes. However, the staff believes that it is also possible to achieve these objectives through alternative requirements that are more flexible, more directly focused on risk, and more aligned and integrated with current regulatory requirements. Accordingly, the staff recommends that this petition be granted, in part, and that the staff develop a rule as described in Option 2 of the rulemaking plan, considering the guidelines concerning risk-informed regulation described in SECY-00-0213, "Risk-Informed Regulation Implementation Plan." The staff recommends that any rulemaking to address worker fatigue should only apply to licensees authorized to operate nuclear power reactors, and that materials licensees otherwise subject to Part 26 should be excluded from the scope of this rulemaking for the reasons described in the rulemaking plan.

The staff believes that the proposed rulemaking would have backfit implications and would require a backfit analysis under 10 CFR 50.109(a)(4). As stated in the rulemaking plan, the staff will conduct an analysis 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.

STAKEHOLDER INVOLVEMENT:

The staff plans to hold stakeholder workshops during the development of the proposed rule.

COORDINATION:

The Office of the General Counsel has no legal objection to the rulemaking plan. The Office of the Chief Financial Officer has reviewed this Commission paper for resource implications and has no objections.

RESOURCES:

The total NRR resource estimate for the staff to complete this rulemaking is approximately 2.6 full-time equivalent (FTE) positions, which are available within the current budget. FTE usage is estimated to be 1.0 FTE in FY 2002, 0.8 FTE in FY 2003, and 0.8 in FY2004. RES FTE usage to provide continued technical assistance is estimated to be 0.3 FTE in FY 2002 and FY 2003 and is available within the current budget. 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 FY 2003. Upon Commission approval of rulemaking, NRR will address needed contract funding in their internal budgeting and planning process.

RECOMMENDATIONS:

That the Commission approve the staff plan to grant, in part, PRM-26-2 by undertaking rulemaking to address fatigue of workers at nuclear power plants.

That the Commission approve the development of a rule using Option 2 of the attached rulemaking plan.

Note that:

- a. Should the Commission approve undertaking rulemaking, stakeholder comments on the petition and the staff's analysis would be addressed in the *Federal Register* notice for the proposed rulemaking.
- b. The staff will take no further action until the SRM is issued.
- c. The staff is currently preparing a related paper for the Commission, "Final Rule Amending Fitness for Duty Rule." The paper proposes options for amending 10 CFR Part 26 to accomplish a variety of objectives, including reducing unnecessary regulatory burden. The staff will coordinate, as appropriate, the resolution of PRM-26-2 with these other proposed revisions to 10 CFR Part 26.

/RA/

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- Attachments:
1. Assessment of the NRC's "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors"
 2. Analysis of Public Comments on the Petition for Rulemaking Filed by Barry Quigley, September 28, 1999 (64 FR 67202)
 3. Rulemaking Plan to Address Fatigue of Nuclear Power Plant Workers

ATTACHMENT 1

**ASSESSMENT OF THE NRC'S "POLICY ON FACTORS
CAUSING FATIGUE OF OPERATING PERSONNEL AT NUCLEAR REACTORS"**

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Executive Summary

On June 15, 1982, the U.S. Nuclear Regulatory Commission (NRC) published Generic Letter 82-12, which included the NRC's "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors." The objective of this policy statement is to ensure, to the extent practicable, that personnel are not assigned to shift duties while in a fatigued condition. The generic letter requested that licensees revise their technical specifications (TS) to ensure that plant-specific administrative procedures are consistent with the guidelines presented in the NRC's policy statement. In 1999, the NRC responded to concerns regarding the implementation of the policy by conducting a preliminary review of the policy's implementation. The result of this review caused the staff to commit to assess the need to revise the policy. This report provides the findings from this assessment.

In March 2000, an NRC working group was formed to assess the policy. This group (1) reviewed the technical and research literature on the issues of fatigue and working hours; (2) collected information on working hour limits imposed in other industries to protect public safety and in the nuclear power industry in other countries; (3) analyzed survey data collected by the Nuclear Energy Institute (NEI) regarding the scope, authorization of deviations from the policy guidelines, and use of overtime; and (4) conducted preliminary evaluations of TSs, enforceability, and risk. The working group also contacted other Federal agencies to determine the status of their fatigue-related programs.

Studies of work scheduling, fatigue, and human performance indicate that the policy allows more hours of work and less rest than the amounts these studies would suggest for ensuring that personnel are not impaired by work-related fatigue. Consistent with this finding, a comparison of the policy guidelines with regulatory limits in other industries where work hours are controlled to protect public safety, and with the work hour limits for personnel at nuclear power plants in other countries, shows that the NRC's policy statement is the least restrictive. Further, the staff's review of plant-specific TSs and data collected by NEI reveals inconsistent implementation of the policy statement with a substantial minority of plants authorizing more guideline deviations than suggested by policy guidance to limit deviations to "very unusual circumstances." The staff also finds that the general and nonmandatory wording of the TSs and related requirements of the *Code of Federal Regulations*, Title 10, Part 26, "Fitness for Duty Programs" (10 CFR Part 26) makes the current regulatory framework difficult to achieve effective and efficient enforcement concerning working hours and fatigue. Despite these findings, few events have been attributed to fatigue at U.S. nuclear power plants. This may be in part the result of the levels of defense-in-depth at nuclear power plants which are designed to reduce the potential for personnel errors to have consequential effects on plant safety. However, the staff notes that difficulties in substantiating fatigue as a cause of an event suggest that the number of events attributed to fatigue should be interpreted with caution and cannot be reported with certainty. In addition, a preliminary study to test the sensitivity of plant core damage frequencies (CDF) to potential changes in human error probabilities caused by fatigue indicates that the effects of personnel fatigue may be risk significant, with increases in CDF on the order of 1E-5/yr.

Having considered these collective findings, the staff believes that the NRC's policy statement has weaknesses that have diminished its effectiveness. However, the staff also believes that there is an adequate technical basis and relevant experience to develop new requirements that are technically sound and practical in a nuclear plant operational setting. A potential model for

such an initiative is the “Fatigue Management” approach that is being pursued by some industries in the United States and abroad. Fatigue management addresses the multiple causes of fatigue through measures that include prevention (e.g., work hour limits, rest requirements, training, and health screening), detection and monitoring, mitigation, and evaluation.

Assessment of the NRC's Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors"

By letter dated February 25, 1999, Congressmen Dingell, Klink, and Markey expressed concerns to former NRC Chairman Shirley Ann Jackson that low staffing levels and excessive overtime may present a serious safety hazard at some commercial nuclear power plants. Similar concerns were expressed in a letter dated March 18, 1999, from David Lochbaum of the Union of Concerned Scientists (UCS) to Chairman Jackson, and in the UCS report, "Overtime and Staffing Problems in the Commercial Nuclear Power Industry." In response to these concerns, the staff conducted a preliminary review and found that few events at nuclear power plants had been attributed to fatigue. However, the staff acknowledged that the number of events attributable to fatigue could not be reported with certainty. Further, NRC inspectors had identified several instances each year in which licensees' use of overtime appeared to be inconsistent with the NRC's "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors" (policy). By letter dated May 18, 1999, the Chairman informed the Congressmen of the staff's findings and stated that the staff would assess the need to revise the policy statement. During the development of an action plan to assess the policy, the NRC received a petition for rulemaking (PRM-26-2), dated September 28, 1999, from Barry Quigley. The petition requests that the NRC amend 10 CFR Parts 26 and 55 to establish clear and enforceable working hour limits to mitigate the effects of fatigue for nuclear power plant personnel performing safety-related work. The staff subsequently established a working group to concurrently process PRM-26-2 and assess the policy.

1.0 History of Policy Development

Following the accident at Three Mile Island, inspection activities conducted by the U.S. Nuclear Regulatory Commission (NRC), together with concerns expressed by some licensed operators, indicated that in certain situations, facility personnel were either required or allowed to remain on duty for extended periods of time. On February 1, 1980, the NRC issued Inspection and Enforcement (IE) Circular No. 80-02, "Nuclear Power Plant Staff Work Hours," which described concerns regarding the effects of fatigue on human performance. In conclusion, the circular stated that licensees should review their administrative procedures to ensure that they establish a sound policy regarding working hours for plant staff who perform safety-related functions. The NRC provided the following interim guidelines: (1) individuals should work no more than 12 hours straight, and no more than 72 hours in a 7-day period; (2) there should be a break of at least 12 hours between work periods; (3) individuals should not work more than 14 consecutive days without having 2 consecutive days off; (4) if an operator is required to work more than 12 hours, the individual's duties should be carefully selected; and (5) special circumstances requiring deviations from these guidelines should be authorized by the station manager.

The guidance provided in IE Circular No. 80-02 was later superseded by a letter dated July 31, 1980, from the Director of the Division of Licensing, Office of Nuclear Reactor Regulation, to all licensees of operating plants and applicants for operating licenses. The letter stated that licensees' administrative procedures shall include a policy concerning overtime work for senior reactor operators (SROs), reactor operators (ROs), and shift technical advisors (STAs). The procedures are to stipulate that overtime shall not be routinely scheduled to compensate for an

inadequate number of personnel. In addition, the letter established specific overtime restrictions, which were generally consistent with those in IE Circular No. 80-02. However, the limitation regarding working no more than 12 hours was qualified to exclude turnover time, and the guidance was clarified to indicate that the use of overtime should be limited to unavoidable or unanticipated circumstances.

On October 30, 1980, the NRC issued NUREG-0737, "Clarification of TMI Action Plan Requirements." Item I.A.1.3.1, "Limit Overtime," of NUREG-0737 required licensees to establish administrative procedures that set forth a policy for controlling overtime. NUREG-0737 also recommended overtime restrictions that were generally consistent with those contained in IE Circular No. 80-02. As in the letter of July 31, 1980, NUREG-0737 stipulated that the overtime restrictions apply in the event that overtime must be used. However, the guidance was not applicable during extended periods of shutdown, and contrary to the letter dated July 31, 1980, was not applicable to STAs.

On February 18, 1982, the NRC published its "Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors" (policy) (47 FR 7352). The objective of the policy statement was 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 decisionmaking ability. Generic Letter (GL) 82-02, "Nuclear Power Plant Staff Working Hours," dated February 8, 1982, disseminated the policy statement as information, and stated that the NRC would request that all licensees revise the administrative section of their technical specifications (TSs) to require procedures that follow the guidelines presented in the policy statement. Following issuance of the policy statement, industry feedback caused the staff to issue a revised policy statement (Table 1).

The revised policy statement was published in the *Federal Register* (47 FR 23836, June 1, 1982) and disseminated by GL 82-12, "Nuclear Power Plant Staff Working Hours," dated June 15, 1982. The revised policy statement clarified that (1) the objective is to have operating personnel work an 8-hour day and a 40-hour week, (2) the limits in the policy statement apply during extended periods of shutdown, and (3) the requirement to consider use of overtime on an individual basis does not apply during periods when the plant is shutdown.

The NRC subsequently developed model TSs, which were provided for reference by GLs 82-16 (September 20, 1982) and 83-02 (January 10, 1983), both of which were entitled "NUREG-0737 Technical Specifications." The NRC chose not to impose the TSs by order, and portions of the policy statement were incorporated (directly or by reference) into the TSs of all but three U.S. commercial nuclear power units. On March 7, 1983, the NRC issued GL 83-14, "Definition of 'Key Maintenance Personnel' (Clarification of Generic Letter 82-12)," to clarify the applicability of the policy statement to maintenance personnel.

The staff previously considered incorporating guidance on working hour limitations into Regulatory Guide (RG) 1.33, "Quality Assurance Program Requirements," which would have endorsed American National Standards Institute/American Nuclear Society (ANSI/ANS) 3.2, "Administrative Controls and Quality Assurance for the Operating Phase of Nuclear Power Plants." Both ANSI/ANS 3.2, 1982 and 1988, include guidelines on working hours that are similar to the policy statement. However, the standard did not include all facets of the policy and the staff has not issued a revision to RG 1.33.

Table 1. Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors

Licensees of operating plants and applicants for operating licenses shall establish controls to prevent situations where fatigue could reduce the ability of operating personnel to keep the reactor in a safe condition. The controls should focus on shift staffing and the use of overtime--key job-related factors that influence fatigue.

The objective of the controls would be to assure that, to the extent practicable, personnel are not assigned to shift duties while in a fatigued condition that could significantly reduce their mental alertness or their decision making capability. The controls shall apply to the plant staff who perform safety-related functions (e.g., senior reactor operators, reactor operators, health physicists, auxiliary operators, and key maintenance personnel).

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. However, in the event that unforeseen problems require substantial amounts of overtime to be used, or during extended periods of shutdown for refueling, major maintenance or major plant modifications, on a temporary basis, the following guidelines shall be followed:

- a. An individual should not be permitted to work more than 16 hours straight (excluding shift turnover time).
- b. An individual should not be permitted to work more than 16 hours in any 24-hour period, nor more than 24 hours in any 48-hour period, nor more than 72 hours in any seven day period (all excluding shift turnover time).
- c. A break of at least eight hours should be allowed between work periods (including shift turnover time).
- d. Except during extended shutdown periods, the use of overtime should be considered on an individual basis and not for the entire staff on a shift.

Recognizing that very unusual circumstances may arise requiring deviation from the above guidelines, such deviation shall be authorized by the plant manager or his deputy, or higher levels of management. The paramount consideration in such authorization shall be that significant reductions in the effectiveness of operating personnel would be highly unlikely. In addition, procedures are encouraged that would allow licensed operators controls to be periodically relieved and assigned to other duties away from the control board during their tour of duty.

2.0 Assessment Approach

The policy assessment was composed of several activities to provide a comprehensive assessment of the policy and facilitate identifying options for resolving potential deficiencies. The activities included (1) an assessment of the technical adequacy of the guidelines for ensuring that personnel are not impaired, (2) a review of the implementation of the policy through technical specifications, (3) an assessment of the adequacy of plant technical specifications and Part 26 fitness for duty requirements for enforcement actions related to plant personnel working hours and fatigue, (4) a comparison of work scheduling practices at nuclear power plants relative to the policy guidelines, (5) an assessment of the incidence of events attributed to fatigue at nuclear power plants, (6) a preliminary assessment of the sensitivity of plant core damage frequencies to fatigue-induced impairment of plant personnel, (7) and a survey of limits and controls for addressing fatigue in other industries and for nuclear plant personnel in other countries.

To conduct the assessment, the staff (1) reviewed the technical and research literature on the issues of fatigue and working hours; (2) collected information on working hour limits imposed in other industries to protect public health and safety and in the nuclear power industry in other countries; (3) analyzed survey data collected by the Nuclear Energy Institute (NEI) regarding the scope, authorization of deviations, and use of overtime; and (4) conducted preliminary evaluations of TSs, enforceability, and risk. The working group also contacted other Federal agencies to determine the status of their fatigue-related programs, including fatigue management.

3.0 Technical Adequacy of the Policy Statement

This section presents a detailed assessment of each element of the policy statement. The individual elements of the policy statement are paraphrased in italics and grouped as: Policy Statement Objectives, Scope of Personnel Covered, Pre-Conditions for Authorizing Guideline Deviations, Work Limits and Rest Requirements, and Guideline Deviation Criteria. Relevant technical findings and bases follow the statement of each individual element to provide insights concerning the relationship between working hours, fatigue, and personnel impairment or performance. The staff notes that nuclear power plants are designed, and their operation controlled, in a manner to minimize the consequences of potential human errors on plant operational safety. As a consequence, there are measures and barriers, in addition to work hour controls, that can reduce the probability of fatigue-induced errors resulting in events leading to core damage or off-site release of radioactive materials. These measures and barriers include plant design characteristics (e.g., fail-safe components, redundant and independent emergency safeguards features) and programmatic controls (e.g., independent verification, post-maintenance testing, and surveillance tests).

Policy Statement Objectives – The general objectives of the policy are based on the premise that fatigue can lead to impaired performance. A large body of scientific literature demonstrates that long work hours cause fatigue and degraded human performance.

Establish controls to prevent situations where fatigue could reduce the ability of operating personnel to keep the reactor in a safe condition - the controls should focus on shift staffing and the use of overtime.

- Excessive working hours and shift work cause fatigue (Akerstedt, 1995; Rosa, 1995).
- Fatigue impairs human performance (Harrison and Horne, 2000; Williamson, 2000; Bobko et al., 1998; Dawson and Reid, 1997; Dinges, 1995; Dinges, 1992; Rosa, 1991).
- Human performance impacts on plant safety, as shown in studies on plant risk (U.S. Nuclear Regulatory Commission, 2000; NUREG-1560, 1997).
- Information Notice 91-36 cited several examples in which NRC inspection revealed that plant staff had worked excessive hours while performing safety-related functions.

Assure that, to the extent practicable, personnel are not assigned to shift duties while in a fatigued condition that could significantly reduce their mental alertness or their decisionmaking capability.

- The ability of people to perform and remain alert varies throughout the day and depends upon underlying physiological processes that operate on a circadian cycle. Human error can increase during circadian ebbs, which occur during certain times of the day and night. By its nature, shift work is an around-the-clock activity that requires personnel to work during periods that are contrary to their internal circadian clocks (Mitler and Miller, 1996; Kecklund et al., 1997; Mitler and Miller, 1997; Folkard, 1997; Bobko et al., 1998).
- Long working hours exacerbate the adverse effects of circadian cycles in alertness (Hanecke, 1998).
- In studies that compared fatigue to blood alcohol concentration (BAC), individuals who were awake for 17 to 19 hours had cognitive psychomotor performance comparable to individuals with a BAC of 0.05 percent (Williamson and Feyer, 2000; Dawson and Reid, 1997).
- Harrison and Horne (2000) reviewed the impact of sleep deprivation on decisionmaking and found that, contrary to popular belief, sleep deprivation impairs decisionmaking even if individuals try to compensate for lack of sleep when responding to heightened stimulation.
- The National Transportation Safety Board (NTSB) reviewed the performance of flight crews involved in major accidents and found that those crew members who had been awake longer than 12 hours before their accidents made more errors overall, and specifically more tactical decision errors, than did crew members who had been awake for less time (NTSB, 1994).
- Fatigue has generalized effects on human performance capabilities. Some of these effects include degraded short-term memory, impaired ability to recognize proper grammar, reduced aversion to risk, and degraded communication behaviors (Dinges, 1995).

Enough plant operating personnel should be employed to maintain adequate shift coverage without routine heavy use of overtime.

- The term “routine heavy use of overtime” is not defined, and no guidance is provided for the related limits.

- Data collected by the NEI (see Section 6) demonstrate that, at some sites, personnel who are covered by the policy statement are assigned considerable amounts of overtime.

The objective is to have operating personnel work a normal 8-hour day, 40-hour week while the plant is operating.

- Lack of adequate days off and extended workdays (overtime) can result in cumulative sleep debt and performance impairment (Williamson and Feyer, 2000; Tucker, 1999; Department of Transportation (DOT), 65 FR 25546; Colquhoun, 1996; Baker et al., 1994; Webb and Agnew, 1974).
- Guidelines issued by the Electric Power Research Institute (EPRI) with regard to preventing fatigue recommend that individuals work no more than four consecutive 12-hour shifts (Baker, 1990).
- When acute sleep loss is sustained (especially beyond 36 hours of sleep deprivation), everyone eventually suffers marked performance deficits (Dinges, 1995).

Scope of Personnel Covered - Industry data demonstrate that there is inconsistency among sites with regard to both the number and the type of personnel covered. This information indicates a need for clearer scope requirements.

The controls shall apply to the plant staff who perform safety-related functions (e.g., senior reactor operators, reactor operators, health physicists, auxiliary operators, and key maintenance personnel).

- GL 83-14 defined key maintenance personnel as those personnel who are responsible for the correct performance of maintenance, repair, modification, or calibration of safety-related structures, systems, or components.
- GL 83-14 included personnel performing or immediately supervising the performance of safety-related functions.
- Licensees, through administrative procedures, defined the scope of personnel at a site that were subject to administrative control of working hours.
- Data collected by the NEI (see Section 6) demonstrate that there is inconsistency among sites with regard to both the number and the type of personnel covered (e.g., a few sites do not cover any maintenance personnel).

Pre-conditions for Authorizing Guideline Deviations

In the event that unforeseen problems require substantial amounts of overtime to be used, or during extended periods of shutdown for refueling, major maintenance or major plant modifications, on a temporary basis, the following limits shall be followed:

- The terms “unforeseen problems” and “substantial amounts of overtime” are not defined, and no guidance is provided.
- The term “temporary basis” is not defined, and no guidance is provided. Also, the policy statement is not clear with regard to extended outages.

Work Hour Limits and Rest Requirements – The policy limits on work hours (16 hours in a 24 hour period, 72 hours in any 7-day period) and the requirement for a minimum 8-hour break

between work periods appear to allow more hours of work and less rest than current research indicates is appropriate for ensuring personnel are not impaired by work-related fatigue. Research concerning cumulative fatigue suggests that the NRC should consider requirements to address the prolonged use of extended work hours of duties for personnel working in excess of this limit. The relaxation that the policy statement allows for work scheduling during outages may no longer be consistent with the staff's understanding of plant risk during shutdown conditions.

An individual should not be permitted to work more than 16 hours straight (excluding shift turnover time) and an individual should not be permitted to work more than 16 hours in any 24-hour period.

- The original policy guidance was a maximum of 12 hours with careful selection.
- The Commission revised the limit from a recommended 12-hour maximum to 16 hours in response to practical concerns that the 12-hour limit required personnel working 8-hour shifts to split shifts when working overtime. This constraint was particularly problematic for using overtime to cover a night shift, as it would require a person to be called in the middle of the night. Therefore, keeping someone over for a full 8 hours is more practical.
- This limit is intended to prevent acute fatigue, but the limit of 16 hours is inconsistent with research findings and the practice in other industries and in the nuclear industry in other countries.
- Human reliability analysis experts have recommended that the NRC guidance state that "the second 8 hours [of a 16-hour shift] should not occur during a person's normal sleep time" (NUREG/CR-1278, Handbook of Human Reliability Analysis with Emphasis on Nuclear Power Plant Applications).
- Studies have shown that the relative risk of having an accident increases dramatically after 9 consecutive hours on the job (Hanecke et al., 1998; DOT, 65FR25544; Colquhoun et al., 1996).
- Other studies have shown that task performance declines after 12 hours on a task (Folkard, 1997; Dawson and Reid, 1997; Rosa, 1991).
- Twelve hours per day was the limit recommended by nine experts who met in 1984 to develop recommendations for NUREG/CR-4248, "Recommendations for NRC Policy on Shift Scheduling and Overtime at Nuclear Power Plants," 1985.
- This limit is less restrictive than the limits imposed on nuclear power plant workers in other countries (see also Section 9).
- This limit is less restrictive than the limits imposed in several other industries that the staff reviewed (see also Section 9).

An individual should not be permitted to work more than 24 hours in any 48-hour period.

- This limit is intended to prevent acute fatigue.
- NUREG/CR-4248 recommends that this limit remain the same.
- Stakeholder comments indicate that this limit is problematic for personnel on 12-hour shifts in that it requires an authorized deviation when even small amounts of overtime are worked.

An individual should not be permitted to work more than 72 hours in any 7-day period.

- This limit could potentially allow a worker to work six 12-hour shifts per week continuously.
- Studies have shown that longer work schedules relate to fatigue (Colquhoun, 1996; Rosa, 1995).
- Human reliability analysis experts have recommended that the NRC set “a maximum of 60 hours in any 7-day period and a maximum of 100 hours in any 14-day period” noting studies indicating that fatigue from long work hours can result in personnel developing their own subjective standards of what is important (NUREG/CR-1278).
- NUREG/CR-4248 recommends a limit of 60 hours of work in a 7-day period.
- This limit is less restrictive than the limits imposed on nuclear power plant workers in other countries (see Section 9).
- This limit is less restrictive than the limits imposed in several other industries that the staff reviewed (see Section 9).
- This limit is intended to prevent cumulative fatigue; however, the limit of 72 hours in any 7-day period is inconsistent with research findings and use in other applications.

The limits all exclude shift turnover time.

- The policy statement excludes shift turnover times from the working hour limits, for practical considerations, but does not explicitly exclude any other parts of a workday (e.g., lunch, breaks).
- A limited number of licensees exclude periods from working hour calculations (e.g. lunch, breaks, training).
- The policy limits were developed on the basis that the normal day includes all parts of the workday except shift turnover.
- There is no technical justification for excluding rest breaks on the basis that such time does not contribute to fatigue. In a proposed revision of its hours of service regulation for motor carriers, the DOT concluded that “all time spent in any work must be counted as on-duty time, since all work can either induce fatigue or deprive the driver of sleep” (DOT, 65 FR 25558, 2000). The DOT conclusion is founded, in part, on the recommendations of an expert panel (Transportation Research Institute, 1998) and is consistent with a large body of research (Tucker et al., 1998; Akerstedt and Landstrom, 1998; Rosa, 1991).

A break of at least 8 hours should be allowed between work periods (including shift turnover time).

- On average, most humans physiologically require about 8 hours of sleep per night (Rosekind et al., 1997; Rosa, 1995).
- A break of 8 hours does not adhere to guidelines from the National Sleep Foundation, which recommends 12 hours off-duty time (National Sleep Foundation, 2000).
- Human reliability analysis experts have recommended that the NRC guidance be “a break of at least 12 hours between all work periods (NUREG/CR-1278).
- One study suggests that at least 16 hours be provided between shifts to provide adequate time for sleep (Kecklund and Akerstedt, 1995).
- The Insurance Institute for Highway Safety recommended a minimum of 12 to 14 hours off duty per day, citing Wylie et al. (1996).
- The Federal Motor Carrier Safety Administration reviewed the issue of rest or off-duty periods and found that continuous time off duty is important. The current regulations

require that drivers have at least 8 continuous hours off duty. A panel of experts criticized this requirement as inadequate because 8 hours off-duty time does not translate into 8 hours of sleep. Thus, the DOT proposal would require a 10-hour work break (DOT, 65 FR 25561).

- A break of 8 hours is less restrictive than the regulations for commercial aviation.

Except during extended shutdown periods, the use of overtime should be considered on an individual basis and not for the entire staff on a shift.

- The blanket relaxation that the policy statement allows for work scheduling during outages may no longer be consistent with the staff's understanding of the variations in plant risk that can occur during shutdown conditions and the heightened challenges to human performance presented by plant outage working conditions, including the increased dependence on manual operator action (NUREG-1449).
- Latent errors that may have previously occurred during an outage play an important role in significant accident sequence precursor (ASP) events (U.S. Nuclear Regulatory Commission, 2000).
- Team performance can be affected by fatigue (Harrison and Horne, 2000; NTSB, 1994).
- Some licensees may have interpreted the statement "for the entire staff on a shift" to mean that a single deviation could cover more than one individual, which was not the intent of the guidance.

Guideline Deviation Criteria – Industry data demonstrate that numerous deviations are authorized, indicating that guidance limiting deviations to very unusual circumstances is inadequate.

Recognizing that very unusual circumstances may require deviation from the guidelines, such deviations shall be authorized by the plant manager, or his deputy, or higher level management. Such authorization shall consider that significant reductions in the effectiveness of operating personnel would be highly unlikely.

- Deviations from the policy statement guidelines increase the risk of fatigue-induced impairment of attention, reasoning, computational skills, oral communications, and decisionmaking (Hanecker, 1998; Dawson and Reid, 1997; Folkard, 1997; Dinges, 1992).
- The policy statement does not set clear limits on the number of hours or days that individuals can be allowed to work at or above guideline limits.
- Data collected by the NEI (see Section 6) show that numerous deviations are authorized.

Procedures are encouraged that would allow licensed operators at the controls to be periodically relieved and assigned to other duties away from the control board during their tours of duty.

- Studies have shown that task variation can be of benefit for limited periods in counteracting degradations in alertness caused by fatigue (Folkard, 1997).

Authorized deviations to the working hour guidelines shall be documented and available for NRC review. Controls shall be included in the procedures such that individual overtime shall be reviewed monthly by the (Plant Superintendent) or his designee to assure that excessive hours have not been assigned (GLs 82-16 and 83-02 which disseminated the policy statement).

- NUREG/CR-4248 recommended guidelines to limit the amount of overtime accumulated over long periods, as well as guidelines to limit the plant manager's authority to deviate from the guidelines. NUREG/CR-4248 also recommended that authorization should be required for individuals working more than 192 hours in a 28-day period or 2260 hours in a year. The long-term limits on overtime were recommended to address the potential for cumulative fatigue effects on nuclear power plant personnel.
- The NRC has not provided any criteria to define "excessive hours."
- Other industries and countries have limits for periods longer than 7 days.

Routine deviation from the above guidelines is not authorized (GLs 82-16 and 83-02 which disseminated the policy statement).

- The UCS prepared a report on "Overtime and Staffing Problems in the Commercial Nuclear Power Industry" (letter from D. Lochbaum to Chairman Jackson, dated March 18, 1999), which presented concerns regarding the level of overtime being worked in the nuclear industry.
- Data collected by the NEI (see Section 6) show that numerous deviations are authorized.

Summary

- Studies of work scheduling, fatigue, and human performance indicate that scheduling of personnel at or near the limits of the NRC policy guidelines for controlling work hours during outages (e.g., 16 hours in a 24-hour period, 72 hours in any 7-day period, and the requirement for a minimum 8-hour break between work periods) can result in degraded human performance from work-related fatigue. Research concerning cumulative fatigue suggests that the NRC consider requirements to address the prolonged use of extended work hours of duties for personnel working in excess of these limits. These findings are generally consistent with past assessments of the NRC's policy guidelines.
- Information gathered from other industries and foreign nuclear power plants indicates that their working hour limits are generally more restrictive than those of the NRC policy statement. Although the adoption of specific limits in other industries and countries may have been influenced by the particular economic or workplace conditions in a given industry or country, the limits are generally consistent with the technical and research information described in this section.
- The policy statement guidelines are not responsive to the variations in plant risk that can occur during shutdown conditions and the heightened challenges to human performance presented by plant outage working conditions.
- Research concerning cumulative fatigue and work hour limits in other industries and countries suggests that the NRC should consider limits for periods longer than 7 days.

4.0 Implementation of the Policy Statement Through Technical Specifications

The staff reviewed the TSs for the 104 nuclear power units licensed to operate. The review revealed variations in how the policy statement was incorporated into TSs. In part, this appears to be a result of changes, over time, in the standard TSs. Working hour commitments could not be found for three units. The staff found that for each of these units, although there was no TS concerning work hours, the licensee had an administrative procedure in place that was largely consistent with the policy. Table 2 summarizes the number of units utilizing each version of the TSs. Version A was promulgated by GL 82-16, "NUREG-0737 Technical Specifications" (pressurized-water reactors [PWRs]) or GL 83-02, "NUREG-0737 Technical Specifications" (boiling-water reactors [BWRs]) as model TSs. The standard TSs incorporated this version and allowed a shorter TS wording (version B). In June 1999, the NRC amended the standard TSs (version C) to remove the specific work hour limits. This change was made in response to an NRC Regulatory Review Group report (August 1993), which cited the policy as an example of the NRC regulating by policy statement. The TSs was consequently revised to be less prescriptive. Licensees adopting the current standard TS relocate specific work hour controls to a licensee-controlled document. Subsequent changes to the work hour controls may be made in accordance with licensee procedure control processes.

Table 2. Working Hour Commitments		
Version	Number of Units	Technical Specifications
A	35	<p>Administrative procedures shall be developed and implemented to limit the working hours of unit staff who perform safety-related functions (e.g., licensed SROs, licensed ROs, health physicists, auxiliary operators, and key maintenance personnel).</p> <p>Adequate shift coverage shall be maintained without routine heavy use of overtime. The objective shall be to have operating personnel work an [8 or 12] hour day, nominal 40 hour week while the unit is operating. However, in the event that unforeseen problems require substantial amounts of overtime to be used, or during extended periods of shutdown for refueling, major maintenance, or major plant modification, on a temporary basis the following guidelines shall be followed:</p> <ol style="list-style-type: none"> 1. An individual should not be permitted to work more than 16 hours straight, excluding shift turnover time; 2. An individual should not be permitted to work more than 16 hours in any 24 hour period, nor more than 24 hours in any 48 hour period, nor more than 72 hours in any 7 day period, all excluding shift turnover time; 3. A break of at least 8 hours should be allowed between work periods, including shift turnover time; 4. Except during extended shutdown periods, the use of overtime should be considered on an individual basis and not for the entire staff on a shift. <p>Any deviation from the above guidelines shall be authorized in advance by the [Plant Superintendent] or his designee, in accordance with approved administrative procedures, or by higher levels of management, in accordance with established procedures and with documentation of the basis for granting the deviation.</p> <p>Controls shall be included in the procedures such that individual overtime shall be reviewed monthly by the [Plant Superintendent] or his designee to ensure that excessive hours have not been assigned. Routine deviation from the above guidelines is not authorized.</p>
Variations on A	9	<p>Variations include 1) no description of the plant staff covered (1 unit), 2) no description of the controls to ensure adequate shift coverage without routine heavy use of overtime or nominal working hours/day/week (2 units) , 3) does not include wording of final paragraph requiring monthly reviews of individual overtime or prohibiting routine deviations from guidelines (7 units), and 4) does not include wording of final paragraph prohibiting deviations (1 unit).</p>
B	9	<p>The amount of overtime worked by unit staff members performing safety-related functions shall be limited in accordance with the NRC Policy Statement on working hours (Generic Letter 82-12).</p>

Table 2. Working Hour Commitments		
Version	Number of Units	Technical Specifications
C	14	<p>Administrative procedures shall be developed and implemented to limit the working hours of unit staff who perform safety-related functions (e.g., licensed SROs, licensed ROs, health physicists, auxiliary operators, and key maintenance personnel).</p> <p>The controls shall include guidelines on working hours that ensure adequate shift coverage shall be maintained without routine heavy use of overtime.</p> <p>Any deviation from the above guidelines shall be authorized in advance by the [Plant Superintendent] or his designee, in accordance with approved administrative procedures, or by higher levels of management, in accordance with established procedures and with documentation of the basis for granting the deviation.</p> <p>Controls shall be included in the procedures such that individual overtime shall be reviewed monthly by the [Plant Superintendent] or his designee to ensure that excessive hours have not been assigned. Routine deviation from the above guidelines is not authorized.</p>
Variations on C	8	Variations include 1) no description of the plant staff covered (1 unit), 2) no discussion of the controls to ensure adequate shift coverage without routine use of overtime (3 units), 3) no description of the periodicity of individual overtime reviews, (6 units), and 4) no requirement for monthly reviews of individual overtime (1 unit).
D	11	Administrative procedures shall be developed and implemented to limit the working hours of unit staff who perform safety-related functions; e.g., senior reactor operators, reactor operators, health physicists, auxiliary operators, and key maintenance personnel. The amount of overtime worked by unit staff members performing safety-related functions shall be limited in accordance with the NRC Policy Statement on working hours (Generic Letter 82-12).
Variations on D	6	Variations include 1) no description of the plant staff covered (6 units) and 2) no discussion of the procedures limiting working hours (2 units).
E	4	Procedures shall be established to insure that NRC policy statement guidelines regarding working hours established for employees are followed. In addition, procedures will provide for documentation of authorized deviations from these guidelines and that the documentation is available for NRC review.
F	1	Written administrative procedures for shift overtime shall be established, implemented, and maintained.
G	1	The amount of overtime worked by unit staff members performing safety-related functions shall be limited and controlled in accordance with approved administrative procedures.
H	1	Administrative procedures shall be developed and implemented to limit the working hours of unit staff who perform safety-related functions (e.g., licensed SROs, licensed ROs, radiation protection technicians, auxiliary operators, and key maintenance personnel).

Table 2. Working Hour Commitments		
Version	Number of Units	Technical Specifications
I	1	The amount of overtime worked by plant staff members performing safety-related functions shall be limited and controlled in accordance with an NRC approved program specified in plant procedures changes to the guidelines in these procedures shall be submitted to the NRC for review.
J	1	Written procedures shall be established, implemented and maintained covering . . . Plant Staff Overtime, to limit the amount worked by staff performing safety-related functions in accordance with NRC Policy Statement on working hours (Generic Letter No. 82-12).
None	3	No commitment found in the TS.

Summary

There are numerous variations on how the policy statement was incorporated into TSs, including no commitment in TSs at three nuclear power units.

5.0 NRC’s Regulatory Requirements Concerning Personnel Working Hours and Fatigue as a Basis for Enforcement Action

The principal components of the current regulatory framework for matters pertaining to working hours and fatigue are (1) the “Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors,” as disseminated by GL 82-12; (2) plant TSs related to this policy statement; and (3) certain requirements of 10 CFR Part 26.

Policy Statement

It is well established that NRC guidance documents cannot prescribe requirements but merely set forth policy pronouncements or advice on a possible method of meeting a regulatory requirement. As a consequence, unless plants have incorporated the guidelines from the policy statement in a license condition or TSs, the guidelines are unenforceable.

Technical Specifications

As noted in Section 3, the TSs for all but three units include limits on the use of overtime. These TSs were implemented in response to GL 82-12, which requested that licensees establish TSs requiring administrative controls that follow the guidance of the policy statement.

A determination of whether a TS can be enforced without controversy rests on whether the language of the TS clearly states a requirement that the “reasonable person” can understand. As stated in Section 3, key terms of the TS have not been defined, and this deficiency results in inconsistent interpretation and implementation by licensees, as well as difficulty for the NRC staff when pursuing enforcement. Specifically, many TSs use the terms routine heavy use of overtime, unforeseen problems, and temporary basis. The NRC has not defined any of these terms and has not consistently pursued enforcement on the basis of the amount or frequency of

overtime authorized. Rather, the NRC has tended to take enforcement action only when it could be shown that overtime was not authorized in writing before the work was performed. Recent data released by the NEI show that many licensees authorize more than a thousand deviations annually from the guidelines. In contrast, the policy statement anticipated that deviations would be required for “very unusual circumstances.”

The staff does not believe that current TSs limiting working hours are sufficient to ensure that licensees meet the intent of the policy statement, or to ensure that the NRC can effectively and efficiently enforce the TS requirements.

The staff notes that the following additional factors complicate consistent enforcement of the TSs:

- The TSs are inconsistent in level of detail from site to site. Only three-quarters of the plant TSs include the quantitative working hour limit guidelines of the policy statement.
- The TSs are inconsistent in specific requirements. Some plant TSs require periodic review of overtime approvals to ensure that excessive hours have not been assigned, while other TSs contain no equivalent requirement.
- The scope of the personnel covered by the TSs has been interpreted inconsistently. The policy statement applies to personnel performing safety-related functions. The staff has found that Senior Reactor Operators (SROs), Reactor Operators (ROs), and non-licensed operators (NLOs) are the only categories of personnel covered at all of the sites that responded to the NEI survey. Although GL 83-14, “Definition of Key Maintenance Personnel (Clarification of GL 82-12),” dated March 7, 1983, defined key maintenance personnel as including personnel who work on safety-related equipment, some sites do not apply the TSs to maintenance personnel.
- Licensees for a limited number of sites have revised their methods for calculating work hours relative to the TS limits so as to reduce the number of deviations authorized without reducing the actual number of hours worked (e.g., by excluding breaks). As a result, the basic measure used to determine whether an individual’s work hours are within or above the TS limits is not implemented consistently from site to site.

10 CFR Part 26, “Fitness for Duty Programs”

The general performance objectives of 10 CFR 26.10 require that licensees provide “reasonable assurance that nuclear power plant personnel . . . are not . . . mentally or physically impaired from any cause, which in any way adversely affects their ability to . . . perform their duties.” Fitness-for-duty (FFD) programs must also provide reasonable measures for the early detection of personnel who are not fit to perform activities.

In addition, 10 CFR 26.20 states that licensees shall establish and implement written policies and procedures designed to meet the general performance objectives and specific requirements of 10 CFR Part 26. As a minimum, the policies and procedures must address the licensee’s policy on FFD, as well as the use of illegal drugs and abuse of legal drugs.

Although 10 CFR Part 26 contains specific requirements pertaining to alcohol and drug usage, it does not include prescriptive requirements regarding fatigue. Rather, 10 CFR 26.20 uses general nonmandatory language to state that licensee policy “should” address other factors that can affect FFD, “such as mental stress, fatigue, and illness.” As a result, it is more difficult to sustain a violation of the regulation in light of 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 licensees’ 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.

Summary

Only the mandatory and unambiguous provisions of the TSs and 10 CFR Part 26 relative to working hours and fatigue are readily enforceable. The broad and non-prescriptive provisions of 10 CFR Part 26 and TS pertaining to fatigue, in the absence of clearly defined terms or measures of fatigue, make it difficult to use this rule to achieve enforcement of matters concerning fatigue and working hours in an effective and efficient manner. The staff must demonstrate, on a case-by-case basis, that a given overtime practice was excessive or caused unacceptable fatigue. Therefore, the staff believes that rulemaking is needed to establish the regulatory basis necessary to ensure that licensees’ work scheduling practices are consistent with the intent of the policy statement.

6.0 Industry Implementation of the Policy Statement

Although the NRC had conducted periodic inspections of the control of working hours for personnel performing safety-related functions, the staff lacked sufficient data to accurately characterize (1) industry control of working hours relative to the policy statement in the GL guidelines and (2) the current trends in the use of overtime relative to the policy statement. The NEI acknowledged the need to accurately characterize industry implementation of the policy statement and agreed to collect data for this purpose. The NEI collected the data in July 2000 and submitted the data to the NRC on August 29, 2000 (Nuclear Energy Institute, 2000). During that data collection process, the NEI asked licensees questions concerning their working hour controls, the scope of personnel to whom the controls apply, their use of deviations from the guidelines for the past 3 years, and their use of overtime for the same period.

Response Rate: Of the licensees for the 66 nuclear power plant sites in the United States, 47 (71%) responded to the NEI’s survey, but not all sites provided complete data. The response rate for deviation data ranged from 28 sites (42%) providing outage deviations data for 1997 to 40 sites (61%) providing deviation data for operating periods in 1999. Similarly, the response rate to the request for overtime data ranged from 26 sites (39%) providing data for 1997 to 36 sites (55%) providing data for 1999. As a result, the staff cannot state with confidence that the data are representative of the distribution of U.S. nuclear power plant sites.

Analytical Constraints: As provided by the NEI, the data do not enable the staff to (1) distinguish a single-unit site from multiple-unit sites, (2) determine how many individuals at a site contributed to the total number of deviations, and (3) compare site responses across questions (e.g., determine the distribution of deviations over a given job category). The NEI did not provide

supporting documents (i.e., administrative procedures for working hour limitations and FFD programs) to the staff. Despite these limitations, the staff was able to gain useful insights concerning the implementation of its policy statement at many sites.

Response Analysis:

Controls: All sites that responded indicated that they had administrative procedures that implement working hour policies. However, licensees for 16 of the 47 sites that responded indicated that their TSs did not include all of the restrictions of GL 82-12.

Scope: The survey requested data concerning how many individuals in each job category were subject to working hour limits. Licensees for 47 sites responded to this question. SROs, ROs, and NLOs are the only job categories covered at all of the sites that responded. No health physics personnel were covered at four of the sites, contrary to the guidance of GL 82-12. In addition, GL 83-14 states that working hour limitations apply to key maintenance personnel; however, four sites did not cover instrumentation and control workers, two sites did not cover chemistry maintenance, four sites did not cover electrical maintenance, and four sites did not cover mechanical maintenance. The staff also found substantial variation among sites with regard to the number of personnel covered by plant work hour limits. The number of maintenance workers covered by working hour limitations at a site ranged from 0 to 554, the number of engineers and other personnel covered by working hour limitations ranged from 0 to 1471, and 16 sites had no engineers (e.g., system engineers) covered by working hour limitations.

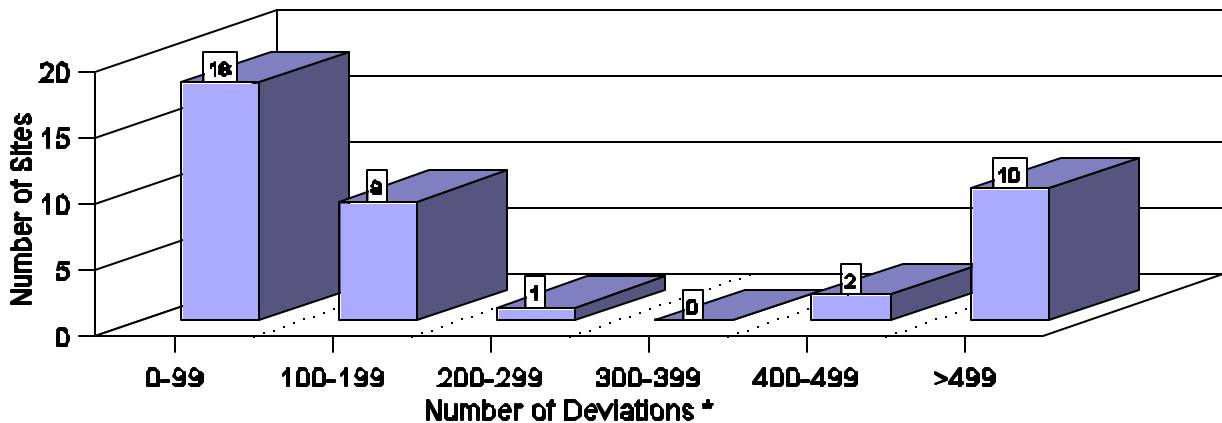
Distribution of Deviations: In response to the survey, sites reported the number of deviations that were authorized from the policy statement limits during outage and non-outage periods for 1997, 1998, and 1999. Table 3 shows that the most commonly used deviations during outage periods in 1999 were from the limit of 72 hours of work in any 7-day period (81.6 percent) and from the limit of 24 hours of work in any 48-hour period (15.1 percent). Authorized deviations for providing less than the minimum 8-hour break and for exceeding 16 hours of work in any 24-hour period collectively accounted for only a small percent of the authorized deviations during outages (3.3 percent). By contrast, the distribution of authorized deviations during non-outage periods was more even. Authorized deviations for working more than 16 hours in any 24-hour period accounted for a much larger percentage in non-outage periods (16.8 percent) than in outage periods (2.7 percent). Authorized deviations for exceeding 72 hours of work in any 7-day period (43.6 percent) and working more than 24 hours in any 48-hour period (36.7 percent) were, as in outage periods, the most common deviations during non-outage periods.

Table 3. Distribution of Deviations - 1999		
Types of Authorized Deviations	During Outage Periods	During Non-Outage Periods

72 hours in any 7-day period	81.6%	43.6%
24 hours in any 48-hour period	15.1%	36.7%
16 hours in any 24-hour period	2.7%	16.8%
Less than the minimum 8-hour break	0.6%	3.0%

Frequency of Deviations: Figure 1 shows that during non-outage periods in 1999, licensees for about two-thirds of the 40 sites that responded authorized less than 200 deviations whereas about one-quarter of the sites authorized more than 500 deviations. The range of deviations during non-outage periods was 12 to 992.

Figure 1. Distribution of Sites by Number of Deviations Authorized During Non-Outage Periods - 1999



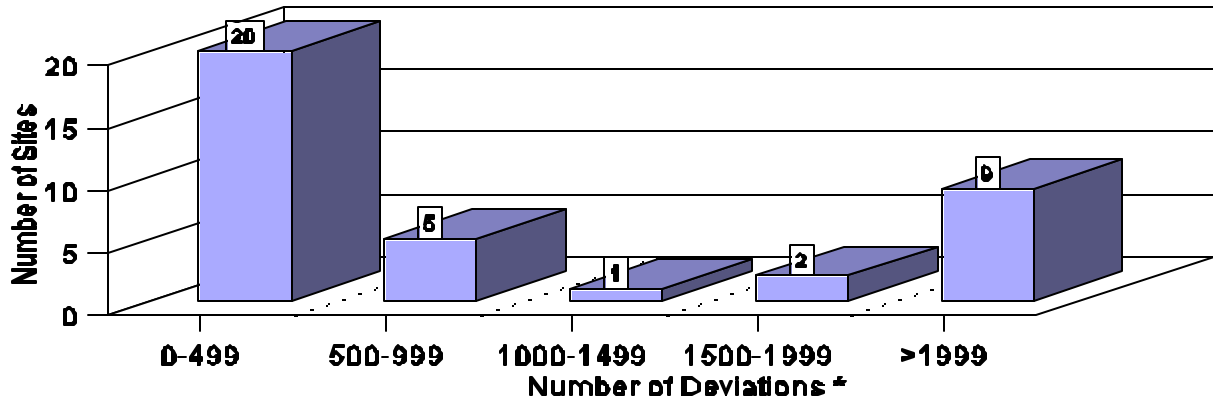
40 of 66 sites reporting data

* Range is 12-992 deviations

Figure 2 shows that during outage periods¹ in 1999, many of the survey respondents maintained relatively low numbers of deviations whereas a substantial minority authorized large numbers of deviations. Specifically, more than half of the 37 sites that responded authorized less than 500 deviations. In contrast, about one-quarter of the 37 sites authorized more than 2,000 deviations, including three sites that authorized more than 6,000 deviations. The range of deviations during outage periods was 7 to 7,553.

¹For this survey, a site was considered to be in an outage if one or more units at a site was not in mode 1.

Figure 2. Distribution of Sites by Number of Deviations Authorized During Outage Periods - 1999

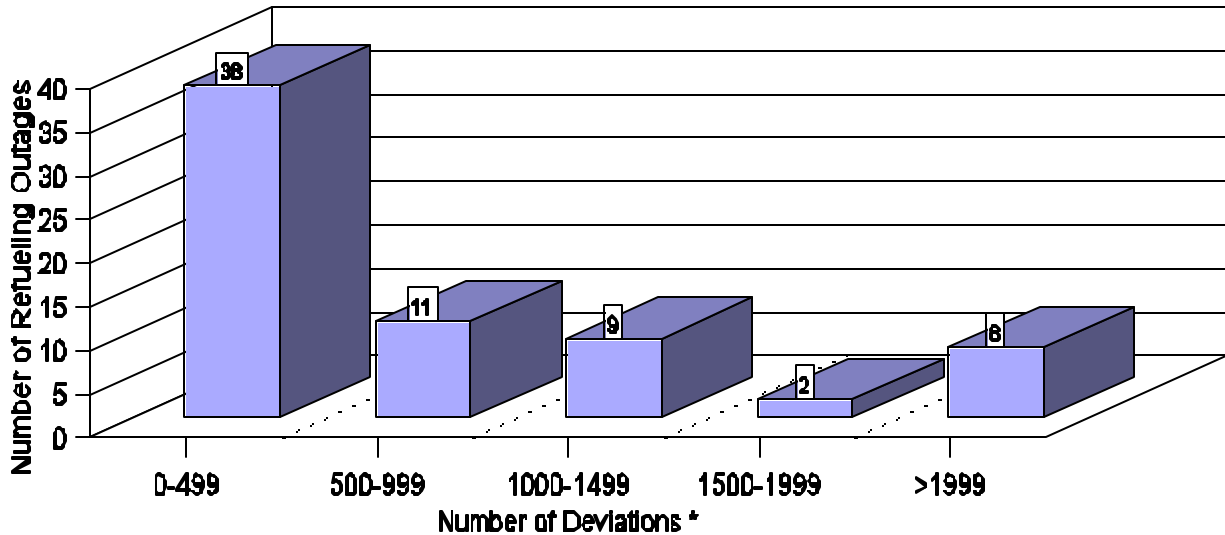


37 of 66 sites reporting data

* Range is 7-7,553 deviations

Survey respondents provided deviation data specific to 68 refueling outages. A wide variation was observed in the number of deviations authorized during a refueling outage. Twenty-five percent of the outages involved less than 100 deviations, whereas 28 percent of the refueling outages involved more than 1,000 deviations (Figure 3). No statistically significant correlation was found between the length of the refueling outage and the number of deviations authorized.

Figure 3. Distribution of Refueling Outages by Number of Deviations Authorized



Data Represents 68 Refueling Outages

* Range is 0-6,733 deviations

Overtime: Figure 4 shows annual overtime use for 1997, 1998, and 1999, and indicates that the percentage of personnel working in excess of 600 hours was higher in 1999 than 1997. At approximately one-fourth of the sites, more than 20 percent of the personnel covered by working hour limits work more than 600 hours of overtime annually. This number is more than two to three times the level allowed for personnel at some foreign nuclear power plants and more than twice the level recommended by an expert panel in 1985 (NUREG/CR-4248).

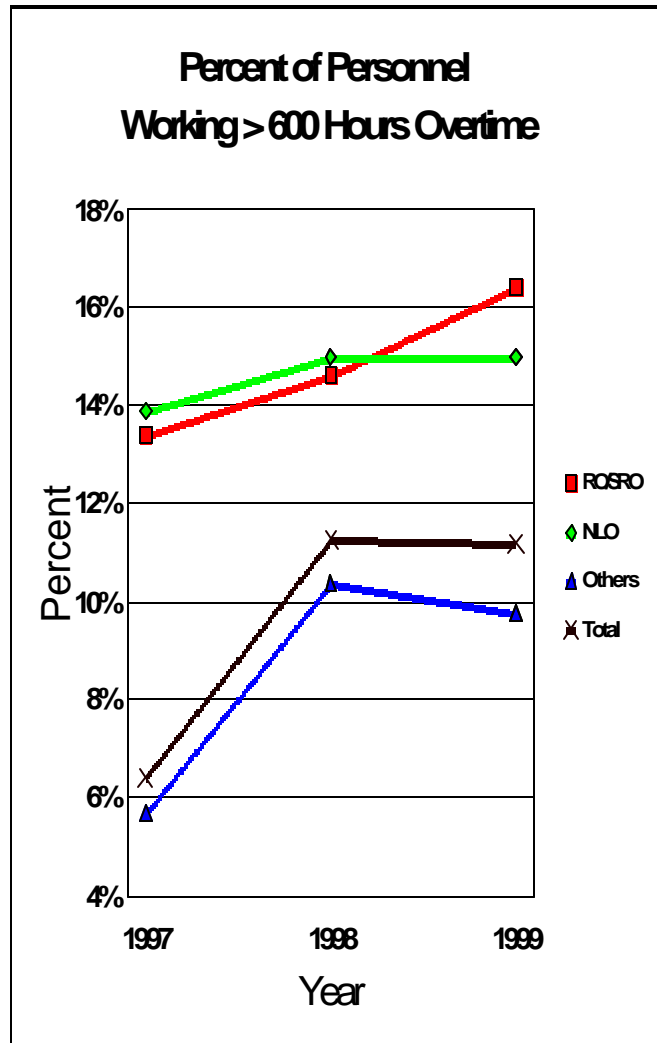


Figure 4. Percentage of Personnel Working More Than Six Hundred Hours of Overtime

NEI Position on Industry Implementation of the Policy Statement

On September 14, 2000, NRC held a public meeting to discuss the data collected by the NEI concerning the implementation of the policy statement. Both the NRC and the NEI presented their respective analyses of the data.

The NEI's assessment of the data is that it supports the Institute's position that rulemaking is not warranted. However, the NEI noted that variation in implementation of the policy statement at the sites may be a result of the guidance having been communicated through several documents, and consolidation of the guidance could be beneficial. The NEI also indicated that its interpretation of the data was that at most sites, the average number of deviations authorized for licensed and non-licensed operators was relatively small. The NEI's principal finding was that the number of deviations authorized per person is relatively low. This argument is supported by calculating an average number of deviations across time and personnel.

The staff does not believe that an analysis using calculated averages provides meaningful insights concerning fatigue for the following reasons:

- The NEI does not know the shape of the underlying distribution of deviations across time and personnel and, therefore, does not know if an average value is representative of the distribution.
- From a technical perspective, fatigue is experienced by individuals during specific periods of time. As a result, fatigue cannot be averaged across time and personnel, and such a statistic is potentially misleading and not technically sound.
- The staff also notes that from a regulatory perspective, the NRC must be mindful of individual licensee performance. This fact was quite evident in the distribution of deviations across sites. In addition, the staff is unable to verify or evaluate the calculation because the level of detail in the data provided to the staff does not allow the staff to perform such calculations.

Summary

Scope of Personnel

- There is inconsistency among sites in both the number and the type of personnel covered by plant work hour limits, and a few sites do not cover any maintenance personnel. This situation appears to be contrary to GL 83-14.

Use of Deviations

The frequency of guideline deviations at a substantial proportion of sites appears to be inconsistent with the intent of the policy because:

- During operating (non-outage) periods in 1999, licensees for one-third of the 40 sites that provided data authorized in excess of 200 deviations annually, while licensees for 3 sites authorized in excess of 800 deviations.

- During outage periods in 1999, licensees for about one-third of the 37 sites that provided data authorized in excess of 1,000 deviations, while licensees for 3 sites authorized in excess of 6,000 deviations annually.
- Licensees authorized more than 1,000 deviations in 28 percent of the refueling outages at plants that responded. In contrast, 25 percent of the refueling outages involved fewer than 100 deviations.

Use of Overtime

- Some sites have large percentages of personnel working in excess of 600 hours of overtime per year (i.e., more than two to three times the level allowed for operators at some foreign nuclear power plants, and more than twice the level recommended by a 1985 expert panel).
- The percentage of personnel working in excess of 600 hours of overtime was higher in 1999 than in 1997.

The staff believes that personnel working in excess of the policy statement guidance can be expected to be at increased risk of fatigue-induced impairment. However, the data illustrate that licensees for many sites do manage their work such that they have few deviations or little overtime.

7.0 Incidence of Fatigue-Related Events

Only a limited number of events at nuclear power plants have been directly attributed to fatigue. This may be in part be the result of the levels of defense-in-depth at nuclear power plants which are designed to reduce the potential for personnel errors to have consequential effects on plant safety. However, the staff is not able to state with certainty the actual number of events that result from fatigue, and any estimates should be interpreted with caution. In fact, plant incident reports typically do not contain much of the critical information needed to determine the contribution of human error. As noted in an EPRI report concerning control room operator alertness, "it is often necessary to rely on anecdotal evidence when presenting the case for the critical importance of operator alertness in the safe and efficient operation of a nuclear power plant" (EPRI, 1990).

One reason that the staff believes that the number of events attributed to fatigue may be underrepresented is that the research literature and operational data suggest that the conditions of shift work in nuclear power operations are such that one would reasonably expect personnel to be at risk of fatigue-induced impairment. This research includes the following examples:

- Studies show that personnel who work more than 12 hours a day are at increased risk of personnel error (Folkard, 1997; Dawson and Reid, 1997; Rosa, 1991). The NEI data concerning the use of deviations from the policy statement indicate that thousands of

person-hours are worked by personnel when they are at increased risk of impairment (see Section 6).

- Several studies show that nuclear power plant personnel exhibit circadian variations in alertness, and there are variations in the incidence of nuclear power plant personnel errors and events that coincide with these circadian variations in alertness (Bobko, 1998; Cox and Cox, 1996; Maloney, 1992).
- Studies show that personnel who are fatigued have impaired ability to maintain their attention (Harrison and Horne, 2000; Williamson, 2000; Bobko et al., 1998; Dawson and Reid, 1997; Dinges, 1995; Dinges, 1992; Rosa, 1991). The staff reviewed the Human Factors Information System (HFIS) data for 1997 through 1999 and found more than 5,000 instances of less-than-adequate independent verification, self-checking, and awareness or attention. These data were compared with HFIS data on findings related to the use of overtime. This analysis revealed that nuclear plants with repeated findings concerning use of overtime have a 50-percent higher incidence of HFIS causal factors related to fatigue.

Another reason that the staff believes that the number of events attributed to fatigue is underrepresented is that event investigation methodologies may not adequately address fatigue as a root cause, as indicated by the following factors:

- Depth of assessment – Most incidents at nuclear power plants are not subjected to an in-depth analysis that would identify fatigue as the underlying cause. Licensee event reporting requirements (10 CFR Parts 50.72 and 50.73) have not included causes of human performance problems at a level that would necessarily identify fatigue.
- Root cause assessment tools – There are no accepted criteria or structured approaches for evaluating the role of fatigue in accidents (Rosekind et al., 1997). As a result, when events are subjected to root cause assessment, fatigue may still not be identified. McCallum and Raby (1995) assessed investigation procedures employed by the NRC, the Federal Aviation Administration (FAA), and several international transport authorities. They found that the existing procedures do not adequately address the factors underlying fatigue as a causal element in cases in which the initial screening suggests fatigue as a factor.
- Lack of objective proof – When conducting a root cause analysis of events that involve personnel error, it is difficult to conclude that fatigue is a cause because there is little objective proof, absent the person sleeping, that the individual was impaired by fatigue. Even when nuclear plant personnel have been found with their eyes closed, they have asserted that they were not asleep, and investigators have concluded that the individual was “inattentive” (e.g., Peach Bottom, 1989).
- Ease of substantiating event causal factors – Fatigue degrades an individual’s abilities but does not necessarily cause the event. For example, the alert individual recognizes an error in a procedure, whereas the fatigued individual does not and implements an incorrect procedure. As a result, an investigator would focus on objective contributing factors (e.g., the procedure error) or describe the behavior (e.g., cognitive error) without citing a contributor, such as fatigue, that is difficult to substantiate.

- Accuracy of post-event observations – When individuals are debriefed following an incident, they may appear alert because of the stimulation of responding to, or potential consequences of, the event. Impairment from fatigue would not be readily apparent in such circumstances.
- Accuracy of self-assessment – Although self-assessment of fatigue can often indicate the level of fatigue, research suggests that other factors may influence such self-assessments (Wylie et al., 1996; Dinges, 1995). In addition, studies have shown that individuals may believe that they are relatively more alert than indicated by physiological indices (Wylie et al., 1996; Dinges, 1995; Rosekind and Schwartz, 1988).
- Veracity of self-assessment – For various reasons, individuals may be reluctant to acknowledge that they were fatigued at the time of an event involving personnel error, including the implication that they were not fit for duty (Horne and Reyner, 1995).

One outcome of these challenges to identifying fatigue as a causal factor is that the investigation identifies the observable effects or consequences of fatigue, rather than fatigue itself.

Other agencies and investigative bodies have come to similar conclusions concerning the attribution of fatigue to events. A letter from Jim Hall, Chairman of the NTSB, to DOT Secretary Rodney E. Slater, dated June 1, 1999, included the following statement.

Fatigue has remained a significant factor in transportation accidents since the Safety Board's 1989 recommendations were issued. Although generally accepted as a factor in transportation accidents, the exact number of accidents due to fatigue is difficult to determine and likely to be underestimated. The difficulty in determining the incidence of fatigue-related accidents is due, at least in part, to the difficulty in identifying fatigue as a causal or contributing factor in accidents. There is no comparable chemical test for identifying the presence of fatigue as there is for identifying the presence of drugs or alcohol; hence, it is often difficult to conclude unequivocally that fatigue was a causal or contributing factor in an accident. . . . Although the data are not available to statistically determine the incidence of fatigue, the transportation industry has recognized that fatigue is a major factor in transportation accidents.

Similarly, the DOT has concluded that fatigue statistics that are founded solely on accident reports underestimate the true extent of the problem (DOT, 65 FR 25545). In addition, the staff has learned that the Air Force Safety Center is revising the documentation to be used by accident investigation teams since they now believe that fatigue is underreported as a factor (Palmer et al., 1996). Also, a U.S. Coast Guard study suggests that direct measurement of fatigue may underestimate its true extent (Maritime Safety Committee, 1997). After the Coast Guard revised its procedures for investigating events, they found that the contribution of fatigue was *20 times greater* than previous estimates.

Summary

- Few events at U.S. nuclear power plants have been attributed to fatigue.

- The number of events attributed to fatigue should be interpreted with caution and cannot be reported with certainty.
- Many factors challenge the ability of event investigators to identify fatigue as a causal factor.

8.0 Scoping Assessment of the Sensitivity of Plant Core Damage Frequencies to Fatigue-Induced Impairment of Plant Personnel

Human errors are an important consideration in risk studies of nuclear power plants. In a probabilistic risk assessment (PRA) framework, the risk significance of fatigue effects can, in principle, be assessed through two classes of PRA model parameters. Specifically, these include the human error probabilities (HEPs), which deal largely but not exclusively with control room actions, and hardware-related parameters (e.g., initiating event rates and component failure probabilities, both of which can be affected by testing and maintenance practices). To date, such an assessment has not been done, partly because of the technical difficulties discussed below. However, since available empirical evidence, referenced below, indicates that fatigue can have a strong impact on human performance, it follows that further analysis to determine the impact of increased fatigue on human error probabilities applied in nuclear power plant PRAs may lead to important risk insights and is therefore warranted. Indeed, data suggest that fatigue, as caused by extended work hours or circadian rhythms, has significant effects on the likelihood of human error. Studies of accident rates in a wide range of industries (Hanecke, et al., 1998; Colquhoun, et al., 1996; Akerstedt, 1995; DOT, 65 FR 25544) indicate that the risk of accidents increases exponentially after 12 hours of work, and in some cases as little as 9 hours of work, and is more than two to three times the highest rates for 8 hour shifts when personnel are at work for 16 hours. It should be cautioned, however, it is not straightforward to determine the quantitative increase in the HEPs used in nuclear power plant PRAs. Factors that require consideration include the portion of time during which fatigue effects are operative, the nature of the tasks on which the data are based, differences in maintenance and control room activities, and the possibility that all HEPs are not universally affected. The staff is not aware of any PRA study that has considered the effects of fatigue.

NRC conducted a scoping study to quantify the potential risk impacts of errors caused by fatigued plant personnel. This study included sensitivity analyses that were performed by increasing the HEPs and quantifying the change in CDF for four nuclear power plants. The results of these sensitivity analyses show that global changes in HEPs can significantly affect the predicted core damage frequency (CDF). It should be emphasized that these results reflect only the sensitivity of core damage frequency to assumed changes in HEPs, and not the sensitivity of core damage frequency to changes in levels of operator fatigue. Additional work in the area of human reliability analysis will be necessary to understand the latter relationship.

Human errors may be sorted into categories for consideration in a probabilistic safety assessment (PSA). First, maintenance-related human errors may result in the failure of accident mitigation equipment. Second, human errors may prevent recovery of required equipment that failed during a plant event. Third, operators may err in mitigation-related actions such as alignment, operation, and control of systems or components. (For example, operators may fail to align alternate injection sources, fail to depressurize in certain scenarios, or fail to start and control pumps). The final category includes human errors that cannot be modeled using PSA techniques.

From a quantitative PSA viewpoint, the total CDF impact of increasing HEPs (as a result of fatigue) falls into the first three categories. Ideally, an analysis of the total CDF change should consider both internal and external initiating events during power operation as well as plant shutdown. However, because of the limited availability of plant models and time, this scoping study considered only at-power internal initiating events that proceed to core damage. There are shutdown-related probabilistic models for two of the plants included in this study (Grand Gulf and Surry), and these models may be useful if the scope of the study needs to be expanded. In addition, the sensitivity analyses were limited to varying the HEPs belonging to the third category. For this scoping study, maintenance-related and equipment recovery related fatigue failures were not included in the sensitivity study. Inclusion of these failures would increase the potential risk significance associated with fatigue; however, further study would be needed to evaluate their relative importance.

The Standardized Plant Analysis Risk (SPAR) models, Revision 3i, were chosen because they can be used to estimate the CDF of an internal event using a detailed HEP methodology. The human error modeling methodology used in these models was derived for the ASP Program. This methodology accounts for several performance shaping factors (PSFs) in calculating the HEPs, including FFD, which implicitly considers fatigue. For this scoping study, the base case HEPs for the types of actions in the third category were increased by multiples of 2, 5, and 10. SPAR models were used for the plants listed in Table 4:

Table 4. SPAR Model Baseline CDF		
PLANT	DESIGN	SPAR MODEL BASELINE CDF
Watts Bar	Westinghouse 4-loop PWR with an ice condenser containment	4.4E-5/yr
Surry	Westinghouse 3-loop PWR with a subatmospheric containment	2.8E-5/yr
Grand Gulf	General Electric BWR 6 with a Mark III containment	1.1E-5/yr
Brunswick	General Electric BWR 4 with a Mark I containment	3.0E-5/yr

The results show that a small variation (a multiple of two) across the board for human errors related to accident mitigation can result in a CDF increase of greater than or equal to 1E-5/yr. Larger multipliers would result in a larger increase. The SPAR human error methodology includes the FFD PSF and, for events analysis, allows the SPAR model user to assume a multiplier of 5 for degraded fitness. This value results in CDF increases in the range of 1E-5/yr and 1E-4/yr. For a multiplier of 10, the increase was estimated to be near 1E-3/yr for the PWR sample plants, and 1E-4/yr for the BWR sample plants. The steam generator tube rupture initiating event was the risk-significant initiator for the PWRs, whereas the transient initiator was

dominant for the BWRs. Caution should be used in reaching generic conclusions on the basis of these results because of differences in plant design and operation.

These findings broadly agree with three earlier risk sensitivity studies, including (1) NUREG/CR-5319, "Risk Sensitivity to Human Error"; (2) NUREG/CR-5527, "Risk Sensitivity to Human Error in the LaSalle PRA"; and (3) BNL L-117(2), "A Comparison of the Sensitivity of Risk to Human Errors in the Oconee and LaSalle PRAs." These studies showed that changes in HEPs of a factor of 5 result in an increase in CDF of a factor of between 4 and 33. In addition, the studies showed that a factor of two change in HEPs interpolates to a change in CDF of between 1E-5 and 1E-4. These findings demonstrate that relatively small changes in HEPs can be significant.

The preceding discussion suggests that the effects of fatigue could, under certain conditions, be risk significant. If risk insights are needed as part of continued fatigue-related studies, a number of conditions would have to be addressed. In particular, the effect of fatigue on HEPs for different actions modeled in the PRAs would need to be determined. The potential credit for fatigue management strategies (including both current licensee practices and possible additions), situations in which fatigue effects may be more prevalent (e.g., outage conditions), and the effects of fatigue on other PRA parameters (other than the HEPs) would also need to be assessed.

Summary

A scoping study of four plants was conducted using SPAR models to test the sensitivity of changes to the CDF when human error probabilities were varied to adjust for the effects of fatigue. The results show that a small variation (a multiple of two) across the board for human errors related to accident mitigation can result in a CDF increase of greater than or equal to 1E-5/yr. These results broadly agree with three earlier risk sensitivity studies that showed that a factor of two change in HEPs interpolates to a change in CDF of between 1.2E-5 and 1.2E-4. These findings indicate that the effects of fatigue may be risk significant.

9.0 Comparison of Working Hour Limits in Other Industries and at Foreign Nuclear Power Plants

The staff reviewed approaches taken by other Federal agencies and in other countries to address the potential for fatigue to adversely affect those personnel performing activities that can affect public safety. Table 5 summarizes the hourly limits on work and rest requirements in the policy statement, PRM-26-2, and the major occupations regulated by other agencies. The last two columns in Table 5 present the proposed revised limits for motor carrier drivers (65 FR 25610, 2000) and the limits for motor carrier drivers in Canada. Many of the other agency regulations are complicated and cover many aspects of their operations. (For example, the FAA has eight different regulations.) Only the most relevant regulations are included in the table. As can be seen from the table, the NRC requirements, collectively, are less restrictive than those of other Federal agencies that limit hours of work in private industry.

The other Federal agencies that the staff identified as regulating hours of work include the Federal Motor Carrier Safety Administration (FMCSA), the Federal Railroad Administration, the FAA, and the U.S. Coast Guard (personnel in safety-sensitive positions), the regulations of which limit the duty hours of personnel performing tasks important to public health and safety. For

example, the FAA has promulgated duty hour regulations for flight crew members, dispatchers, aviation maintenance technicians, and air traffic controllers.

It is sometimes asserted that the work tasks and characteristics in nuclear power plants are different from the other occupations that have overtime controls; therefore, information from other occupations may be inapplicable. By comparison to many other work environments (e.g.,

Table 5. Hourly Limits on Work and Rest in the NRC’s Policy Statement, the NRC Petition, and Other Industries

	NRC GL 82-12	NRC Petition	Comm. Pilot (flight time)	Air Force Pilots	Air Traffic Control	Marine	Rail	Truck Drivers (drive time)	Truck Drivers (Proposed)	Truck Drivers (Canada)
Hrs worked in a 24-hr period	16	16	8 to12	12	10	8 to15	12	10	12	13
Length of rest	8	16	9 to18			10	8 or 10	8	10	8
Hrs worked in a 48-hr period	24	24								
Hrs worked in a 72-hr period						36				
Hrs worked in a 7-day period	72	60 or 72	30 or 34		24			60	60	60
Hrs rest in a 7-day period			24						32 to 56	
Hrs worked in a 14-day period		108 or 132 or 144								
Hrs worked in a 30-day period			100 or 120	125						

Hrs worked in a year		2496 or 2704	1000 or 1200						
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truck cabs, airplane cockpits), nuclear power plant control rooms, in general, provide relatively favorable light and temperature environments for mitigating the effects of fatigue.² Nuclear power plant operators are also able to move freely about the control room, interact with other operators, and engage in a variety of activities during the course of a work period. These factors are conducive to operators maintaining a higher level of subjective alertness. These factors, however, do not counteract an individual's physiological need for sleep and are not likely to completely mitigate the degradations in cognitive performance that result from sleep deprivation.

The physiological effects of fatigue are predominantly influenced by how long an individual is awake, how much sleep an individual has recently obtained, and the point at which the individual is in his or her circadian cycle of alertness (Kecklund et al., 1997). Research has also shown that team performance is affected by fatigue (Harrison and Horne, 2000; NTSB, 1994) suggesting that whereas members of a crew may help each other remain alert, a crew environment does not ensure fatigue will not degrade performance. The occupations regulated by the other Federal agencies are themselves different, ranging from marine officer and air traffic controller to maintenance personnel. Despite the diversity of occupations and tasks, the other Federal agencies have set stricter limits on hours of work and rest and have given management less authority to deviate from those limits. Although the stricter limits in other industries may reflect concerns about the influence of the specific work environments on fatigue, those limits may also reflect the potential in certain industries for operator performance degradations to directly affect safety.

General Regulatory Approach – The staff found that the NRC's general approach to plant personnel fatigue (i.e., limiting the number of hours worked) is consistent with the approach taken by other Federal agencies. However, the NRC has not put these limits in a regulation as have other Federal agencies that have a public safety mission. Instead, the NRC uses plant-specific TSs as the means to implement the limits (see Section 4).

Specific Limits – The staff found that the policy statement for allowing 16 hours in a 24-hour period and 72 hours in a 7-day period is less restrictive than the limits imposed in several of the other industries reviewed; however, none of the other industries include the limit of no more than 24 hours of work in any 48-hour period. In addition, the NRC's policy guidance for a minimum break of at least 8 hours between work periods is the shortest of the surveyed industries. The NRC's policy statement also does not provide guidance to limit work hours accumulated over periods longer than 7 days, whereas commercial and air force pilots have limits for longer periods of time.

Deviations – The policy statement allows flexibility that is not provided in other agency regulations. Although the objective of the policy statement is to have 8- or 12-hour days and nominal 40-hour weeks, limits are set for unforeseen problems and extended periods of

² Low frequency noise levels from sources such as ventilation systems and rotating equipment may be at levels conducive to fatigue at some plants. Environmental conditions for operator activities outside of the control room are highly variable.

shutdown. A few other agencies allow limited flexibility. For example, regulations for seamen apply “except in an emergency when life or property [is] endangered” (46 CFR 8104 (b)).

Limits for Nuclear Power Plant Personnel in Other Countries – In addition to the survey of working hours in other industries, the staff surveyed regulators of nuclear plants in other countries. The limits are set by national labor law, regulations, or union agreements. These limits are consistent with the technical and research information described in Section 3, but in some cases their adoption may have been influenced by economic conditions. The information presented in Table 6 was extracted from the data for ease of comparison. The actual data and source documents are more detailed. The information in the table includes working hour information from EDF, the utility in France; the Health and Safety Executive in the United Kingdom; SKI, the regulator in Sweden; STUK in Finland; HSK, the Swiss regulator; JAERI in Japan; HAEA, the Hungarian regulator; CSN, the Spanish Regulatory Agency; and the Canadian Nuclear Safety Commission. The last column includes the general guidance from the European Union (EU) on working hours (Directive 93/104/EC of 23 November 1993), which many EU countries have adopted. The EU conventions are based on research findings and are quite restrictive, but individual countries and industries do modify them for their particular situation. As can be seen from Table 6, the foreign limits on working hours are more restrictive than the limits stated in the current NRC policy statement. Except for Finland, the maximum hours in a 24-hour period are either 8 or 12, as compared to the 16 allowed by the NRC. The highest weekly maximum is 48 hours, as opposed to the 72 hours allowed in the United States, Spain, and Finland. There is no category for hours worked in a 48-hour period; however, there are monthly and yearly maximums that are not included in the NRC policy statement. The staff also obtained information on the average number of deviations expected in a year, the extent of those deviations, and the reasons for such deviations. Typically, the utilities would average one period a year during which deviations would be allowed on a plant-wide basis for outages or emergencies. The extent of the deviations would be 1 to 2 hours a day for France and Japan, but as many as 6 to 8 hours a day in the United Kingdom.

Summary

- The NRC policy statement is generally the least restrictive of the Federal agencies that regulate hours of work in other industries and allows more flexibility than other agency regulations.
- Tasks and task environment can influence whether an individual feels alert or drowsy but the physiological effects of fatigue are predominantly influenced by how long an individual is awake, how much sleep the individual has recently obtained, and the point at which the individual is in his or her circadian cycle of alertness.
- The foreign limits on working hours are more restrictive than those of the NRC policy statement and apply to a broader group of personnel. These limits are generally consistent with the technical and research information described in Section 3, but in some cases their adoption may have been influenced by economic conditions.

Table 6. Hourly Limits on Work and Rest in the Foreign Nuclear Industry

	France	UK	Sweden	Finland	Switzerland	Japan	Hungary	Spain*	Canada	EU-Gen
Hrs worked in a 24-hr period	10 w/o auth.; 12 w/auth.	8 hrs in 24 (Avg. over 17 wks)		16		8	8 hr; 6 hr hazardous duty	12	12	
Length of break				8 hrs between work periods 24 hrs/wk			11 hrs between work periods	8 hrs between work periods	72 hrs after three 12-hr shifts; 48 hrs after two 12-hr night shifts	11
Hrs worked in a 7-day period	35	48 hrs/wk (avg. over 17 weeks)	Regular 40/wk; Shift workers 36/wk	72	45	40		72	48	48
Hrs worked in a 30-day period		120	50 hrs OT/month special reason				180 on-call hrs			
Hrs worked in a year	1600	2050	150 hrs OT/yr.	250 OT	170 hrs OT		200 hrs OT		2480	
Night work										8/24
Freq. of deviation	Once/yr Emerg. or outages	Once/yr Emerg. or outages		<1/yr Operational events	Emerg.	Emerg.	Emerg.	As authorized by Plant Super.	Emerg.; need Ministerial permit	
Extent of deviation	1-2 hrs/day	6-8 hrs/day		> 8hrs	2 hrs/day	1-2 hrs/day	Once/wk, 6-8hrs/day			
Personnel covered	All	All	All	All, plus special limits for operators	All	All	All	Shift personnel and operators	All non-management	All

	France	UK	Sweden	Finland	Switzerland	Japan	Hungary	Spain*	Canada	EU-Gen
Basis	National labor law	Regulation based on EU convention	National labor law and union agreement	National labor law and union agreement	National labor law	National labor law	National labor law and union agreement	Union Agreement	National labor law and union agreement	

*for 5 of 9 plants

10.0 Description of Fatigue Management Programs

In addition to surveying current regulations, some of which were established many years ago, the working group surveyed current initiatives in industry to address fatigue. Fatigue Management Programs (FMPs), sometimes referred to as Alertness management programs, are becoming prevalent in many industries that require shift work. These programs are being championed by industry and labor organizations throughout the transportation and process industries. Most are derived from work performed for the military and the aerospace industry. Dr. Mark Rosekind, formerly of the National Aeronautics and Space Administration (NASA)/Ames, is often credited for his work in defining the broad elements necessary for an effective FMP (Table 7). The major elements of FMPs include prevention (e.g., work hour limits, rest requirements, training, health screening), detection and monitoring, mitigation, and evaluation. The NASA/Ames program is widely used as it is viewed as providing the most advanced material while still being predicated on scientific consensus.

Several Government agencies (the FMCSA, FAA), consultants (Rosekind and Associates; Circadian Technologies, Inc.), industries (railroads and truckers), and companies (rail and shipping) have implemented or expanded upon the NASA/Ames approach. For example, most major rail routes west of the Mississippi River use FMPs that allow and encourage napping to maintain alertness. Fatigue management is also used in Australia in the rail, trucking, and electric power industries. Some companies have also incorporated risk management in their FMPs. To minimize system risk, analytical tools are used to integrate the risk from personnel impairment with operational risk assessment to support decisions concerning scheduling and job assignments. A similar approach has been implemented by a rail transport company in Canada. Most tailor the generic FMP elements to their specific industries, companies, or work sites. One private firm claims to have provided assistance in developing and implementing FMPs to 60 percent of the Fortune 500 firms. Research is underway regarding specific approaches in specific environments (e.g., testing of different shift schedules at railroads and the use of napping while at work). Some future countermeasures have much research yet to be done before they are completely understood. However, other than limited self-assessments and program refinements, there have not been any publicly available formal studies to assess the overall effectiveness of FMPs.

Table 7. Elements of a Fatigue Management Program

Prevention

- ! Training, for example, sleep hygiene; effects of shift work, diet, exercise, alcohol, caffeine, medications, and sleep environment; and circadian physiology
- ! Work hour limits and rest requirements
- ! Medical review for sleep disorders, for example, health screening programs

Detection and Monitoring

- ! Supervisory observation
- ! Self-assessment
- ! Alertness monitoring

- ! Analytical tools for assessing fatigue
- ! Root cause analysis

Mitigation

- ! Error reduction techniques, for example, communications, self-checking, independent verification
- ! Task/access limitations, for example, work distribution, risk considerations
- ! Rest provisions, for example, rest breaks, napping

Research and Evaluation

- ! Bright light technology
 - ! Melatonin
 - ! Alertness monitoring systems
 - ! Environmental considerations, for example, lighting, noise, temperature
-

The DOT has identified operator fatigue as a significant issue affecting all transportation modes and consequently classifies operator fatigue management as a DOT “Flagship Initiative.” In August 2000, the DOT held a conference on “Operator Fatigue Management.” The conference brought together representatives from industry, labor, Government, and the research community to discuss their plans for a cross-modal research program in fatigue management. The DOT’s proposed effort is budgeted at \$12 million, with the intent to have transportation industry partners match the DOT resources over 3 years. The elements of this initiative are to develop a fatigue management reference resource, to investigate fatigue management analytical systems, and to develop fatigue management evaluation tools and methods. The work is to be coordinated by the DOT Human Factors Coordinating Committee across all modes of transportation.

On October 26-27, 2000, the Federal Transit Administration, the American Public Transportation Association, the Community Transportation Association of American, and the National Sleep Foundation held a symposium on tools for managing fatigue in transit. The symposium included an extensive cross section of fatigue experts and others concerned with fatigue and its effects on transit. Operational and labor issues were emphasized.

Summary

Several other industries have addressed the matter of personnel fatigue through industry - labor initiatives to develop fatigue management programs. These programs combine several methods to prevent, detect and mitigate fatigue and include elements of working hour limits and rest requirements.

11.0 Conclusions

Nuclear power plants are designed, and their operation controlled, in a manner to minimize the consequences of potential human errors on plant operational safety. As a consequence, there are measures and barriers that can serve to reduce the probability of fatigue induced errors at nuclear power plants resulting in events leading to core damage or off-site release of radioactive materials. Nevertheless, the assessment of the policy indicates that from both technical and

regulatory perspectives, there are attributes of the policy and its implementation that cause the policy to be less than wholly effective in ensuring that fatigue does not significantly degrade the ability of personnel to perform functions important to plant operational safety.

The assessment of the technical adequacy of the guidelines indicated that - -

- Studies of work scheduling, fatigue, and human performance indicate that scheduling of personnel at or near the limits of the NRC policy guidelines for controlling work hours during outages can result in degraded human performance from work-related fatigue.
- Personnel whose work hours exceed the policy guidelines (e.g., when guideline deviations are authorized) are at increased risk of impairment and of committing fatigue-induced errors.
- The policy statement does not provide clear guidance on the magnitude or frequency of deviations from the guidelines that are acceptable.
- The policy statement guidelines are not responsive to the variations in plant risk that can occur during shutdown conditions and the heightened challenges to human performance presented by plant outage working conditions.
- The policy statement addresses only working hours, not the fundamental issue of fatigue.

The staff also reviewed individual plant TSs and assessed the ability of the NRC to enforce its requirements concerning working hours and fatigue. The staff found that - -

- There are numerous variations on how the policy statement was incorporated into TSs, including no reference in TSs at three nuclear power units.
- Key terms of the TSs have not been defined, resulting in inconsistent interpretation and implementation.
- Only the mandatory and unambiguous provisions of the TSs and Part 26 relative to working hours and fatigue are readily enforceable in an efficient and effective manner. Substantial effort is required to enforce the broad and non-prescriptive provisions, even in extreme circumstances.

The assessment of industry implementation of the policy also indicates deficiencies. Some of these problems might be traced to lack of definition of some terms (e.g., very unusual circumstances) and inconsistencies in interpretation. Data reviewed in this assessment, which show that - -

- There is inconsistency among sites in the scope of personnel covered by plant work hour limits, and a few sites do not cover any maintenance personnel. This circumstance appears to be contrary to GL 83-14.

- The frequency of guideline deviations at a substantial proportion of sites appears to be inconsistent with the intent of the policy. At one-third of the sites that responded, more than a thousand guideline deviations are authorized annually.
- Licensees of many sites manage their work such that they have few deviations or little overtime.
- Some sites have large percentages of personnel working in excess of 600 hours of overtime per year. The percentage of personnel working in excess of 600 hours of overtime was higher in 1999 than in 1997.

The staff considered the incidence of events attributed to fatigue at nuclear power plants and found that there were few. This may be in part the result of the levels of defense-in-depth at nuclear power plants which are designed to reduce the potential for personnel errors to have consequential effects on plant safety. However, the staff believes that the number of events attributed to fatigue should be interpreted with caution and cannot be reported with certainty. The staff's conclusions were based on the following considerations:

- Research literature and operational data suggest that the conditions of shift work in nuclear power operations are such that one would reasonably expect personnel to be at risk of fatigue-induced impairment.
- Studies show that nuclear power plant personnel exhibit circadian variations in alertness and that there are variations in the incidence of nuclear power plant personnel errors and events that coincide with these circadian variations in alertness.
- Several factors challenge the ability of investigators to identify fatigue as the cause of an event, including the fact that fatigue cannot be objectively proven. As a result, event investigations are more likely to identify the observable effects of fatigue (e.g., inattention or cognitive error), rather than fatigue itself.

As part of the policy assessment, the staff conducted preliminary assessments of the influence of fatigue on plant risk. Although a more detailed study would be necessary to have confidence in the assessed influence of fatigue on plant risk, the preliminary findings indicate that the effects of fatigue may be risk significant. These findings include the following:

- Studies concerning extended work hours (e.g., more than 12 hours) suggest that fatigue-induced personnel impairment can increase human error probabilities by a factor of more than two to three times baseline human error probabilities.
- A scoping study using SPAR models shows that a small variation (a multiple of two) across the board for human errors related to accident mitigation can result in a CDF increase of greater than or equal to 1E-5/yr.

- These results broadly agree with three earlier risk sensitivity studies that showed that a factor of 2 change in HEPs interpolates to a change in CDF of between 1.2E-5 and 1.2E-4.

The staff reviewed the regulatory approaches and limits of other agencies that controlled working hours of personnel for the purpose of protecting public health and safety. Limits in other settings can be influenced by a variety of practical considerations, such as operational constraints in the industry and socioeconomic factors. Tasks and task environments can also influence whether an individual feels drowsy or alert and may have also influenced the limits specified in a particular industry. Nevertheless, research has shown that the physiological effects of fatigue are predominantly influenced not by tasks but by how long an individual is awake and at what point the individual is in his or her circadian cycle of alertness. Consequently, the predominant influence, human physiology, is common to all industries, and the staff believes that considering the limits in other industries collectively can provide useful insights. The staff drew the following conclusions:

- Collectively, the NRC guidelines are less restrictive than limits imposed by Federal agencies that regulate hours of work in other industries.
- The NRC policy statement allows more flexibility than the regulations of other agencies.
- The working hour limits on nuclear power plant workers in other countries are more restrictive than those of the NRC policy statement.
- Other industries and countries have limits for periods of more than seven days.
- The limits in other industries and countries generally appear more consistent with limits that research on work scheduling and fatigue would suggest are appropriate for ensuring human reliability.

On the basis of these findings, the staff believes that weaknesses in the NRC policy statement have diminished its effectiveness. However, the staff also believes that there is an adequate technical basis and relevant experience to develop new requirements that are technically sound and practical in a nuclear plant operational setting. Current approaches being pursued by some industries in the United States and abroad suggest that the NRC should consider methods that address the fundamental issue of fatigue from any cause, not just working hours. Such measures, as implemented in FMPs, include prevention (e.g., work hour limits, rest requirements, training, health screening), detection and monitoring, mitigation, and evaluation.

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ATTACHMENT 2

**ANALYSIS OF PUBLIC COMMENTS ON THE
PETITION FOR RULEMAKING FILED BY BARRY QUIGLEY
SEPTEMBER 28, 1999
(64 FR 67202)**

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OVERVIEW

The Nuclear Regulatory Commission (NRC) published for public comment a notice of receipt of a petition for rulemaking (PRM) dated September 28, 1999. The petition was docketed by the NRC on October 7, 1999, and was assigned Docket No. PRM-26-2. The comment period for the petition began on December 1, 1999, and expired February 14, 2000. Comments received after this date were considered, the last of which was received on July 5, 2000.

The petitioner requested that the NRC (1) add enforceable working hour limits to 10 CFR Part 26, (2) add a criterion to 10 CFR 55.33(a)(1) to require evaluation of known sleeping disorders, (3) revise the NRC Enforcement Policy to include examples of working hour violations warranting various NRC sanctions, and (4) revise NRC Form 396 to include self-disclosure of sleeping disorders by licensed operators. The petitioner also requested changes to NRC Inspection Procedure 81502, "Fitness for Duty Program."

One hundred and seventy-six comment letters were received, representing comments from the public, NRC licensed individuals, public interest groups, the Professional Reactor Operator Society, nuclear power plant licensees (utilities), the Nuclear Energy Institute (NEI), a consortium of utilities, and the petitioner (who provided two additional letters clarifying the petition). Each letter received was assigned a number (1 to 176) and specific comments contained in each letter were given a decimal designation (e.g., 1.1, 1.2, 2.1, 2.2, 161.3, 161.4). The comments were grouped into 17 subject matter categories. Within each category, the summarized comments are presented with their accompanying staff analyses. At the end of the document, there is a reference list of all citations mentioned in the staff's analyses. Copies of the letters are available for public inspection and copying for a fee at the Commission's Public Document Room located on the first floor of the NRC Headquarters Building (One White Flint North), 11555 Rockville Pike, Rockville, MD. The letters may also be viewed on the NRC's Web site, nrc.gov/NRC/rule.html, Rulemaking Web Site, "News, Information and Contacts for Current Rulemaking."

Though the Commission received many comments concerning the specific requirements proposed in PRM-26-2, the majority of the comment letters (157 of 176 [89%]) expressed support for amending the rules, generally following the objectives discussed by the petitioner. These letters of support (1) cited the importance of ensuring that personnel who perform safety-related functions are not impaired by fatigue, (2) expressed concern that the NRC did not have a regulation limiting working hours and the perception that the NRC lacked the authority to enforce the policy guidelines, (3) asserted that the guidelines were ambiguous and interpreted not to apply when the plant is in an outage, (4) asserted that "the NRC appears to look the other way" when licensee work scheduling practices appear inconsistent with the guidelines, and (5) expressed the concern that utility restructuring and cost competition will cause reduced staffing levels and increased working hours and fatigue. Several commenters noted that the Federal Government had established work hour limits for personnel in other industries and suggested that such limits should apply to nuclear power plant workers.

In general, comments in opposition to the petition (18 of 176 [10%])¹ expressed the opinion that existing regulatory requirements (i.e., technical specifications (TSs) and 10 CFR Part 26, “Fitness for Duty Programs”) were adequate for ensuring that personnel were not impaired by fatigue, that the proposed requirements would impose unnecessary and excessive burden that could not be justified through a backfit analysis, and that industry performance data refute the petitioner’s argument that a rule is necessary to prevent fatigued personnel from performing safety-related work.

¹One letter was assessed as neither supporting or denying the petition for rulemaking.

SUMMARY OF COMMENTS

The following table identifies the number of comments received by commenter affiliation:

Summary of Public Comments Received for Petition for Rulemaking PRM-26-2

<i>Number of comments received</i>	<i>Commenter affiliation</i>	<i>Comment number</i>
242	Public citizens	1.1; 2.1; 3.1; 4.1; 5.1; 6.1; 7.1; 8.1; 8.2; 8.3; 8.4; 8.5; 8.6; 9.1; 9.2; 9.3; 10.1; 10.2; 11.1; 11.2; 11.3; 11.4; 12.1; 12.2; 12.3; 12.4; 12.5; 14.1; 14.2; 14.3; 14.4; 15.1; 16.1; 16.2; 16.3; 16.4; 17.1; 18.1; 19.1; 19.2; 20.1; 21.1; 22.1; 23.1; 24.1; 25.1; 26.1; 27.1; 28.1; 29.1; 30.1; 31.1; 32.1; 33.1; 34.1; 35.1; 35.2; 36.1; 37.1; 38.1; 39.1; 40.1; 41.1; 41.2; 42.1; 43.1; 44.1; 44.2; 45.1; 46.1; 47.1; 48.1; 49.1; 50.1; 51.1; 51.2; 52.1; 53.1; 53.2; 54.1; 55.1; 56.1; 56.2; 57.1; 58.1; 59.1; 60.1; 61.1; 62.1; 62.2; 63.1; 64.1; 64.2; 64.3; 65.1; 66.1; 67.1; 68.1; 69.1; 70.1; 71.1; 72.1; 73.1; 74.1; 74.2; 75.1; 76.1; 76.2; 77.1; 77.2; 77.3; 78.1; 79.1; 80.1; 80.2; 80.3; 81.1; 82.1; 83.1; 84.1; 85.1; 86.1; 87.1; 87.2; 87.3; 87.4; 88.1; 89.1; 89.2; 89.3; 89.4; 90.1; 90.2; 91.1; 92.1; 93.1; 94.1; 95.1; 96.1; 97.1; 97.2; 97.3; 98.1; 99.1; 100.1; 101.1; 102.1; 103.1; 104.1; 105.1; 106.1; 107.1; 108.1; 109.1; 110.1; 111.1; 111.2; 111.3; 112.1; 113.1; 114.1; 115.1; 116.1; 117.1; 118.1; 118.2; 119.1; 120.1; 121.1; 122.1; 123.1; 124.1; 124.2; 124.3; 124.4; 125.1; 126.1; 126.2; 127.1; 128.1; 129.1; 129.2; 130.1; 131.1; 132.1; 133.1; 133.2; 133.3; 134.1; 134.2; 134.3; 134.4; 134.5; 134.6; 134.7; 135.1; 135.2; 136.1; 137.1; 138.1; 138.2; 139.1; 140.1; 141.1; 142.1; 143.1; 144.1; 145.1; 145.2; 145.3; 145.4; 147.1; 148.1; 148.2; 148.3; 148.4; 150.1; 154.1; 154.2; 154.3; 154.4; 154.5; 154.6; 154.7; 155.1; 155.2; 155.3; 155.4; 162.1; 162.2; 162.3; 176.1; 176.2; 176.3; 176.4; 176.5; 176.6; 176.7; 176.8; 176.9; 176.10; 176.11
10	NRC licensed individual	149.1; 149.2; 149.3; 151.1; 151.2; 152.1; 152.2; 152.3; 152.4; 152.5
10	Public interest group	13.1; 13.2; 13.3; 13.4; 146.1; 146.2; 146.3; 146.4; 156.1; 156.2

<i>Number of comments received</i>	<i>Commenter affiliation</i>	<i>Comment number</i>
4	Professional Reactor Operator Society	153.1; 153.2; 153.3; 153.4
47	Utilities	158.1; 158.2; 158.3; 158.4; 158.5; 158.6; 158.7; 159.1; 159.2; 159.3; 160.1; 160.2; 160.3; 160.4; 160.5; 160.6; 160.7; 160.8; 160.9; 160.10; 163.1; 164.1; 165.1; 166.1; 166.2; 166.3; 166.4; 166.5; 167.1; 167.2; 167.3; 167.4; 167.5; 167.6; 168.1; 168.2; 168.3; 168.4; 168.5; 169.1; 170.1; 171.1; 172.1; 172.2; 172.3; 174.1; 175.1
15	Nuclear Energy Institute	161.1; 161.2; 161.3; 161.4; 161.5; 161.6; 161.7; 161.8; 161.9; 161.10; 161.11; 161.12; 161.13; 161.14; 161.15
17	Consortium of utilities	157.1; 157.2; 157.3; 157.4; 157.5; 157.6; 157.7; 157.8; 157.9; 157.10; 157.11; 157.12; 157.13; 157.14; 157.15; 157.16; 157.17
9	The Petitioner	173.1; 173.2; 173.3; 173.4; 173.5; 173.6; 173.7; 173.8; 173.9

ANALYSIS OF COMMENTS

1.0 Adequacy of Current Guidance - Policy and Technical Specifications

1.1 Comment: Several commenters stated that the NRC lacked appropriate regulations to prevent excessive overtime (comments 8.2; 11.3; 14.3; 16.2; 30.2; 35.1) or that the NRC provided only guidelines and had no authority to enforce the guidelines (comments 12.3; 87.2; 89.2; 124.3; 176.1).

Analysis: The NRC currently does not have a regulation that limits the working hours of nuclear plant staff. Rather, in 1982 the Commission issued its “Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors.” The guidelines contained in the policy were subsequently implemented by most licensees through the adoption of plant TSs. Although the TS wording and details are not uniform across sites, the TSs, in general, require administrative procedures to limit the working hours of plant staff who perform safety-related functions. The NRC has the authority to enforce the requirements of the TSs. However, the guidelines do not establish maximum limits on overtime and plant TSs allow the plant manager (or a designee) to approve deviations from the guidelines.

The staff also notes that the current standard TSs for plant staff working hours do not include specific guidelines for limiting working hours. Rather, the standard TSs requires administrative controls that include guidelines on working hours that ensure adequate shift coverage is maintained without routine heavy use of overtime. Although it is incumbent upon licensees with the current standard TSs to establish guidelines that meet this objective, licensees may implement guidelines that differ from those in the policy. The NRC has not defined the term “routine heavy use of overtime,” nor has it provided guidance concerning limits that would preclude “routine heavy use of overtime.” As a result, in these instances the NRC does not have a clear basis for evaluating the adequacy of licensee administrative guidelines relative to their TS requirements.

1.2 Comment: One commenter stated that there is so much ambiguity in the guidelines that the policy does not prevent misuse of overtime on a day-to-day basis (Comment 151.2). In contrast, many commenters stated that the NRC’s current overtime guidance is sufficient to ensure that overtime is not abused (comments 157.3; 161.3; 159.1; 160.1; 163.1; 164.1; 165.1; 166.1; 168.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1).

Analysis: Certain key terms in the “Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors” and in plant TSs have not been defined. This is a likely contributor to inconsistent implementation of the policy among nuclear plant sites and to some instances of licensees controlling working hours in a manner that is inconsistent with the staff’s interpretation of the policy. As noted in the analysis of comment 1.1, whereas the TSs allow the use of deviations from the guidelines, it is not clear when such deviations are prohibited by the TSs because they constitute “routine heavy use of overtime.” Similarly, whereas the Commission provided guidelines that allowed deviations to the policy to be approved for “very unusual circumstances,” the frequency of deviations observed by NRC inspectors and data collected by the NEI suggests that this precondition for authorizing deviations results in differences in application because of a lack of uniform criteria for “very unusual circumstances.” A data collection effort by NEI concerning industry implementation of the policy guidance was conducted during July 2000. Approximately half of the plant sites provided deviation data. The analysis of the sites providing data disclosed that (1) during normal operations, about a third of the sites that provided data authorized more than 200 deviations annually and (2) during plant outages, about a third of the sites that provided data authorized more than a thousand deviations annually (NEI, August 29, 2000). The frequency of guideline deviations appears inconsistent with the intent of the policy.

1.3 Comment: One commenter stated that some licensees have pushed limits on overtime to the extent that they have and are creating error-likely situations (comment 134.2).

Analysis: The NRC, through issuance of the “Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors,” provided guidelines on working hours that were consistent with the objective of ensuring that the mental alertness and decisionmaking abilities of plant staff were not significantly degraded by fatigue. As noted in letters dated May 18, 1999, from former NRC Chairman Shirley Ann Jackson to Congressmen Dingell, Klink, and Markey, a review of NRC inspection reports indicates that inspectors have found several instances each year of

licensee work scheduling practices that did not appear to be consistent with the general objectives or specific guidelines of the policy statement. As discussed in the analysis of the previous comment, data collected by NEI concerning industry implementation of the policy guidance show that approximately a quarter of the sites have a substantial percentage of personnel covered by working hour limits working in excess of 600 hours of overtime annually. In addition, the percentage of personnel in the survey sample working in excess of 600 hours of overtime annually has increased since 1997 (NEI, August 29, 2000). Although the data alone are insufficient to demonstrate conclusively that “error-likely” situations have been created, the amount of overtime appears inconsistent with the intent of the policy. The data are sufficient, nonetheless, for the Commission to take action to preclude such “error-likely” situations from occurring.

1.4 Comment: One commenter stated that the guidelines are insufficient to prevent abuse of overtime and cited (1) concerns reported to the NRC in which it has been stated that some plants inappropriately exclude certain activities from working hour calculations, (2) instances in which individuals were authorized to work after reporting that they were unfit for duty because of fatigue, and (3) instances of disciplinary letters being placed in the files of individuals who have declined work because of fatigue. The commenter also stated that a plant planned an outage that required personnel to work 20 consecutive days of 12-hour shifts (comment 173.4). Another commenter identified that the cumulative effect of fatigue is ignored (comment 176.2).

Analysis: The NRC is aware of these concerns and has taken specific actions to fully understand and address each of them on a case-by-case basis. However, the examples raise important generic questions concerning the interpretation of the “Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors;” the applicable plant TSs; 10 CFR Part 26, “Fitness for Duty (FFD) Programs”; and the interrelationship of these guidelines and requirements. For example, it is important to appropriately consider the range of activities that are considered in overtime calculations; for example, “on call” status can contribute to fatigue (Torsvall et al. 1987). With respect to the scheduling of 20 consecutive 12-hour shifts during an outage, the staff acknowledges that such practices are not consistent with guidelines for preventing fatigue that recommend no more than four consecutive 12-hour shifts (Electric Power Research Institute, 1990). Though it is likely that such schedules would cause cumulative fatigue effects (Rosa, 1995; Dinges et al. 1997; Totterdell et al. 1995), it is not clear that such a schedule would be prohibited by plant TSs for personnel performing safety-related functions. The staff believes that such practices should be evaluated in the development of an agency approach to this issue.

1.5 Comment: One commenter stated that plant personnel would generally only be asked to work increased overtime to support outages once in 18 months (in most cases for about 30 days) (comment 160.10).

Analysis: Most overtime is worked during outages and the duration of outages has on average become shorter during recent years, with outage durations frequently on the order of 30 days. In some instances short outage durations are being achieved, in part, by scheduling workers for large numbers of consecutive days of work without intervening days off. A data collection effort by NEI concerning industry implementation of the policy guidance was conducted during July 2000,

which included data representing 68 individual refueling outages. During those 68 refueling outages, about a quarter of the outages had hundreds (341-997) of deviations to the policy guidance. More than another quarter of the outages involved thousands (1024-6733) of deviations to the policy guidance. Some of the outages, however, experienced relatively few deviations, and 17 involved under 100 deviations (NEI, August 29, 2000). There is also evidence to indicate that lack of adequate days off and extended workdays can result in a cumulative sleep debt and performance impairment (65 FR 25546, Colquhoun et al. 1996, Dinges et al. 1997, Tucker et al. 1999; Webb and Agnew, 1974). Insights concerning shutdown risk (NUREG-1449) and latent errors (NRC, March 6, 2000) suggest that human performance during outages can be an important influence on plant risk.

2.0 Enforcement of Current Guidance

2.1 Comment: Several commenters stated that the NRC seems to “look the other way” when plant owners abuse overtime guidelines (comments 8.3; 11.4; 14.4; 16.3; 30.3).

Analysis: The staff does not believe that the NRC “looks the other way” when licensee work scheduling practices do not appear to be consistent with the policy guidelines or plant TSs. Nevertheless, the staff acknowledges that the lack of clear guidance with respect to the use of deviations from overtime guidelines has contributed to difficulties in consistently enforcing the applicable plant TSs and administrative procedures.

Until the implementation of the NRC’s revised reactor oversight process,² NRC inspectors reviewed each licensee’s use of overtime approximately once every 18 months. The findings from these inspections were documented in NRC inspection reports. In general, inspectors documented the number of deviations from the TS limits that had occurred during the time period that they had sampled and noted whether any of the deviations occurred without proper written authorization. The NRC took enforcement action when it was clear that the number of deviations, or the failure to authorize deviations, was inconsistent with the licensee’s TSs or administrative procedures. The Commission acknowledges that lack of clear criteria in the TSs concerning the use of deviations from working hour guidelines may have contributed to the NRC’s determining that a violation could not be substantiated in instances that may have appeared, to some, to involve excess use of overtime.

2.2 Comment: Several commenters stated that the proposed rule is not necessary because working hours of individuals are controlled by site administrative procedures as required by TSs (comments 158.2; 160.9; 167.3; 172.3) and that the NRC has the authority to enforce the requirements of the TS (comments 145.4; 159.4; 161.14). One commenter stated that the

² The NRC discontinued routine inspections of overtime use with the transition to the revised reactor oversight process (RROP). This change is considered appropriate and consistent with the general design of the RROP which is intended to identify indications of plant safety problems and cause licensees and the NRC to initiate more focused analyses and inspections when program performance thresholds are exceeded.

petitioner did not adequately explain why existing requirements fail to minimize personnel fatigue (comment 167.2).

Analysis: With the exception of three nuclear plant units, licensees have plant TSs concerning the working hours of plant staff who perform safety-related functions. Although the TS wording and details are not uniform across sites, the TSs, in general, require administrative procedures to limit the working hours of plant staff who perform safety-related functions. The NRC has the authority to enforce the requirements of the TS. However, as noted in analyses of comments 1.1, 1.2, and 2.1, the NRC has not been able to consistently enforce the requirements of the TSs because of the lack of clear criteria in the TSs for permitting deviations from the established work hour limits. As a result, there have been instances in which the NRC has determined that it could not enforce compliance with the TSs through licensee practices (e.g., operating personnel working in excess of 80, 90, and even 100 hours in a week) appeared to be inconsistent with the objective of the Commission policy (on which the TSs were based), which is to ensure that personnel are not assigned to shift duties while in a fatigued condition that could significantly reduce their mental alertness or decisionmaking abilities.

The work hour limits contained in the TS requirements, even if enforced, may not ensure that personnel are not impaired by fatigue. For example, research indicates that the current guideline for a break of at least 8 hours between work periods (including turnovers) may not be adequate to prevent fatigue. This guideline does not allow for the 8 hours of sleep most individuals require because turnovers, commuting, and time to get to sleep and prepare for the next day of work are part of this 8-hour break (65 FR 25547). Research indicates that at least 16 hours between shifts should be provided in order to obtain a sleep duration of 7 to 8 hours (65 FR 25554, Kecklund and Akerstedt, 1995). In addition, substantial research indicates that other factors (e.g., sleep disorders, illness) can affect worker fatigue (Kryger, Roth, and Dement, 1994; Lewis and Wessely, 1992), and these factors are not effectively addressed by limits on working hours in the absence of other fatigue management practices.

3.0 Interpretation of Current Guidance

3.1 Comment: Several commenters stated that the guidelines of the policy are interpreted to apply only when the plant is running [operating] (comments 8.5; 12.4; 13.4; 19.2; 62.1; 97.3; 156.2), and several other commenters recommended that the NRC establish working hour limits that can be enforced whether the plant is running [operating] or not (comments 80.3; 87.4; 89.4; 111.2; 124.4; 133.3; 135.2; 162.3).

Analysis: The “Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors” sets forth an objective of a 40-hour week while a plant is operating. The policy also includes guidelines for the control of overtime in the event that “unforeseen problems” require substantial amounts of overtime to be used, or during extended periods of shutdown for refueling, major maintenance, or plant modifications. In addition, the policy states that if “very unusual circumstances” arise requiring deviation from the guidelines, such authorizations should be made by the plant managers, a deputy, or higher levels of management. The policy, therefore, provides guidance for both when the plant is operating and when the plant is shutdown. The Commission

acknowledges that the use of authorized deviations from the guidelines, which occurs more frequently when a plant is shutdown, may provide the appearance that the guidelines do not apply when the plant is shutdown. Clarification of the applicability of the content of the outline and work schedule limits consistent with plant conditions and risk will also be considered by the Commission as part of the proposed rulemaking. The frequency of guideline deviations does appear to be inconsistent with the intent of the policy.

3.2 Comment: One commenter stated that current guidelines are being interpreted as not including breaks or non-safety-related activities (comment 155.3). Two commenters stated that the limits should apply at all times that an employee is on the job (comments 90.2; 148.3).

Analysis: The “Policy on Factors Causing Fatigue of Operating Personnel at Nuclear Reactors” excludes shift turnover times from the policy working hour limits of 16 hours in any 24-hour period, 24 hours in any 48-hour period, and 72 hours in any 7-day period. The Commission did not explicitly exclude any other parts of a workday in the policy guidelines. The staff is aware of a limited number of instances of licensees excluding specific periods from working hour calculations. Such exclusions can (1) result in licensee working hour calculations of as much as 84 hours in a 7-day period of work without requiring an authorization to exceed the plant’s administrative limits on working hours, (2) do not appear to be consistent with the objective of the policy and, (3) may result in personnel impaired by fatigue. In addition, the exclusion of rest breaks on the basis that such time does not contribute to fatigue does not appear to be scientifically justified. In a proposed revision of its hours of service regulation for motor carriers, the Department of Transportation (DOT) concluded that “all time spent in any work must be counted as on-duty time, since all work can either induce fatigue or deprive the driver of sleep” (see 65 FR 25558, May 2, 2000). The DOT conclusion is based, in part, on the recommendations of an expert panel (Transportation Research Institute, 1998) and is consistent with a large body of research that indicates that the benefits of breaks (without sleep) are transitory (Akerstedt and Landstrom, 1998) and that fatigue accumulates throughout the work period, particularly on the night and morning shifts (Rosa, 1991; Tucker et al., 1998). Research indicates that recovery from fatigue on breaks, even when sleeping, is reduced if personnel are “on call” (Torsvall et al., 1987). Thus, rest periods provided during the work shift may provide temporary benefits but may not contribute to long-term recovery from fatigue. The staff recommends that the development of any regulation concerning personnel fatigue should address any time periods to be specifically excluded and the basis for the exclusion.

4.0 Adequacy of Current Regulations – Part 26, “Fitness for Duty Programs”

4.1 Comment: Four commenters supported the proposed rulemaking and noted that fatigue can produce decreases in worker fitness equivalent to a blood alcohol content of 0.05 percent. They reasoned that Part 26 should therefore explicitly address fatigue as it currently prohibits on-duty employees from having a BAC of 0.04 percent or higher (comments 8.4; 9.2; 12.1; 13.3).

Analysis: Research (Fairclough and Graham, 1999; Dawson and Reid, 1997) that indicates that personnel who are fatigued from sleep deprivation can have levels of impairment that are comparable to those of individuals with blood alcohol levels more than double the level prohibited by Part 26. Research suggests that comparable impairments occur whether the sleep deprivation occurs as loss of one night’s sleep or as a result of partial sleep loss accumulated over several

nights (e.g., Wesensten, Balkin, and Belenky, 1999). It is notable that this research indicates that sleep-deprived people are more aware of their performance declines than individuals under the influence of alcohol. Such research supports, and is consistent with, addressing personnel fatigue as a factor that can affect personnel FFD.

4.2 Comment: Many commenters stated that the proposed rulemaking is unnecessary because licensees are already aware of the need to limit overtime to reduce chances of fatigue. Some of these commenters noted that Part 26 general performance objectives already require that licensee FFD programs protect against fatigue. They recommended that the Commission continue to rely on these licensee programs in which supervisors are trained to detect fatigue and, when fatigue is detected, to take action to ensure that the fatigued employee is not a threat to safety (comments 145.3; 152.3; 153.1; 159.1; 160.1; 161.2; 163.1; 164.1; 165.1; 166.1; 168.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1).

Analysis: The staff believes that the policy statement and the associated plant TSs have caused licensees to be aware of the need to reduce the chances of fatigue. However, as described in the analyses of other comments (e.g., comments 1.2; 1.3; 1.4), the staff is aware of work scheduling practices that do not appear to be consistent with the objective of ensuring that personnel are not impaired by fatigue. The staff notes that the general performance objectives of Part 26 require licensees to provide reasonable assurance that personnel are not impaired from any cause that in any manner impairs their ability to safely and competently perform their duties. As noted in some public comments, licensees have asserted that behavioral observation programs provide assurance that personnel are not impaired by fatigue. The staff, however, does not consider behavioral observation programs to provide, by themselves, adequate assurance that personnel are not impaired (see analysis of Comment 4.3).

4.3 Comment: Several commenters stated that the licensee behavioral observation programs already required by Part 26 are sufficient to detect fatigue. Two commenters disagreed with this assertion and stated that the supervisory oversight required by these programs is not sufficient to detect impairment. One commenter stated that supervisory training does not always occur and that reliance on behavioral observation may mean waiting for someone to make a mistake. Another commenter questioned how a supervisor who is potentially fatigued (as during a refueling outage) could be expected to detect a subordinate's fatigue (comments 158.6; 167.6; 172.2; 173.1; 173.2; 176.3; 176.6).

Analysis: Because of the limitations of behavioral observation for detecting and deterring personnel impairment (see analysis of comment 17.5), the staff has always maintained that behavioral observation programs should be only one element within multifaceted and comprehensive FFD programs (NUREG/CR-5227). Consequently, Part 26 has always required licensee programs to implement drug and alcohol testing, in addition to behavioral observation, as other important elements of their worker FFD programs. Similarly, behavioral observation could be an element of a licensee approach to addressing personnel impairment from fatigue, but behavioral observation by itself would not be sufficient. The staff also notes that current behavioral observation programs may be identifying individuals who appear to be impaired through the use of "for-cause testing" (i.e., drug and alcohol testing) but such testing for an individual impaired by fatigue would yield negative results. A licensee could subsequently return the individual to duty

without identifying or correcting the cause of the impairment. As a result, the staff does not believe that the requirements of Part 26 have ensured the implementation of effective measures to address fatigue.

5.0 Enforcement of Current Regulations – Part 26, “Fitness for Duty Programs”

5.1 Comment: Several commenters recommended that the petition for rulemaking be denied because they believe Part 26 already grants the NRC ample authority to ensure that licensees address potential workforce fatigue issues. They noted that 10 CFR 26.20(f) allows the Commission to review licensees’ written policies and procedures to ensure that they meet the performance objectives of Part 26 (comments 159.1; 160.1; 161.13; 163.1; 164.1; 165.1; 166.1; 168.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1). One commenter (comment 173.9) disagreed with this assertion and stated that the protections provided by the performance objectives of Part 26 programs are currently not sufficient to address potential fatigue problems because Part 26 uses the word “should,” thus making the attainment of these objectives nonmandatory.

Analysis: The NRC has the authority under Part 26 to address potential workforce fatigue issues. However, 10 CFR 26.20 (f), which permits the NRC to “at any time review the licensee’s written policy and procedures to assure that they meet the performance objectives of this part [i.e., 10 CFR 26.10],” by itself does not provide the assurance that licensees are satisfactorily addressing potential workforce fatigue issues. Licensees may have written policies and procedures to address overtime and fatigue (e.g., TS requirements) but, as indicated in the analysis of comment 1.1, the NRC does not have a clear basis for evaluating the adequacy of these licensee policies and procedures. In addition, as indicated by a second commenter, the regulatory provision of 10 CFR 26.20, which states “licensee policy *should* also address other factors that could affect fitness for duty such as mental stress, fatigue and illness (emphasis added),” is a nonmandatory regulatory provision. Thus, the licensee’s written FFD policy may not explicitly address fatigue. This approach essentially allows licensees to address fatigue on an ad hoc basis and permits considerable variation and potentially ineffective actions by licensees with respect to fatigue issues.

6.0 Adequacy of Current Guidance - Other

6.1 Comment: One commenter stated that quality assurance programs at nuclear power plants require independent review of manipulations of safety-related equipment and changes to key procedures, thereby addressing the latent effects of fatigue, such as valve mispositioning and procedures with technical errors (comment 168.5).

Analysis: The staff acknowledges that independent verification is an aspect of licensee quality assurance programs. However, the staff considers it not judicious to rely on independent verification as a prevention of fatigue-related errors. Quality assurance provides independent verification of operator actions after the actions have been completed. These verifications typically relate to implementation of operator actions performed on a system that has been isolated for maintenance. In those cases, the verification provides an opportunity to correct errors before they have actual consequences for system operation. However, independent verification is a personnel

action, that is itself subject to fatigue-induced errors. In addition, operator fatigue may result in errors during routine system operation or during response to abnormal operating occurrences that have immediate consequences for system performance (U.S. NRC, March 6, 2000). Quality assurance programs do not include actions that would prevent the latter fatigue-induced errors. Therefore, it would be inappropriate for the NRC to rely on quality assurance programs to prevent human performance problems associated with overtime and operator fatigue.

6.2 Comment: One commenter stated that the use of human performance tools, such as self-checking, peer checking, place keeping, and three-way communications, provides a greater opportunity to minimize human error than does the proposed rule by the petitioner (comment 158.3).

Analysis: Human performance tools such as the ones listed by the commenter provide the opportunity to minimize human error. However, it is not judicious to rely solely on those tools to prevent fatigue-related errors because one reason individuals sometimes fail to use such human performance tools is that they are fatigued. Fatigue can cause individuals to be less communicative, have impaired short-term memory, and become more inclined to take risks (Dinges, 1995; Dinges et al. 1997). These factors can affect the likelihood that an individual will self-check, remember to self-check, or ask for peer verification. Other recent research (Dorrian, Lamond, and Dawson, 2000) suggests more accurate self-monitoring in fatigued individuals but only at a global level and only when specifically prompted. These results suggest that though such human performance tools indeed may be useful, several variables may affect their utility, thus indicating that they should not be relied on exclusively.

7.0 Other Federal Regulation of Working Hours

7.1 Comment: A few commenters stated that the NRC's approach to worker fatigue should be consistent with that of other Federal agencies (comments 146.4; 154.6; 162.2). Similarly, several commenters noted that the Federal Government has established working hour limits for other industries, such as the trucking and airline industries, and suggested that such limits be applied to nuclear power plant workers (comments 41.2; 44.2; 51.2; 53.2; 64.2; 74.2; 80.2; 97.2; 111.3; 118.2; 124.5; 129.2; 133.2; 138.1). Alternatively, two commenters stated that the transportation industry guidelines are not appropriate for the nuclear industry (comments 149.2; 152.2).

Analysis: As part of the assessment of this petition, the NRC reviewed the regulatory approaches and specific requirements of other Federal agencies that have addressed worker fatigue, as well as the approaches taken to address fatigue in other industries and countries. The staff acknowledges that tasks and task environments (e.g., whether an individual is working in isolation or as a member of a crew) can influence alertness; however, the NRC focused on identifying lessons learned through the implementation of other agency, industry, and country requirements and programs to gain insights that might be applicable to the nuclear industry. In addition, the staff notes that tasks and task environments may not be as important as such factors as how long an individual remains awake, how much sleep an individual receives, and the time of day (e.g., Kecklund et al. 1997). Research generally shows that fatigue is associated with performance decrements at a basic level; across a variety of tasks, fatigue has been shown to cause memory problems, slowed responding,

lapses, and false responses (Dinges, 1992; Dinges, 1995). It is sometimes asserted that the work tasks and characteristics in nuclear power plants are different from the other occupations that have overtime controls; therefore information from other occupations may be inapplicable. Research has shown that the physiological effects of fatigue are largely independent of occupation (Kecklund et al., 1997). Research has also shown that team performance is affected by fatigue (Harrison and Horne, 2000; NTSB, 1994). In addition, the occupations regulated by the other Federal agencies are themselves different, ranging from marine officer and air traffic controller to maintenance personnel. Despite the diversity of occupations and tasks, the other Federal agencies have, in nearly every instance, set stricter limits on hours of work and rest and have given management less authority to deviate from those limits.

8.0 Utility Restructuring/Cost Competition

8.1 Comment: Several commenters indicated that cost pressures associated with utility restructuring will cause reduced staffing levels and a subsequent increase in working hours and worker fatigue at nuclear plants (comments 8.1; 9.1; 10.2; 11.2; 13.2; 14.2; 16.1; 126.1; 146.3; 148.4; 154.5).

Analysis: Deregulation and restructuring can impose economic pressures that could create the potential for a variety of consequences on the nuclear industry and its workers. For example, following deregulation in the United Kingdom, British Energy reduced staffing and increased overtime for certain personnel (Nuclear Installation Inspectorate, 1999). A Nuclear Energy Agency report (NEA, 2001) notes that it is common for owners of nuclear power plants to reduce operating and maintenance costs by reducing the size of plant staff and outsourcing some work to specialist contractor organizations. The report notes that such actions could result in a loss of technical competence and resources within the utility's organization. The NEA report also identifies excessive overtime causing operator fatigue as a potential direct safety challenge resulting from market competition. However, plant owners may vary substantially in the approaches they take to staffing and overtime in response to deregulation. In addition, although staffing shortages may cause overtime, other factors also contribute to overtime, and overtime is one of many contributors to fatigue. Regulatory options that ensure worker fatigue does not compromise plant operational safety, regardless of the cause of fatigue, would address the potential effects of deregulation on worker fatigue.

8.2 Comment: Two commenters stated that there has been an increase in overtime caused by cost containment pressure (comments 154.3; 155.2).

Analysis: The NRC has reviewed nuclear industry reported use of overtime for the past 3 years. NRC analysis of survey data collected by NEI concerning industry control of working hours indicates that for the sample of sites responding to the survey, the percentage of individuals working more than 600 hours of overtime was higher in 1999 than 1997 (NEI, August 29, 2000). The staff believes that it is prudent for the Commission to pursue a regulatory option that ensures that plant operational safety is not compromised by worker fatigue.

8.3 Comment: Several commenters indicated that licensees have sufficient incentive in a competitive electricity market to maintain staffing at sufficient levels and to develop reasonable work schedules (comments 161.7; 157.1; 159.1; 160.1; 163.1; 164.1; 166.1; 168.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1).

Analysis: A competitive electricity market provides licensees with incentives to ensure that their staffing levels support reliable energy production in a cost-effective manner. Many factors may influence a licensee's decisions concerning staffing, routine work scheduling, and use of overtime. Though the NRC can not predict with certainty the effects of a competitive electricity market, one possible result, as evidenced by deregulation of nuclear energy in the United Kingdom, is decreased staffing and increased overtime (Nuclear Installation Inspectorate, 1999; NEA 2001).

8.4 Comment: Three commenters indicated that the NRC has taken measures to ensure that its regulatory authority and programs are adequate to ensure public health and safety in a competitive electric industry environment (comments 157.2; 166.4; 168.2).

Analysis: The NRC has taken measures to ensure that deregulation does not compromise nuclear plant safety. Electric utility deregulation is an ongoing process. As some of the commenters noted, the NRC is assessing its regulatory programs and making adjustments as needed. For example, the NRC has issued a "Final Policy Statement on the Restructuring and Economic Deregulation of the Electric Utility Industry" (NRC Policy Statement 7590-01-P, October 20, 1997) that addresses potential safety impacts on NRC power reactors that could result from, specifically, the economic deregulation and restructuring of the electric utility industry. The Office of Nuclear Reactor Regulation (NRR) has revised its Standard Review Plan (SRP) (NUREG-0800) to provide the staff with guidance with which to implement the policy statement provisions. Additionally, the NRR has revised other parts of the SRP (e.g., Chapter 13, "Conduct of Operations," Sections 13.1.1, "Management and Technical Support Organization," and 13.1.2-1.3, "Operating Organization") to ensure that the technical qualifications of proposed organizations involved in mergers and license transfers continue to satisfy NRC requirements.

9.0 Data Quality and Interpretation

9.1 Comment: Two commenters disagreed with the petitioner's statement that NRC inspection reports listed 87 occurrences of staffing as less than adequate, while the industry, using data from the licensee event reports (LERs), listed only 11 for the same time period (comments 157.4; 168.2).

Analysis: The NRC's reporting guidelines and requirements for LERs are not the same as those for NRC inspection reports. Therefore, it is not appropriate to equate summary findings from inspection reports with findings from LERs.

9.2 Comment: Two commenters stated that the petitioner attempts to equate certain categories in the NRC's Human Factors Information System (HFIS) database to fatigue-related issues. The petitioner cites the following categories in the HFIS database to support his position.

- ! Work practices or skill of the craft less than adequate - 4913 occurrences
- ! Nonconservative decisionmaking or questioning attitude less than adequate -1805 occurrences
- ! Self-checking less than adequate - 618 occurrences
- ! Awareness or attention less than adequate - 2389 occurrences

The petitioner states that the 9725 occurrences included in these four categories account for almost 30 percent of the total HFIS entries for 1996 through 1998. The petitioner states that while there are certainly other causes for these occurrences, such as distractions and interruptions, fatigue most probably played a role in a respectable percentage of them (comments 157.5; 168.2).

Analysis: The NRC maintains an HFIS database that contains analyzed coded information from LERs and inspection reports involving human performance. Experienced contractor staff review each LER and inspection report and then assign specific codes that describe such items as the personnel department, work type, and human performance contributing factors. From the HFIS database, the percentage of items in the database that involved fatigue cannot be determined; however, most items in the HFIS are not the result of root cause analysis, and, therefore, it is reasonable to postulate that some percentage, particularly those items coded in categories such as “awareness or attention inadequate” or “self-checking inadequate” may have been caused by fatigue. Such an interpretation is supported by a large number of studies concerning the effects of fatigue (Dinges, 1995; Dinges et al. 1997) and is consistent with the DOT’s interpretation of vehicular accidents involving inattention (65 FR 25545, May 2, 2000). See also the analysis of comment 9.6.

9.3 Comment: Two commenters stated that the petitioner’s citation of an NTSB report and comparison of funds allocated for fatigue research by the DOT versus that of the NRC do not appear to be relevant to the nuclear industry (comments 157.6; 168.2).

Analysis: The staff understands the commenter as stating that NTSB findings concerning fatigue in transportation, or the amount of research conducted on fatigue in transportation, are not relevant to the nuclear industry because of differences between the industries in work environments and the use of other controls (e.g., independent verification) to ensure personnel errors do not adversely affect safety. Findings concerning fatigue from other industries must be interpreted with caution, as should the potential for safety consequences, but the lessons learned and research findings from other industries can be of value if considered with careful attention to the differences and similarities in the tasks and task environments. See also the analysis of comments 6.1 and 9.8.

9.4 Comment: Two commenters disagreed with the petitioner’s reference to the Peach Bottom incident in 1987 as fatigue related (comments 157.7; 168.2).

Analysis: The petitioner did not state that the Peach Bottom incident in 1987 was fatigue related. Rather, the petitioner stated that the Commission took action in response to operator inattentiveness (i.e., napping). The commenter pointed out that the Peach Bottom incident was

caused by significant management deficiencies. The staff agrees that management deficiencies were the higher level cause. Although work schedules and staffing levels may have contributed to personnel sleeping while on duty, the Commission cannot state with certainty why individuals were sleeping. As noted by the petitioner, few significant events can be precisely attributed to fatigue.

9.5 Comment: Two commenters indicated that the petitioner believes that some fatigue errors have latent effects that may not be discovered for quite some time. The commenters stated that if the effects of fatigue were substantial, or if fatigue errors contributed to a substantial number of errors, the traceability to fatigue would be obvious, or at least more direct and subject to confirmation (comments 157.8; 168.2).

Analysis: Errors caused by fatigue, like errors from any cause, may not be immediately discovered and could have latent effects. Identifying the causes of an error long after the error has been committed is difficult because memories and records of the specific activity leading to the error may be incomplete. As a result, fatigue may not be reliably identified as the cause of errors with latent effects. The commenters state that if fatigue contributed to a substantial number of events, the traceability of fatigue would be obvious, or at least more direct and subject to confirmation. The staff agrees that a large number of events from any cause provide more opportunities to identify the cause directly, or indirectly through trending and correlation. In fact, some studies reviewing large numbers of events at nuclear power plants have shown variations in event frequency that are consistent with daily variations in operator alertness (Bobko, 1998; Cox and Cox, 1996; Maloney, 1992). Although these studies provide indirect evidence of the influence of fatigue on operator performance, it is not clear that if fatigue contributed to a large number of events the traceability would be obvious or more direct (see analyses of comments 9.6 and 10.1).

9.6 Comment: One commenter stated that more incidents in the nuclear industry are attributable to fatigue and excessive working hours than the number actually reported. The commenter also noted that errors as a result of fatigue are likely not to be immediately identified. However, several commenters asserted that the lack of reported data does not establish that the NRC or licensees underreport fatigue as a root cause. In response, the petitioner refutes the statement that few events are attributed to fatigue because fatigue is a third-tier cause of an event and, therefore, if we do not look deep enough, we will not find fatigue as a root cause (comments 154.2; 161.6; 159.1; 160.1; 163.1; 164.1; 165.1; 166.1; 168.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1; 173.3; 176.7).

Analysis: The staff considers it likely that fatigue is under reported as an event causal factor. There are a limited number of events at U.S. nuclear plants that have been attributed to fatigue. However, several factors affect the ability of the NRC and licensees to determine that fatigue is a cause of an event, including the level of detail provided in event reports and the depth of event analysis conducted. Also, employees are generally reluctant to freely admit that they were fatigued (e.g., Horne and Reyner, 1995), and research indicates that individuals are not necessarily good at estimating their physiological sleepiness (Dinges, 1995; Wylie et al, 1996). More importantly, whereas the effects of fatigue can be observed and documented (e.g., inattention to detail, nonconservative decisionmaking) fatigue cannot be objectively proven as the underlying cause. Given these considerations, and in light of findings concerning current work-scheduling practices at nuclear power plants and risk of personnel impairment, the Commission believes that the number of events attributed to fatigue should be interpreted with caution and cannot be reported with

certainty. Other agencies and investigative bodies have come to similar conclusions concerning the attribution of fatigue to events. A letter from Jim Hall, Chairman of the National Transportation Safety Board (NTSB), to DOT Secretary Rodney E. Slater, dated June 1, 1999, included the following statement.

Fatigue has remained a significant factor in transportation accidents since the Safety Board's 1989 recommendations were issued. Although generally accepted as a factor in transportation accidents, the exact number of accidents due to fatigue is difficult to determine and likely to be underestimated. The difficulty in determining the incidence of fatigue-related accidents is due, at least in part, to the difficulty in identifying fatigue as a causal or contributing factor in accidents. There is no comparable chemical test for identifying the presence of fatigue as there is for identifying the presence of drugs or alcohol; hence, it is often difficult to conclude unequivocally that fatigue was a causal or contributing factor in an accident. . . . Although the data are not available to statistically determine the incidence of fatigue, the transportation industry has recognized that fatigue is a major factor in transportation accidents.

Also, a recent study by the U.S. Coast Guard further suggests that direct measurement of fatigue may understate its true extent (McCallum et al. 1996).

In summary, these reports indicate (1) the need for detailed event investigation and root cause analysis to reliably identify fatigue as a causal factors, as well as (2) the likelihood that fatigue statistics based solely on accident reports that directly cite fatigue underestimate the true extent of fatigue-related incidents.

9.7 Comment: Several commenters refuted the statement by the petitioner that "fatigue most probably played a role in a respectable percentage" of certain occurrences in the NRC's HFIS database (comments 161.8; 159.1; 160.1; 163.1; 164.1; 165.1; 166.1; 168.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1).

Analysis: Items coded in the HFIS database in categories such as "awareness or attention inadequate" or "self-checking inadequate" could have fatigue as a contributing factor. However, the HFIS database does not show what percentage of "awareness or attention inadequate" is due to fatigue.

Fatigue increases the likelihood that a worker will not pay sufficient attention to the task at hand. HFIS data show that "awareness or attention inadequate" contributes to a significant number of the total reported items. Though fatigue is not likely involved in all of these cases, the staff's review of (1) research concerning worker hours, fatigue, and fatigue effects, considered in conjunction with (2) industry work scheduling practices (see analyses of comments 1.3, 1.5), and 3.1, and (3) findings related to the estimation of fatigue-related incidents in other industries (see analysis of comment 9.6) lead the staff to conclude that fatigue is a probable contributor to some percentage of these items in the HFIS database.

9.8 Comment: Several commenters stated that the petitioner inappropriately compared fatigue-related events cited by the NTSB and the NRC. The commenters stated that it is not appropriate to assume that the fatigue experienced by truck drivers, who operate in a sedentary, isolated environment, is relevant to nuclear operators, who are stimulated by other operators and various tasks that must be performed throughout the shift.

The petitioner responded to the commenters with additional comments stating that NTSB data are relevant because parallels can be drawn between control room crews and flight crews. Parallels can also be drawn between field operators, maintenance workers, engineers, and technicians who often work alone at boring tasks, and truck drivers and train operators (comments 161.10; 173.5; 159.1; 160.1; 163.1; 164.1; 165.1; 166.1; 168.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1).

Analysis: In general, fatigue-related incidents are more likely to happen after more hours are worked, regardless of the type of task. Different tasks and task environments can influence the level of fatigue. However, the difference between different specific work tasks is small and, in most cases, not statistically reliable (Kecklund et al. 1999). Fatigue degrades performance at a basic level (attention and perception), and these effects are seen across a wide variety of tasks that require execution of complex responses (Dinges, 1992; Dinges, 1995).

10.0 Fatigue as a Contributor to Events

10.1 Comment: A few commenters indicated that, in their experience, fatigue has not been a significant contributor to events or issues at their plants and that data from the NRC attribute few significant events to fatigue (comments 158.4; 160.4; 167.4; 168.3).

Analysis: The NRC has attributed few events specifically to fatigue. However, fatigue may be a contributing factor to a larger number of events for the following reasons:

- ! Depth of assessment - Most incidents at nuclear power plants are not subjected to a root cause analysis, and, as a result, many events are attributed to proximal causes (e.g., inattention to detail), some of which may have fatigue as the underlying cause.
- ! Lack of tangible proof - When conducting a root cause analysis for events that involve personnel error, it is difficult to conclude that fatigue is a cause because there is little tangible proof, absent the person sleeping, that the individual was impaired by fatigue. Even when individuals have been found with their eyes closed, they have asserted that they were not asleep, and investigators have concluded that the individual was “inattentive.”
- ! Lack of accepted assessment criteria - There are no accepted criteria or structured approaches for evaluating the role of fatigue accidents (Rosekind et al. 1997).
- ! Relative prominence or ease of substantiating event causal factors - Fatigue degrades an individual’s abilities but does not necessarily cause the event by itself. For example, the alert individual recognizes an error in a procedure, whereas the

fatigued individual does not and implements an incorrect procedure. As a result, it is easy for an investigator to focus on tangible contributing factors (e.g., the procedure error) or to describe the behavior (e.g., cognitive error) without citing a contributor that is difficult to substantiate.

- ! Efficacy of post-event observations - When individuals are debriefed following an incident, they may appear alert because of the stimulation of responding to, or potential consequences of, the event. Impairment from fatigue would not be readily apparent in such circumstances.
- ! Accuracy of self-assessment - Although self-assessment of fatigue can often provide an indication of the level of fatigue, research suggests that other factors may influence such self-assessments (e.g., Dinges, 1995; Wylie et al. 1996). In addition, studies have shown that individuals may believe they are relatively more alert than indicated by physiological indices (e.g., Rosekind and Schwartz, 1988).
- ! Veracity of self-assessment - For various reasons, individuals may be reluctant to acknowledge that they were fatigued at the time of an event involving personnel error, including the implication that they were not fit for duty (e.g., Horne and Reyner, 1995).

See also the staff's analysis of comment 9.7 concerning the contribution of fatigue to certain items in the HFIS.

10.2 Comment: Several commenters stated that individual plant data on human performance events indicate that night shift work does not produce a greater number of errors or that events that occur on night shift are not due to fatigue (comments 159.1; 160.1; 161.11; 163.1; 164.1; 165.1; 166.1; 168.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1).

Analysis: There is substantial scientific literature that clearly demonstrates the significant role that fatigue, sleep loss, and "circadian rhythms" (i.e., an individual's "internal timekeeper or clock") play in contributing to errors and accidents (Kryger, Roth, and Dement, 1994; Akerstedt, 1995; Dinges, 1995; Folkard, 1997). The circadian trough, or lowest levels of function (reflected in, for example, alertness, performance, subjective mood, and body temperature), occurs around 3:00 a.m. to 5:00 a.m., with many human functions showing reduced levels between 12:00 a.m. and 6:00 a.m.. Sleepiness shows the most severe low at 3:00 a.m. to 5:00 a.m., with a less marked but significant expression again at about 3:00 p.m. to 5:00 p.m.. Many studies have demonstrated the decreased performance and the increased errors and accidents associated with night work and the window of the circadian low point in operational settings. These findings range from reduced response speed on a variety of tasks to missing warning signals to minor hospital accidents. As described in the analysis of comment 10.1, for a variety of reasons event analyses may not be sensitive to fatigue as a contributing factor, and, consequently, plant data may currently fail to show higher rates of fatigue-related incidents on night shifts. The greater amount of work performed on day shifts, relative to night shifts, may also cause the appearance that night work does not cause a greater number of errors.

10.3 Comment: A number of commenters stated that industry performance data refute the petitioner's argument that the rule is necessary to prevent fatigued personnel from performing safety-related functions (comments 159.1; 160.1; 161.12; 163.1; 164.1; 165.1; 166.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1).

Analysis: The data referred to by the commenters, by and large, refer to overall nuclear industry performance and cite a trend of fewer events, in total, as having occurred from about the latter part of the 1980s through the middle of the 1990s. Though the data reported for plant performance may be indicative of an overall improvement, these data do not support or refute the effect of fatigue as a contributor to safety-significant events. Fatigue may remain a significant contributor to safety-related plant events, but the frequency at which it is a contributor may have diminished as a function of fewer plant events.

10.4 Comment: One commenter stated that the petitioner's claim that a "respectable percentage" of certain categories of events in the NRC's Human Factors Information System (HFIS) are likely due to fatigue is "pure speculation." Rather, the commenter noted that studies by utilities and independent consultants have shown that one of the predominant causes of human error is the failure of workers to verify or validate what they think is the right way to perform a particular task (comment 168.4).

Analysis: A common cause of errors is the failure to verify that an action or intent is correct. The NRC's HFIS database contains 5,326 cases of "awareness or attention less than adequate" in the past 3 years. However, individuals may fail to verify because they are fatigued. As indicated by recent research (Dinges, 1995; Dinges, 1992), fatigue can cause individuals to be less communicative, have impaired short-term memory, and become more inclined to take risks. A frequently observed effect of fatigue in complex operational settings is the progressive "disorganization" of behavior. Personnel begin to perform actions out of sequence, that is, doing the right things at the wrong time. All of these factors can affect the likelihood that an individual will self-check, remember to self-check, or ask for peer verification.

11.0 Burden

11.1 Comment: One commenter stated that the petition would require more mandatory overtime imposed on workers who traditionally do not work overtime and would adversely affect morale (comment 149.3).

Analysis: The petition for rulemaking does not propose requirements that would directly require mandatory overtime. However, licensees could choose to meet the petitioner's proposed limits on work hours by changing the distribution of overtime across personnel rather than using alternative approaches to reduce overtime. The staff acknowledges that licensees who choose to limit overtime for some personnel by establishing mandatory overtime for other personnel could adversely affect personnel morale.

11.2 Comment: One commenter stated that the petition would increase outage times and could affect the continued ability to meet outage schedules. Another commenter stated that extending outage durations could prove to increase risks with regard to shutdown safety (comments 152.4; 160.7).

Analysis: Many factors affect outage duration, and the amount of overtime allowed and worked is only one of these factors. Other factors that affect outage duration and risk include the experience of the outage staff, use of roving outage personnel, and the quality of outage planning. Limiting the number of hours worked will not necessarily change existing licensee outage policies and practices. The effect overtime has on outage duration and risk depends, in large part, on the actions taken by, and the policies and practices of, individual licensees as well as regulatory limitations.

11.3 Comment: Two commenters stated that keeping separate records of working hours of individuals performing safety-related work, as opposed to work that is not safety related, would be difficult and represents an unjustified and unnecessary regulatory burden (comments 157.9; 160.5).

Analysis: The petitioner did not propose any specific tracking requirements, nor did the petitioner propose any administrative obligation to maintain a system to record safety-related and non-safety-related hours worked. The staff acknowledges that licensees would likely implement a tracking process to assist personnel in maintaining their working hours within the proposed limits but anticipates that such tracking processes would not differ substantially from those implemented to meet existing TS requirements. The petition does not make a distinction between safety-related and non-safety-related work and, therefore, the staff does not understand the proposed requirements to imply a need to record hours accordingly.

11.4 Comment: Two commenters stated that the proposed requirement for initial and continuing mitigation training for all personnel performing safety-related work, their supervisors, and their managers is excessive and represents a significant regulatory burden. In addition, inasmuch as many facilities use overtime to conduct training, the training requirements of the petition would exacerbate the use of overtime (comments 160.3; 153.3).

Analysis: The staff is not aware of recurrent training that is normally conducted using overtime, and it is the staff's belief that the proposed training requirements would not require the use of overtime to conduct the training. It is likely that the proposed training would not require a substantive increase in existing FFD training.

11.5 Comment: One commenter stated that limiting the number of hours worked would result in a decrease in individual income for some personnel (comment 152.5).

Analysis: The petition limits overtime allows up to 75 percent overtime in any 7-day period and up to 30 percent overtime in a year.

11.6 Comment: Two commenters stated that working hours must remain flexible to allow management the ability to control operations and maintenance costs, as well as fulfill the needs and desires of professional employees. Conversely, granting the petition would constrain licensee flexibility and would compel licensees to increase staff at nuclear facilities (comments 160.2; 166.5).

Analysis: The proposed limits on working hours provide substantial flexibility. As noted in the analysis of comment 11.5, the proposed limits allow up to 75 percent overtime in any 7-day period and up to 30 percent overtime in a year.

11.7 Comment: One commenter stated that the petitioner's limits on overtime of the petition remove the incentive for contract workers to relocate for outages (comment 160.6).

Analysis: The limits on overtime could have the effect of decreasing an incentive for contractors to relocate for outage work. However, the petitioner's proposed limits would have a minimal effect on this incentive in that the limits would allow for as much as 75 percent overtime in a 7-day period. The Commission also notes that whereas the petition limits working hours to ensure that personnel are not impaired by fatigue, the petition in no way limits plant staffing or the recruitment or compensation of personnel.

11.8 Comment: One commenter stated that consideration of the cost of a proposed rule should include cost savings from reduction of overtime (comment 173.7).

Analysis: Should the Commission approve rulemaking, the economic impact of the rule will be evaluated in the regulatory analysis.

12.0 Backfit

12.1 Comment: Many commenters stated that new overtime requirements would constitute a backfit and could not meet the requirements of the backfit rule. The proposed new requirements would not fall into any of the three exceptions in the backfit rule. Further, the new requirements would not constitute a substantial increase in protection of public health and safety because existing licensee practices and procedures have been designed to address worker fatigue. Unless the NRC can demonstrate that fatigue is a root cause or a substantially contributing factor to significant plant events, the NRC cannot show that there is a significant safety issue that could be remedied by a proposed rule (comments 157.15; 159.1; 160.1, 161.15; 163.1; 164.1; 165.1; 166.1; 167.5; 168.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1).

Analysis: The petitioner's proposal, if adopted as a rule, would constitute a backfit as defined in 10 CFR 50.109. However, the staff disagrees that none of the exceptions in the backfit rule would apply and also disagrees that the proposed rule could not result in a substantial increase in the protection threshold of the backfit rule.

The staff agrees with the general thrust of comments arguing that there must be a reasonable causative link between fatigue and adverse events. However, the staff takes issue with the commenters' implicit argument that unless the NRC has demonstrated that significant problems attributable to fatigue have occurred in the past, the Commission cannot adopt requirements intended to preclude occurrence of fatigue-induced or fatigue-aggravated problems. Nothing in the Atomic Energy Act of 1954, as amended, or in general administrative law suggests that the agency is so constrained.

The staff disagrees with the commenters' underlying contention that licensees' existing voluntary practices with respect to working hour limits legally preclude a Commission finding under the backfit rule that rulemaking requirements either (1) are necessary to provide reasonable assurance of adequate protection or (2) constitute substantial additional protection to public health and safety. The backfit rule itself contains no provision addressing the legal effect of voluntary practices, and the statements of consideration for the 1985 and 1988 rulemakings (50 FR 38097, September 20,

1985; 53 FR 20603, June 6, 1988) do not contain any discussion of the significance, if any, of the existence of voluntary initiatives when making the appropriate findings under the backfit rule.

Indeed, there are two aspects of voluntary practices that the Commission regards as significant factors to be considered when determining whether the NRC should forego the adoption of mandatory requirements on the basis of the asserted voluntary practices.³ First, voluntary practices may not be uniformly implemented by all licensees; there may be great variation in the scope and quality of implementation of voluntary practices among licensees. A few licensees may have chosen not to implement a voluntary practice. Thus, an aggregate consideration of overall industry performance may obscure poor performance or high risk by individual licensees that chose not to implement a given voluntary practice (or an integrated set of practices). Second, by their very nature, voluntary practices are nonbinding and may be modified or discontinued by a licensee. In view of these characteristics of voluntary practices, the mere existence of voluntary practices *per se* does not legally preclude the Commission from adopting regulatory requirements addressing matters that are the subject of the voluntary practices. In determining *as a matter of policy* whether the Commission should forego the adoption of mandatory requirements on the basis of voluntary practices, it is appropriate to consider the extent to which written commitments exist with respect to the voluntary practice, the extent of implementation by licensees, and the likelihood of continuing implementation of the initiative by licensees.

12.2 Comment: A commenter suggested that the direct and indirect costs of the proposal are not justified, given the complexity of the proposal and the burdensome nature of its implementation (comment 161.5).

Analysis: The NRC will prepare a backfit analysis and a regulatory analysis for the proposed rulemaking that provides the NRC's estimate of the costs of implementing the proposed rule. Commenters will be requested to provide specific information to assist the staff in accurately determining these costs.

13.0 Scope of Personnel

13.1 Comment: Several commenters suggested that the scope of any proposed regulatory effort apply to all workers. Several other commenters suggested the scope also cover managers, safety inspectors, and engineers. One commenter requested that all maintenance workers be added (comments 12.2; 56.2; 76.1; 77.3; 87.3; 89.3; 124.2; 148.2; 176.5). One commenter stated that the scope of employees once voluntarily subject to Generic Letter 82-12 has been reduced in recent years by some licensees. Another commenter claimed that employees are being reclassified as management, in which case they do not have to be paid overtime, while doing the same job they have done for years (comments 154.4; 155.1). One commenter recommended that the scope of the additions to 10 CFR Part 26 be clarified from "personnel performing safety-related work" to "personnel covered by the licensee's Fitness for Duty program" (Comment 146.2). One

³ Guidance concerning the consideration of industry initiatives in regulatory analyses is provided in NUREG/BR-0058, Revision 3, "Regulatory Analysis Guidelines of the Nuclear Regulatory Commission," July 2000, which states that "two sets of value-impact estimates are to be derived: one based on "no credit" and the other based on "full credit" for industry initiatives. These results will have equal weight and will be presented for sensitivity analysis purposes."

commenter and one other supporting commenter stated that the petitioner has proposed a scope that is arbitrary. For example, an engineer working at the site would be covered while the same engineer working for a contractor off site would not. The same commenter went on to state that the petitioner has not shown that any increase in the scope of workers is needed (comments 157.10; 168.2).

Analysis: An important element of a proposed regulatory requirement is the scope of personnel covered. The scope of personnel covered by overtime policy guidance and most licensee TSs are those individuals who perform safety-related functions. The NRC, in conjunction with an industry effort, collected information on the job categories currently subject to working hour controls required by plant TSs (NEI, August 29, 2000). The NRC is also aware that some licensees have decided not to apply the TS limits to employees they have determined do not perform safety-related functions. Should the Commission approve rulemaking, the staff will consider the petitioner's comments and the information collected in determining the scope of personnel affected by any changes in the NRC's regulatory approach.

14.0 Limits

14.1 Comment: Two commenters stated that the petitioner's proposed limits on working hours are judged to be arbitrary (comments 157.11; 168.2).

Analysis: The staff does not view the petitioner's proposed limits as arbitrary. The petitioner provided a rational basis for the proposed limits. In addition, the staff notes that the proposed limits are generally consistent with the limits currently in the policy, and with an expert panel's proposed modification of the policy limits (NUREG/CR-4248).

14.2 Comment: In one commenter's experience, employees who work the night shift rarely take full advantage of their day off to rest and relax, instead remaining awake during the day to be with their family. Returning to night shift work causes their bodies to try to adjust to a rapid change in shift schedule and may affect their ability to think clearly and work safely. [The staff understands the commenter to imply that the proposed requirements would cause personnel on the night shift to have a day off while working nights, and this effect could be detrimental (comment 160.8)].

Analysis: Shift workers, particularly those working nights, can be challenged by conflicting demands for sleep and spending time with family members, or attending to other life demands that must be accomplished during the day. The staff agrees that schedules should be designed to minimize frequent transitions between day and night schedules. Nevertheless, the staff believes that the proposed requirements can be complied with, through proper scheduling, without an undue frequency of daytime-to-nighttime transitions for workers.

14.3 Comment: Several comments indicated that the petition could cause a licensee to put a plant through a shutdown transient rather than exceed the overtime limits for one or two key maintenance staff (comments 159.1; 161.4; 163.1; 164.1; 165.1; 166.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1). One commenter indicated that plant shutdowns caused by the unavailability of key maintenance staff would be the result of inadequate resource management and that plants could avoid a shutdown by requesting a notice of enforcement discretion (comment 173.8).

Analysis: The petition may have the potential for causing a plant to enter an unscheduled shutdown. However, the staff views this situation as having little chance of occurring and an even smaller chance of recurring at plants. The petition allows for up to two 16-hour shifts per week to accommodate such circumstances. If a plant experienced an unplanned shutdown because one or two key maintenance staff exceeded the overtime limits, this condition would likely warrant detailed follow up by the licensee as part of its ongoing corrective action program. Effective implementation of the corrective action program by the licensee would ensure that the problem would not recur.

14.4 Comment: Several comments indicated that the petition could result in many more turnovers and disruptions of teams working together, which could, in turn, lead to more personnel errors and ultimately to more events (comments 159.1; 160.1; 161.5; 163.1; 164.1; 165.1; 166.1; 168.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1).

Analysis: The petition may have the potential of causing more turnovers and disruptions of teams working together, which could, in turn, lead to increases in personnel errors and ultimately to more events. However, the staff notes that the petition's proposed limits allow for routine use of 12-hour shifts. Effective scheduling should allow for most tasks to be conducted within a 12-hour shift. If time in excess of 12 hours is required, the staff notes that several studies have shown that personnel accident risks increase exponentially after 12 hours of work (65 FR 25544, May 2, 2000; Folkard, 1997). Consequently, the rate of error caused by turnovers and disruptions may not be significantly higher, and could be lower. In addition, if a licensee determined that turning over a task to a new crew was in its best interest, the petition's proposal allows up to two 16-hour shifts in a 7-day period to accommodate such instances.

14.5 Comment: Some commenters stated that the petitioner's bases for limits are flawed or unfounded, and some commenters proposed to modify the petitioner's limits as follows:

The basis for the 16-hour shift limit is flawed because their experience has shown that individuals finishing an overnight shift can, and do, sleep during the day (comment 166.2).

- ! The basis for the 16-hour shift limit is unfounded because the petitioner provided no evidence that the assumed 24-hour period of wakefulness associated with 16-hour shifts occurs (comment 166.3).
- ! The petitioner's limit of 60 hours per week during non-outage periods should be changed to 72 hours (comment 134.3).
- ! The petitioner's limit of 108 hours per 2-week period during non-outage periods should be changed to 132 hours (comment 134.4).
- ! The petitioner's limit of 132 hours per 2-week period during outage periods should be changed to 144 hours (comment 134.5).

Analysis: The staff disagrees that the petitioner's proposed limits for 16-hour shifts are unfounded and believes that the proposed limits have technical merit. A number of studies find performance declines after 12 to 16 hours on task (Rosa, 1991; Folkard, 1997; Dawson and Reid, 1997). Nevertheless, the staff acknowledges the importance of a sound technical basis for any limitations

on working hours that the Commission may consider. Similarly, the staff acknowledges that there are practical considerations that may warrant limits that could differ from those based solely on human physiology and fatigue. If the Commission directs the staff to develop or modify specific working hour limits, the staff would address these considerations as part of that effort.

14.6 Comment: Two commenters stated that the petitioner’s request to revise 10 CFR Part 26 to require that employees be specifically monitored for signs of fatigue had no value because Section 26.22 currently requires that managers and supervisors receive training to ensure that they understand behavioral observation techniques for detecting degradation in performance, impairment, or changes in employee behavior (comments 157.13; 168.2).

Analysis: The commenters’ characterization that the petition mandates that employees be specifically monitored for fatigue is incorrect. The petition would require licensees to provide training in the monitoring and detection of fatigue to supervisors of personnel who perform safety-related work. Although it is implicit that observation for fatigue would occur through current behavioral observation practices, the staff disagrees that the proposed requirement would have no value. Part 26 principally establishes requirements related specifically to drugs and alcohol. For example, 10 CFR 26.22(3) requires training in “techniques for recognizing drugs, and indications of the use, sale, or possession of drugs.” No comparable requirements or emphasis in Part 26 specifically addresses training related to fatigue. Consequently, the petitioner’s proposal for requiring training specific to the monitoring and detection of fatigue (which could differ substantively from training related to drugs and alcohol) has merit and is not inconsistent with the current structure and level of detail of Part 26.

14.7 Comment: Two comments were received indicating that the petitioner’s request to revise 10 CFR Part 26 (Section 26.20) to eliminate general reference to the issue of fatigue is unsupported, unwarranted, and of no value (comments 157.14; 168.2).

Analysis: The petitioner stated his purpose for proposing to remove the word “fatigue” from 10 CFR 26.20 as follows: “This change is necessary to eliminate conflict from the prescriptive working hour limits and inclusion of the word ‘fatigue’ in a statement that is essentially only a recommendation as indicated by the word ‘should.’” If an amendment to 10 CFR Part 26 is warranted, the staff will review 10 CFR 26.20 to ensure that the wording is appropriate, unambiguous, and internally consistent.

15.0 Sleeping Disorders — Part 26, “Fitness for Duty Programs”

15.1 Comment: One commenter and an endorser indicated that NRC Form 396 and 10 CFR Part 55 should not be revised to require self-disclosure and evaluation of known sleep disorders because the existing process already allows factors related to fatigue and sleep disorders to be raised and evaluated in the medical evaluation of an individual. The commenter noted that NRC Form 396 (1-2000) relating to “Certification of Medical Examination by Facility Licensee” requires the physician to certify that the applicant meets the “fitness for duty requirements for licensed operators” (comments 157.12; 168.2). In contrast, two commenters recommended revising NRC Form 396 to include disclosure of known sleeping disorders (comments 134.7; 145.2). In addition, another commenter stated that a criterion should be added to 10 CFR 55.33(a)(1) to require evaluation of known sleeping disorders (comment 145.1).

Analysis: The staff agrees that sleeping disorders can affect employee performance (Kryger, Roth, and Dement, 1994). Therefore, the staff agrees that requiring disclosure of known sleep disorders may be appropriate.

NRC Form 396, used by applicants for operator and senior operator licenses, states that a physician conducted a physical examination using the guidance contained in ANSI/ANS 3.4-1996 or ANSI/ANS 3.4-1983 as endorsed by the applicable NRC regulatory guide (Regulatory Guide (RG) 1.134, Revision 2 or 3). The form also provides spaces for the physician to recommend areas in which the applicant's operator license might be restricted (conditioned). Although the form does not specifically address or prompt the physician to consider sleeping disorders, American National Standards Institute/American Nuclear Society (ANSI/ANS) 3.4 does specify that the physician shall note whether the applicant has "an established history or clinical diagnosis of... any mental or psychological condition that could cause impaired alertness, judgment, or motor ability."

The NRC may consider revising NRC RG 1.134 to add an exception to Section C, "Regulatory Position," addressing sleeping disorders. If the regulatory guide was revised, then revision of 10 CFR 55.33(a)(1) would likely not be needed.

15.2 Comment: One commenter requested that references to sleep disorder symptoms (as in Section (3)(a)(iii) of the petitioner's proposed changes) should not be included because such diagnosis should be conducted by a medical professional (comment 134.6).

Analysis: Section (3)(a) of the petitioner's proposed changes refers to the petitioner's request for the proposed rule to require that licensees provide initial and continuing fatigue mitigation training to personnel performing safety-related work, their supervisors, and managers. The training would be provided so that individuals can be sensitized as to whether they might want to seek a medical diagnosis. It is not the staff's understanding that training would be for the purpose of self-diagnosis or in lieu of a diagnosis by a medical professional.

16.0 Other Sources of Fatigue

16.1 Comment: Several commenters argued that there are a number of other factors that affect fatigue. For example, activities outside of work, such as family obligations and lack of sufficient sleep, can contribute to fatigue. The commenters stated that the rule may, therefore, not be effective. One commenter specifically stated that imposing strict limits on working hours would not address the licensee's inability to control an individual's activities outside the work environment (comments 153.2; 158.5; 161.9; 159.1; 160.1; 163.1; 164.1; 165.1; 166.1; 168.1; 169.1; 170.1; 171.1; 172.1; 174.1; 175.1).

Analysis: Many factors, in addition to working hours, may affect an individual's level of fatigue. Whereas it is possible that an individual could diminish the "fatigue prevention" value of working hour limits by engaging in other activities during rest periods, it is certain that an individual will not obtain sufficient rest if his or her work schedule does not include adequate time for rest. As a result, working hour limits have shortcomings but are not without merit. Such limits are the principal means employed by the DOT for several modes of commercial transportation, despite acknowledging the same shortcomings for those workers (see 65 FR 25558, May 2, 2000). In addition, the proposed amendment to Part 26 addresses fatigue through other measures in addition

to working hour limits. These measures include training of personnel in fatigue mitigation, training of supervisors in fatigue monitoring and detection, and evaluating the contribution of fatigue for specific categories of events and incidents. These additional measures would serve to address fatigue from any cause, including failure of individuals to make effective use of available rest periods.

17.0 Alternative Proposals

17.1 Comment: One commenter proposed a simplified set of working hour limits, as follows:

1. No more than 28 hours in a 48-hour period
2. No more than 80 hours in any 7-day period
3. No more than 280 hours in any 28-day period
4. No more than 2,800 hours in any calendar year

The commenter also proposed that shift turnover time be limited as proposed by the petitioner (comment 154.7).

Analysis: The staff has reviewed the regulatory limits on working hours in other industries and in the nuclear industry of other countries. Should the Commission approve rulemaking, the staff will consider the commenter's proposed limits along with other regulatory limits and relevant findings in formulating a proposed regulatory approach.

17.2 Comment: One commenter proposed that working hour limits during plant shutdown should be 60 hours per week, as when the plant is running [operating], to prevent potential overtime abuse. For example, if there is a problem on the unit that is running [operating], technicians and operators from the unit that is shutdown may likely be required to work on the running [operating] unit even after having worked 70 hours on the other (i.e., shutdown) unit (Comment 176.9).

Analysis: The staff acknowledges the concern and recommendation provided by the commenter. Any regulatory approach that the staff develops related to fatigue and overtime will be sensitive to overtime issues that are particular to staffing at multi-unit sites.

17.3 Comment: One commenter agreed with the biweekly limit on overtime hours but recommended a cap on how many weeks of overtime should be allowed (Comment 176.10).

Analysis: The staff will take the commenter's concern into consideration in developing any potential change in the NRC's regulatory approach.

17.4 Comment: Two commenters stated that if the NRC is truly concerned about overtime, the NRC could track overtime in a manner that is nonintrusive on the license holder. The commenters suggested that overtime of key safety personnel could be tracked as an input to an indicator of plant risk (comments 153.4; 176.4).

Analysis: The burden imposed by any regulatory option that the Commission may consider must be evaluated relative to the potential safety benefits of the option. Although the NRC is evaluating whether it may be possible to use some measure of overtime as an input to an indicator of plant

risk, it is not immediately apparent how this objective might be accomplished to obtain a valid input. The staff also does not believe that such an approach, by itself, would be an effective means of ensuring that personnel are not impaired by fatigue.

17.5 Comment: Two commenters proposed that as an alternative to the petition, the Commission should consider reinforcing the existing standards and programs for behavioral observation (comments 157.16; 168.2).

Analysis: Behavioral observation, as an adjunct to other methods for ensuring that personnel are not fatigued, can be of value. However, the staff's preliminary review indicates that behavioral observation, by itself, would not provide reasonable assurance that personnel are not impaired by fatigue (see analysis of comment 14.6). As noted in NUREG/CR-5227, "Fitness for Duty in the Nuclear Power Industry: A Review of Technical Issues," behavioral observation in conjunction with "for-cause" testing was not considered to be an adequate basis for not using random testing to identify substance abuse, principally because of the limitations of behavioral observation. In the case of alcohol or substance abuse, personnel may be impaired without conspicuous changes in behavior that would be noticed by a supervisor (Emery, 1986; Barnes et al. 1988), and for various reasons, supervisors and workers may fail to act upon indications of abuse they do detect (Kurtz, Googins, and Williams, 1980). Similar, and perhaps more significant, deficiencies may occur in behavioral observation of fatigue given that there is no clear indicator of fatigue, such as smell, as there is to aid the detection of alcohol. In addition, individuals may be more reluctant to raise a concern about an individual's FFD as a result of fatigue because the reasons for this type of impairment (e.g., long work hours, night shifts) are likely to be viewed as more socially acceptable or unavoidable.

17.6 Comment: One commenter stated that if the NRC believes the petition is necessary, the NRC should first change the FFD inspection module to include fatigue observation, conduct several inspections using the revised module, and then determine the appropriate action (comment 158.7).

Analysis: As noted in the analyses of comments 14.6 and 17.5, behavioral observation is not likely to be sufficiently sensitive to identify impairment caused by fatigue. In addition, the alerting effect that NRC observation would likely have on most personnel would mask much of the appearance of any impairment personnel may be experiencing. Specifically, individuals can be subjectively alert in response to a stimulating condition (e.g., a conversation with their supervisor) while at the same time they are physiologically fatigued and have impaired cognitive functioning (Rosekind and Schwartz, 1988). As a result, a series of inspections that have the objective of observing whether personnel are impaired by fatigue would not be particularly useful.

17.7 Comment: One commenter stated that the NRC should study reaction times of people over 40 (comment 21.1).

Analysis: Safe nuclear power plant operations are not dependent on operators making manual responses within seconds. The staff does not believe that reaction time studies, which typically focus on small variations in response times, would provide meaningful insights with respect to ensuring safe nuclear power plant operations.

17.8 Comment: One commenter stated that the individual worker should have input in determining if he or she is too fatigued to work extended hours (comment 176.11).

Analysis: As mentioned in the analysis of comment 10.1, the reliability of correctly assessing one's own level of fatigue is questionable. Research has demonstrated that "there is a discrepancy between the subjective report of sleepiness/alertness and physiological measures"; in general, individuals will report higher levels of alertness than are indicated by physiological measures (Royal Aeronautical Society, 1997). While subjective reporting alone may not guarantee an accurate assessment of one's physiological state, together with other appropriate measures self-reports may contribute to an overall psycho-physiological assessment of an individual's ability to perform required tasks successfully.

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ATTACHMENT 3

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

CONTENTS

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APPENDIX 1: SUMMARY OF RULEMAKING OPTIONS TO ADDRESS WORKER FATIGUE

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-hour 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 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

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.

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 impairment. However, Option 4 requires licensees to limit and manage the risks associated with

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."

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

¹⁰63 FR 8546 (February 19, 1998).

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 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

APPENDIX 1

SUMMARY OF RULEMAKING OPTIONS TO ADDRESS WORKER FATIGUE

Summary of Rulemaking Options to Address Worker Fatigue

		Staff Options		
General Requirement	Option 1: Implement proposals of PRM-26-2.	Option 2: Amend Part 26 to establish thresholds for work hour controls and risk-informed deviation process. Amend Part 26 and RG 1.134 to address fatigue from other causes through existing licensee programs.	Option 3: Amend Part 26 to establish work hour controls.	Option 4: Amend Part 26 to require licensees to assess and manage risk associated with schedules and conditions that cause fatigue and impaired alertness. Amend Part 26 and RG 1.134 to address fatigue from other causes through existing licensee programs.
Work hour limits	Prescriptive, addresses cumulative fatigue, limits vary by type of worker and plant status.	Set thresholds based on modification of current policy guidelines to address technical and enforcement issues.	Same as Option 2	None. Licensees determine appropriate risk management actions based on assessment of schedules using a fatigue metric in conjunction with an assessment of worker tasks, conditions, and responsibilities.
Exceptions to limits	Available for pre-defined plant conditions including activation of the emergency plan, shutdown for severe weather, plant transients, major engineered safety feature actuations, and extended shutdowns.	Individual above work hour threshold is assumed impaired. Exception requires licensee finding of no undue risk considering tasks to be performed, sensitivity of tasks to fatigue effects on performance, and ability to mitigate.	Option 3a: Same as Option 2	Not applicable. However, assessments of schedules and conditions causing fatigue and impaired alertness must encompass the actual schedules and conditions. Unscheduled overtime could require an assessment of the specific conditions if not bounded by prior assessments.
			Option 3b: Exceptions only for pre-defined plant conditions as proposed in Option 1.	
Assessment and Corrective Action	Assessment of fatigue required for certain conditions and events occurring while exception invoked.	Exceeding exception threshold requires corrective action. Assessment of fatigue concurrent with for-cause FFD tests.	Option 3a: Exceeding exception threshold requires corrective action.	Licensee monitors effectiveness in limiting and managing risks of fatigue and impaired alertness. Assessment of fatigue concurrent with for-cause FFD tests.
			Option 3b: None	

Methods to Address Other Sources of Fatigue	Training for mitigation of and monitoring for fatigue. Sleep disorder screening.	Training for mitigation of and monitoring for fatigue. Sleep disorder screening.	None	Training for mitigation of and monitoring for fatigue. Sleep disorder screening.
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