Fitness for Duty: Managing Fatigue and Safety in 24/7 Operational Settings

Mark R. Rosekind, Ph.D.

President and Chief Scientist

Alertness Solutions

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Executive Summary

Human operators are physiologically challenged by the 24/7 demand to meet modern society's requirements and expectations. The need for 24/7 operations has created known safety risks related to fatigue, sleep and circadian disruption. The U.S. Nuclear Regulatory Commission (NRC) has proposed a rule that includes work hour limits, education, and fatigue assessment to manage fatigue-related risks in the nuclear generating electric industry. This document addresses three aspects of the proposed NRC rule and provides some recommendations to enhance the final proposed rule.

First, the challenge of managing fatigue in 24/7 operational settings is examined from a larger context. Understanding the physiological factors that underlie fatigue, the complexity of multiple factors that create challenges for change, and the role of policies and scientific data to effectively manage fatigue are important perspectives when considering the proposed NRC rule.

Second, a scientific examination of two specific aspects of the proposed NRC rule is undertaken. The issue of proposed recovery breaks (i.e., 24 hrs off in 7 days and 48 hrs off in 14 days) is evaluated from the physiological perspective related to acute sleep loss and recovery from a cumulative sleep debt. The scientific analysis indicates that in its current form, the concept is applied arbitrarily and in an artificial manner. Though a valid concept, its application would be enhanced through a more refined approach. The issue of using collective group averages also was examined and determined that this approach should be eliminated because it obscures the potential fatigue-related risks represented by individual operators.

Third, there is a brief discussion of the education and fatigue assessment elements of the NRC proposal. Enhancements are suggested that will increase the effectiveness of these activities in the final implementation.

The NRC is commended for acknowledging the complexity of the issues under consideration, seeking to create a scientifically based rule, and proposing activities to effectively manage fatigue in the 24/7 operations of the nuclear generating electric industry.

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Introduction

Modern society functions 24 hours a day and 7 days a week, and meeting this 24/7 demand creates significant physiological challenges for the human operators responsible for maintaining safe and effective operations. A variety of approaches are used to minimize the known fatigue-related safety risks associated with 24/7 operations and are intended to optimize individual operators' fitness for duty. It is in this context that the U.S. Nuclear Regulatory Commission (NRC) has proposed a new rule to manage fatigue through duty hour limits and other complementary activities [1]. There are three specific aspects of the proposed NRC rule that will be addressed in this document, all relevant to managing fatigue and safety risks in 24/7 operational settings such as the nuclear generating electric industry.

First, the context and challenges of 24/7 operations will be considered. This includes understanding the physiological factors that underlie fatigue and how they create safety, performance, and alertness risks. One critical tool to manage fatigue involves the use of regulatory duty hour policies that set limits for duty and rest. Another tool is the extensive and relevant scientific literature that exists regarding sleep and circadian rhythms and that can be used to guide the specifics of these policy structures. Both the policy structure and the scientific findings are necessary but not sufficient to fully address the complexity of managing fatigue risks in 24/7 operations. Efforts to effectively address fatigue in around-the-clock operations must acknowledge the inherent complexities and utilize a comprehensive approach to address multiple factors.

Second, the proposed NRC rule represents significant and important progress as a model for addressing fatigue-related fitness for duty issues in around-the-clock work settings. Two specific issues included in the proposed NRC rule will be examined in an attempt to further enhance its scientific foundation and operational effectiveness to manage fatigue. These two issues are: 1) cumulative sleep debt recovery opportunity related to 24 hrs off in 7 days or 48 hrs off in 14 days and 2) the use of group averages for work hour limits.

Third, the proposed NRC rule includes some innovative approaches to education and fatigue assessment. These two areas will be discussed to identify ways that could enhance their effectiveness in optimizing operator fitness for duty.

Overall, the NRC is to be commended for extensive and excellent efforts to acknowledge the importance of managing fatigue, incorporating a scientifically based approach into the proposed rule, and extending beyond duty hour limits to include education and fatigue assessment. The comments provided in this document[1] are intended to strengthen the NRC proposal further by elaborating relevant scientific findings and considering the translation of those findings into operational implementation that will effectively optimize operators' fitness for duty.

I. The context and challenges of 24/7 operations

Modern society has evolved to demand 24/7 operations in many diverse areas, ranging from vital services to conveniences. For example, it is expected that transportation services will be provided around-the-clock, moving people and goods, through the air, on highways, and on the water. Healthcare services can be accessed at any time of the day or night and individuals expect that public safety (law enforcement, fire fighting, and emergency medical services) will respond to needs whenever required. Information technology, the global economy, communications, military operations and energy needs are all provided on a 24/7 basis. This includes the nuclear generating electric industry and the vital energy it provides to power critical activities in society.

This 24/7 societal demand creates significant, and well-documented, challenges to human physiology, especially regarding sleep and circadian rhythms. Humans are biologically designed to sleep at night and be active during the day: physiological programming that is in direct

[1] Some concepts and information provided here were drawn from *Managing Safety, Alertness and Performance through Federal Hours of Service Regulations: Opportunities and Challenges* [2].

opposition to a 24/7 society [3]. An extensive scientific literature clearly shows that sleep and circadian disruption degrade alertness and performance, leading to increased errors, incidents, and accidents.

a. Physiological factors that underlie fatigue

While there are a variety of complex factors that can affect fatigue, two primary physiological systems that have been scientifically demonstrated to affect alertness, performance and safety will be discussed: 1) sleep (specifically, acute sleep loss and cumulative sleep debt), and 2) circadian rhythms (time of day effects on sleep, alertness and performance). These two physiological systems interact and regulate the amount of sleep and sleep loss – the most relevant factors for the present discussion regarding the proposed NRC rule. Information is provided for these two systems as a scientific foundation for the discussion of the NRC proposed rule. However, other factors, such as continuous hours of wakefulness and sleep disorders, can also contribute to sleep loss and should not be ignored for their roles in creating fatigue.

i. Sleep: acute sleep loss and cumulative sleep debt. Generally, the scientific literature has shown that adult humans need "around" 8 hrs of sleep per day to provide consistent optimal waking alertness and performance [4]. However, there is often a discrepancy between the amounts of sleep that individuals obtain versus what they physiologically require, with the tendency for people to sleep less than needed [5]. Therefore, individuals who chronically obtain less than sufficient sleep may not be able to adequately determine their sleep need that provides optimal waking function. Also, while there is a range of individual sleep requirements, the average is around 8 hrs [6].

When an individual obtains less than sufficient sleep, it can significantly reduce alertness and performance. There are two general ways in which sleep loss is characterized: acute sleep loss and cumulative sleep debt. Acute sleep loss usually refers to the amount of sleep obtained in a 24 hr period that is less than an individual's required amount. Therefore, an individual with an 8 hr sleep need who only sleeps 5 hrs has an acute sleep loss of 3 hrs. The amount of acute sleep loss will affect subsequent alertness and performance during the following period of wakefulness.

Generally, obtaining 2 hrs less sleep than an individual needs will result in statistically significant alertness and performance decrements and the scientific literature indicates that such reductions are associated with "significant performance impairment" [7]. Controlled laboratory studies have shown that these performance decrements are comparable to performance levels when ingesting alcohol. For example, in one study, 2 hrs of sleep loss resulted in reduced performance that was equivalent to a .045% alcohol level (BrEC) [8]. Four hours of sleep loss showed an equivalent performance reduction to a .095% alcohol level (BrEC) [8]. In general, it has been found that the greater amount of acute sleep loss, the greater the decrease in alertness and performance [7, 9, 10].

There is an ongoing debate about the amount of "core" sleep that is needed to maintain a basic or acceptable level of performance and the average individual requirement (i.e., is it 7.5 to 8 hrs or 7.5 hrs or 7 to 8 hrs?). However, from a policy perspective, when individual sleep need cannot be systematically established, general averages are the most practical to use. Even with this perspective, it is clear that providing an 8 hr sleep opportunity is sufficient for an average 7.5 hr sleeper but it will result in sleep deprivation for an individual who needs 8.5 hrs of sleep. "One size" policies will not fit all, due to individual differences related to sleep need.

When translating this physiological sleep requirement into operational practices or regulatory policies, it is critical to consider an appropriate length of time to allow an 8 hr sleep period. In most cases, this is reflected in a minimum "off-duty" rest or break period. However, the off-duty "rest" period should include time for both an 8 hr sleep opportunity and time for other needs (e.g., personal). Therefore, an 8 hr off-duty period is not sufficient to provide an 8 hr sleep opportunity and will result in an acute sleep loss. This is the physiological basis for providing an off-duty rest period that is longer than 8 hrs. The NRC rule that provides a break or off-duty rest of 10 hrs is a critical and significant element that directly addresses this issue. The 10 hr break or off-duty period provides an opportunity for an 8 hr sleep period and other "awake" off-duty time to attend to other needs. This should provide a sufficient sleep opportunity to meet an individual's sleep requirement and minimize or eliminate any acute sleep loss. Obviously, when the break period provides even more time off, such as 12 or 16 hrs of off-duty time, this creates an even greater buffer to minimize or eliminate any acute sleep loss. Therefore, acute sleep loss can be eliminated or significantly minimized by providing a sleep opportunity that is sufficient for a person to meet their individual sleep need on a daily basis.

When an individual loses sleep over time, the acute sleep loss builds into a cumulative sleep debt. For example, an individual that obtains 2 hrs less sleep than the individual requires over four consecutive nights will accumulate a sleep debt of 8 hrs, equivalent to a full night of sleep loss. As indicated above, 2 hrs of acute sleep loss is the level that can create significant performance decrements. Additionally, the accumulated sleep debt over several days will further contribute to significantly degraded alertness [7, 9]

Parallel decrements also occur in objective performance. Recent studies of chronic partial sleep deprivation have systematically examined the effects of different levels of sleep loss on performance [11, 12]. The results clearly show that as an individual's sleep amount decreases and their sleep debt increases over time, there are significant reductions in performance. These changes appear to be "dose dependent," that is, the greater the sleep loss the more significant the reduction in performance.

From an operational and regulatory perspective, a cumulative sleep debt is typically addressed by a recovery opportunity that is determined by the number of hours worked or consecutive days worked. The recovery "time off" is intended to "zero out" any accumulated sleep debt. Generally, scientific studies have shown that two sleep periods can erase a cumulative sleep debt and return an individual to usual baseline levels of alertness and performance [10, 12, 13]. A low cumulative sleep debt may be "zeroed" by only one period of recovery sleep, while a high sleep debt may need more than two sleep periods to be resolved [10, 14].

Managing both acute sleep loss and cumulative sleep debt should be core elements of any scheduling or regulatory policy that addresses fatigue-related fitness for duty issues.

ii. Circadian rhythms: time of day effects on sleep, alertness and performance. Another core physiological factor that underlies fatigue is related to the internal circadian clock. This clock, located in the suprachiasmatic nucleus of the hypothalamus, regulates internal rhythms of biological functions, alertness, performance, and mood on an approximately 24-hr cycle [15]. The circadian clock provides the basic programming for humans to be awake and active during the day and to sleep at night. On a 24-hr basis, the circadian clock controls programmed periods of sleepiness and alertness. For example, the "low point" of the circadian clock occurs at about 3 to 5 am when the lowest levels of alertness, performance, temperature, activity and others occur. Recently, studies have shown that the performance reductions associated with this circadian low can extend later into the morning, until perhaps 7 or 8 am [16-18]. There are a variety of scientific studies that demonstrate that this period represents a window of vulnerability for performance decrements. Another reduction in alertness occurs around 3 to 5 pm. Though less severe than the reductions during the night, there is a consistent drop in alertness during the late afternoon [7, 9]. The circadian clock also programs windows for alertness that are sometimes referred to as "wake maintenance zones" [19-20].

This physiological, circadian fatigue factor is expressed in data collected in an extensive number of diverse work settings. For example, a recent review of incident risk associated with different shift schedules found that in relation to the morning shift, relative risk increased 18% on the afternoon shift and by 30% on the night shift [21].

The programming associated with the circadian clock contributes to fatigue in a variety of ways. An individual working through the night does so in contradiction to natural biological programming. Similarly, day sleep involves opposing the underlying program of the circadian clock. Therefore, time of day (circadian factors) will affect alertness, performance and quantity and quality of sleep. Schedules can disrupt the circadian clock by day to night variability, changing start times, non-24 hr cycles, time zone changes and more.

Circadian rhythms are extremely complex and many facets are not being addressed in this very brief introduction. There is a tremendous amount of scientific knowledge regarding circadian rhythms, such as the effects of light on circadian phase, non-adjustment to night work, the role of melatonin secretion for timing of the clock, identifying circadian phase, and much more. Generally, it is this circadian complexity that has impeded efforts to incorporate circadian considerations into regulatory structures. One effort to address circadian issues is reflected in the United Kingdom's Civil Aviation Authority's regulations regarding flight, duty, and rest limitations [22].

Circadian rhythms represent one of the core physiological factors that can underlie fatigue. It is critical to acknowledge that societal demands for 24/7 operations in many vital services represent an inherent conflict with human physiological design. Also, while there are efforts to facilitate adjustment of the circadian clock for night work or in jet lag situations, there are many circumstances where these strategies may be ineffective, impractical or actually worsen the outcomes. Therefore, there is no known method to eliminate the performance and alertness decrements associated with the window of circadian low that can be applied to the diversity of operational situations that involve night work or irregular schedules. This includes regulatory policy that cannot control the biological programming of the circadian clock or its low point. However, informed scheduling practices that acknowledge circadian principles can provide greater stability and predictability and be beneficial in managing circadian factors in 24/7 operations.

There are significant challenges posed by incorporating physiological knowledge on sleep requirements and hours of continuous wakefulness into Federal policies that address fatigue. Attempts to integrate, or even reflect, circadian considerations in scheduling and regulatory policies are an even more daunting exercise compared to addressing the sleep and wakefulness issues.

b. Addressing the complexity inherent in 24/7 operations

There are a variety of operational, physiological, and many other factors that are relevant to managing fatigue in operational settings. For example, five such factors include: 1) diverse operational requirements, 2) individual differences, 3) complex sleep and circadian physiology, 4) history, and 5) economics. A brief consideration of each factor provides a context for understanding the complexity of this issue.

i. Diverse operational requirements. In the nuclear generating electric industry there are diverse operational requirements. Clearly, there can be some general patterns and practical matters that affect and can create similarities, but the diversity of operations remains significant. Therefore, a regulatory concept or approach that involves an entirely ruled-based structure will not be able to encompass this diversity and cannot account for every possibility, operation or exception. In fact, care must be exercised in any regulatory concept to include appropriate flexibility, and to incorporate a performance or outcome based goal that reflects the diverse operational requirements.

ii. Individual differences. Another factor is that there are tremendous individual differences among the operators in the nuclear generating electric industry. Individuals differ according to age, gender, job experience, sleep needs, health status, employers, marital and family status, safety records, attitudes, and more. How each one of these factors affects their individual response and management of fatigue in their professional life is extremely difficult to know and certainly has not been extensively quantified. This is especially relevant in regard to interactions among these factors. Again, any regulatory concept or approach that attempts to limit the options available to address these core issues is unlikely to cover every variation.

iii. Complex sleep and circadian physiology. There is an extensive and significant scientific literature that exists describing the current state of knowledge about sleep and circadian rhythms and it clearly demonstrates that these physiological factors are complex. Also, there are almost 90 different sleep disorders that have been described, can be diagnosed, and a variety of treatments exist for these disorders. These sleep disorders can degrade alertness and performance, create safety risks, and predispose individuals to further impairment from the effects of sleep loss and circadian disruption. The scientific knowledge related to the interaction of sleep and circadian processes continues to evolve and further demonstrates the complexity of how these physiological factors will affect performance, alertness and safety in operations. It is also important to recognize that there is a scientific literature examining sleep and circadian rhythms in operational settings. These studies have evaluated a range of issues and in different work environments.

iv. History. Another challenging factor is history. While operations evolve over time, there are usually historical roots that underlie modern practices. Sometimes it can be difficult to change longstanding policies and practices that an operational environment considers well tested and understood. Classically, these practices are viewed as having proven their utility and value over time and there can be significant resistance to change. However, beyond a natural tendency to resist change, departing from established practices also can introduce risk by imposing new and untried methods. This is especially true when there are unknowns that could affect a variety of areas that accompany the change. Also, from a regulatory perspective, it can take decades before actual change occurs. When a new approach is implemented, it has the potential to be in place for a long time before further revisions might be considered. This adds to the resistance regarding change and an interest in having the "perfect" solution because of the time that the "new" structure might be in place before it is examined or altered. Therefore, when overall performance and safety is acceptable, then it is prudent for a regulatory approach to rely on historical precedent and to be conservative in the application of new and untried methods.

v. Economics. The varied economic issues associated with Federal policies regarding duty hours and fitness for duty represent another significant challenge. While presented in the context of safety, regulatory issues become contentious when considering how they affect diverse economic factors. Whether it is a corporate issue about the cost of running operations or operators' issues about their livelihood and ability to support themselves and family, varied perspectives demonstrate that the economics touch corporate viability and individual quality of life. Cost/benefit analyses provide some context for these issues but may not fully address the corporate, individual or public safety concerns that can be affected by the economic considerations. It is critical that these economic factors be weighed explicitly; otherwise, they can affect outcomes without being fully acknowledged. In actual, real-world applications, these economic factors often are not quantified or followed.

c. Federal duty hour policies: necessary but not sufficient

Just one straightforward example is needed to highlight the limitations of relying solely on a duty hour policy approach (whether Federal or organizational) to address fatigue. Regulations can be used to require an off-duty period and it could even require a specific sleep opportunity within this off-duty period (though this is often not explicitly identified). However, no regulation can control physiological sleep. Whether an individual chooses not to sleep (e.g., by engaging in other activities) or is affected by the myriad of factors that can disturb sleep (e.g., sleep disorder, illness, anxiety, environmental factors and many more), a duty hour regulation cannot control sleep physiology (i.e., quantity and quality of sleep). In fact, while individuals can "force" themselves to stay awake (for a limited time), it is not possible to "force" them to sleep. Sleep by regulatory demand is not a viable or realistic expectation of any work hour policy or structure. Therefore, a regulatory duty hour approach will never be sufficient to ensure sleep or fully address the complex nature of managing multiple fatigue factors. Though a duty hour approach cannot fully address fatigue factors, it is essential to provide a reasonable assurance that the risk of fatigue related events are being managed.

However, this example also highlights why duty hour policies are necessary and have a central role in managing fatigue. Without a required and appropriate length off-duty period, that allows a reasonable sleep opportunity, the entire issue of obtaining adequate sleep to maintain performance and alertness becomes irrelevant.

While Federal duty hour policies provide a critical and central structure for managing fatigue, there also should be consideration of the need to respond to unforeseen circumstances and operational flexibility. The policies must be enacted in real-world situations that are affected by diverse unplanned and uncontrolled circumstances. Therefore, within the established structure, mechanisms to provide operational flexibility to manage these events makes a regulatory scheme even more realistic and effective.

The position that an entirely ruled-based structure cannot address the diverse operational requirements or individual differences, is not intended to suggest that simply increasing the number of "rules" will be any more useful. Multiple policy "rules" also may be ineffective when trying to determine which specific areas to address. Furthermore, creating more complex rules may not be effective in managing the complexity of situations they are intended to address.

d. Scientific guidance for duty hour policies: necessary but not sufficient

There is a tremendous amount of significant scientific research that can be extremely informative and helpful in guiding operational decision-making (e.g., scheduling) and providing input to regulatory efforts to manage fatigue. However, there are limitations to the scientific data available that should be fully acknowledged. There are no studies that address every operational variation that exists within any work setting. Once again, the complexity of the physiology and the diversity of operations limit the availability of relevant or appropriate scientific research. Even where data exist, they may not fully address the specific operational or regulatory issue under consideration. Given the physiological complexities associated with sleep and circadian rhythms, a regulatory approach or structure that relies on scientific findings for justification of each element will struggle with the data that are available to be fully supported. For example, while there is a large and consistent database of findings on sleep need and the effects of sleep loss on performance and alertness, there are no solid data to address cumulative work hours on a long-term basis, such as over a month or year. Therefore, it can be more straightforward and scientifically based to establish specific requirements for daily or short-term off-duty periods, and more difficult to identify a solid, scientifically based monthly or annual duty hour limitation.

While some policies may include such limitations, they are not based on scientific data. Also, when attempting to incorporate data into a policy position, there may be conflicting findings and it becomes necessary to understand what might be causing these differences (e.g., different methods, measures, populations, statistics).

By acknowledging and incorporating solid, relevant scientific data into policies, there is the opportunity to establish an objective, neutral scientific foundation. From this perspective, integrating scientific guidance into duty hour policies is necessary but will not be sufficient to address the diverse and specific limitations that are reflected in Federal and organizational policies or in actual operations.

e. The complexity requires a comprehensive approach

These brief examples related to diverse operational requirements, individual differences, sleep and circadian physiology, history, economics and the necessary but not sufficient role of federal policies and scientific data demonstrate the complexity of managing fatigue in 24/7 operational settings. Conceptually, it is unrealistic to expect that only one approach can fully or effectively address even the majority of all these complex factors. In fact, given human physiological design (i.e., the need for sleep and circadian rhythms) it is unclear how fatigue can be, or even expected to be, eliminated from around-the-clock activities. However, an approach that acknowledges the complexity and physiological realities can provide an opportunity to reduce fatigue-related risks. Using a comprehensive, programmatic approach provides a context for addressing the complexity and provides a risk management strategy that can be tailored for diverse issues. For example, a comprehensive fatigue management approach that includes education, alertness strategies, scheduling and duty/rest policies, healthy sleep (e.g., identifying sleep disorders such as sleep apnea), a scientific foundation, and supporting policies provides many more opportunities to address the complex issues that have been identified (See section I.b) [23].

Recommending a comprehensive fatigue management approach should not be construed to suggest or interpreted to indicate that the need or role for Federal duty hour policies should be minimized or eliminated. A comprehensive fatigue management approach does not support this view in any way. Federal duty hour policies have a critical, even central, role in this comprehensive approach. However, in this context, these regulations are not considered the single solution to addressing fatigue. Rather, they provide a vital and core structure that addresses some essential elements of managing fatigue. When complemented by other components, such as education, alertness strategies, healthy sleep, etc., there is an opportunity to minimize fatigue-related risks with a more comprehensive approach that acknowledges the inherent complexity of this safety issue. The importance and central role of Federal duty hour policies must be fully acknowledged, as well as the obvious and critical limitations of the approach.

II. Examining two issues in the proposed NRC rule

First, it must be acknowledged that the proposed NRC rule represents significant progress in addressing fitness for duty and managing fatigue-related risks in a 24/7 operational setting. It is beyond the scope of this document to identify and discuss each of the elements in the proposed rule, whether to acknowledge strengths or suggest areas for further consideration. Instead, two specific issues in the proposed NRC rule will be examined in an attempt to enhance their scientific foundation and operational effectiveness to manage fatigue. These two issues are: a) cumulative sleep debt recovery opportunity related to 24 hrs off in 7 days or 48 hrs off in 14 days and b) the use of group averages for work hour limits [26.199(d)(2)(ii) and (iii) and (f)].

a. Cumulative sleep debt recovery opportunity

i. Acute sleep loss and cumulative sleep debt. As previously discussed, there are two elements of sleep loss that are critical to address in any duty hour policy: acute sleep loss and cumulative sleep debt. These have both been described earlier in Section I.a.i. While many duty hour policies will emphasize specifics of the duty length (i.e., actual work hours), the amount of sleep prior to the duty period is a critical predictor of subsequent performance and alertness. Therefore, obtaining sufficient sleep, and eliminating or minimizing any acute sleep loss, is crucial to maintaining optimal performance and alertness during the following duty period. This is the core principle that drives policies that "provide for breaks that are sufficient length to allow an individual to obtain restorative rest" (p. 50589 of [1]). The NRC proposed rule addresses this by requiring a 10-hour break between successive work periods.

As previously discussed, this 10-hour break provides an 8 hr sleep opportunity and time for other personal needs ("daily living obligations"). This 8 hr sleep opportunity should be adequate for an individual to meet their daily sleep requirement and not create any acute sleep loss. *By definition, if there is no acute sleep loss, there will be no cumulative sleep debt.* This has been clearly demonstrated in an elegantly controlled laboratory study of chronic sleep restriction and total sleep deprivation [24]. This study involved chronic sleep restriction at three doses (4 hr, 6 hr or 8 hr time in bed) for 14 consecutive days. This important study is often cited for its significant contributions to demonstrating the effects of chronic sleep restriction. However, the results also clearly showed that the group with 8 hrs time in bed showed no statistically significant changes in performance over the 14 consecutive day period. Eliminating acute sleep loss resulted in no cumulative sleep debt and in consistent performance across 14 consecutive days. The data clearly demonstrated that sleep restriction (i.e., 4 or 6 hr time in bed) resulted in a cumulative sleep debt over time and significantly reduced performance, while obtaining adequate sleep (no acute sleep loss, no cumulative sleep debt) resulted in consistent performance over a 14-day period.

It should be noted that in circumstances where there is a break or off-duty period longer than 10 hrs, then there is even more time and flexibility for obtaining an 8 hr sleep opportunity and attending to daily living obligations.

ii. Work hour limits provide further sleep loss protection. The proposed NRC rule also includes work hour limitations as follows: up to 16 hrs in any 24-hour period, 26 hours in a 48-hour period and 72 hours in a 7-day period [(26.199(d)(1)]. These work hour limits create further protection against acute sleep loss and cumulative sleep debt by creating scheduling scenarios that will both limit work hours and enforce sufficiently long break periods to obtain adequate sleep.

For example, applying the maximum work hours permitted in the proposed NRC rules could create the work/rest pattern portrayed in Schedule A.

Schedule A.

Day	1	2	3	4	5	6	7
Duty hrs	16	10	16	10	16	4	
Off hrs	10	12	10	12	10	18	24

Note that the maximum work day is followed by the minimum break time for only one day, when the 26 hour limit restricts the second day to 10 hours work time and a 12 hour break period. This cycle is repeated only one more time when after the fifth day, there would only be 4 hrs of work time before reaching the maximum of 72 hrs. This could be followed by a 42 hr break or off-duty period.

While Schedule A maximizes the limits, it may not be feasible to have a 4 hr work period on the last day. Therefore, Schedule B shows an example of maximizing work limits for 4 days, followed by two 10 hr workdays.

Schedule B.

Day	1	2	3	4	5	6	7
Duty hrs	16	10	16	10	10	10	
Off hrs	10	12	10	12	10	10	24

Note that this schedule would involve a 6 consecutive day work schedule that could be followed by a 34 hr break or off-duty period.

While it is an interesting exercise to "max out" the work hour limits, the more common schedules that cover 24/7 operations in the nuclear generating electric industry involve 8 hr or 12 hr work shifts [25]. Schedule C is an example of six 12 hr workdays, that reaches the maximum 72 work hour limit. This schedule provides a daily 12 hr break and at the end of the 72 work hours could result in a 36 hr break or off-duty period.

Schedule C.

Day	1	2	3	4	5	6	7
Duty hrs	12	12	12	12	12	12	
Off hrs	12	12	12	12	12	12	24

All of these schedules provide a minimum 10 hr break between work periods, and in some schedules longer break periods. Also, due to the work limits, these schedules create a minimum of 24 hrs off after consecutive workdays and up to a potential 42 hr recovery opportunity.

As continually noted, the complexity and diversity of schedules presents an important caveat. Any variation in these schedules that might include night work, day sleep or differing lengths of work periods could alter their potential effects on individual operators. One example is that by ending the consecutive work days with a night shift could reduce the off-duty period to 24 hrs rather than the longer periods portrayed.

iii. Cumulative sleep debt recovery: proposed 24 hrs off in 7 days and 48 hrs off in 14 days. The proposed NRC rule [26.199(d)(2)] extends beyond the minimum daily 10 hr break between successive work periods to provide 24 hrs off in any 7-day period and 48 hrs off in any 14-day period. These breaks or off-duty periods are intended to provide opportunities to recover from any cumulative sleep debt from the preceding consecutive work periods. However, as demonstrated in the previous sections, the 10 hr break should be adequate to obtain sufficient sleep and eliminate or minimize any potential acute sleep loss. By definition, there should be no cumulative sleep debt and no need for a recovery opportunity. As previously explained, this was very clearly demonstrated by the study that showed 8 hrs time in bed resulted in no cumulative sleep debt and no significant change in performance over a 14 day period [24].

As demonstrated by the potential maximum schedules and example variations portrayed in the previous section, it is clear that the work hour limits provide further protection. In summary, these example schedules, even when "maxed out," provide a 10 hr break period or greater after individual work periods and at the end of the consecutive workdays, there is a minimum 24 hr off-duty break, that potentially can be up to a 42 hr break.

Therefore, artificially requiring a 24 hr break every 7 days or a 48 hr break every 14 days is completely arbitrary and there is no scientific justification to support these specific numbers. In fact, they are contrary to: 1) scientific data showing that by eliminating acute sleep loss, there is no 'build up' of a cumulative sleep debt and no need for a recovery period; 2) the schedules portrayed, which provide enough recovery and sufficient sleep opportunities; and 3) the conceptual rationale and effectiveness of the 10 hr break and work hour limits included in the proposed NRC rule [26.199(d)(2)(i)].

Two examples, one schedule and one policy, further illustrate the artificial nature of these proposed breaks. Schedule D portrays a 7 consecutive day work schedule, with the longest workday on day 7. Note that the work period is 10 hrs followed by a 14 hr break period for the first six consecutive workdays, an off-duty period that should provide adequate time to obtain a sufficient sleep opportunity.

Schedule D.

Day	1	2	3	4	5	6	7
Duty hrs	10	10	10	10	10	10	12
Off hrs	14	14	14	14	14	14	12

Though a 7 consecutive day work schedule, there is sufficient opportunity to meet sleep need, create no acute sleep loss and therefore no cumulative sleep debt. Artificially introducing a 24 hr break as a recovery opportunity for a cumulative sleep debt into this schedule could potentially have no effect on the physiological fatigue factors that are its intended objective.

The policy example is drawn from NASA policies regarding duty/rest limits. NASA addresses scheduling factors in their agency-wide policy as well as center-specific policies for three different centers including Kennedy Space Center, Langley Research Center and Marshall Space Flight Center [26-29]. All of these policies establish the maximum number of consecutive workdays as 7 days, with a 1-day off recovery period after the 7th consecutive workday. In contrast, the proposed NRC regulation would require a recovery period after the 6th consecutive workday. The NASA policy intent is the same as the proposed NRC rule, to provide a recovery period for any potential cumulative sleep debt. This example demonstrates that without specific scientific data or guidance, the timing of the recovery "break" period is arbitrary. In fact, there are benefits to schedule stability and work continuity that would suggest in some situations extending the number of consecutive workdays would be a more useful approach. When adequate rest periods are provided, the stability and continuity benefits would be greater than the artificial introduction of a rest day.

iv. Recovery concept is scientifically supported — refine the approach. As portrayed in the previous schedules and in the application of the 10 hr break period and work hour limits, there are circumstances where no acute sleep loss or cumulative sleep debt would be expected.

Conceptually, and supported by scientific data, in these situations individuals can show no significant changes in performance for 14 consecutive days. However, as previously noted, night work, day sleep or other scheduling factors can affect sleep, alertness, and performance. For example, scientific data have clearly demonstrated that daytime sleep amounts are significantly reduced compared to nighttime sleep amounts [30, 31]. Therefore, situations will exist where individuals will not obtain sufficient sleep during their 10 hr break. This acute sleep loss, if experienced over multiple days would create a cumulative sleep debt. Obviously, providing an appropriate recovery opportunity to "zero out" any cumulative sleep debt is an important element of a work hour policy.

Therefore, it is recommended that the NRC consider refining the approach used for providing recovery opportunities that address potential cumulative sleep debt circumstances. For example, there could be different approaches offered for situations known to be associated with the potential for a cumulative sleep debt, such as working consecutive night shifts. Other approaches might be offered for varying work period durations (8 vs 10 vs 12 hrs), in which recovery sleep will vary depending on time of day (i.e., circadian factors). They also could be based on the amount of break/off-duty time provided, which could be more directly connected to potential acute sleep loss. Using a more refined approach, appropriate policies could be developed for sufficient short-term recovery opportunities and evaluate how they are extended or even needed for application to longer duration work periods (e.g., the 7 vs 14 day timeframe).

Recently, the Accreditation Council for Graduate Medical Education (ACGME) established new policies for medical resident duty hours [32]. The new policies addressed many of the same issues related to physiological fatigue factors that are identified in the proposed NRC rule. One policy element involves providing "1 day in 7 free from all educational and clinical responsibilities, averaged over a 4-week period" (Section VI. B. 3. of [32]). Again, the concept of a recovery opportunity to address cumulative sleep loss and fatigue is applied but with a refinement that provides flexibility to average the days over four weeks. There are potential problems with this approach as well but it does represent an attempt to address the issue with some flexibility and to tailor the recovery opportunities to the circumstances.

When considering refinements to the approach used for recovery opportunities, it also provides the occasion to review the language used for the policy. For example, in the current proposed NRC rule it is unclear whether the 24 and 48 hrs off could be additive in a 14-day period. That is, would an individual get 24 hrs off in a 7-day period and 48 hrs off in a 14-day period, for a total of 72 hrs off in the 14-day period? The intent should be clarified in explicit language.

Providing recovery opportunities for a potential cumulative sleep debt is an important element of a work hour policy. The proposed NRC rule on this issue illustrates the significant challenges of applying the available science to complex 24/7 operations. In its current form, the proposed policy is arbitrary and artificially applied and may not lead to the intended outcomes. However, refinements that tailor the policy to circumstances known to create an acute sleep loss would target the situations that would benefit most from the recovery opportunities. These refinements, based on scientific data, would further enhance the already strong policies proposed in the NRC rule.

b. The use of group averages for work hour limits

The proposed NRC rule includes the use of a collective average for further work hour controls [26.199(f)]. Specifically, this involves "a maximum collective average of 48 hours per person per week" (p. 50617 of [1]). Also, the NRC stated its interest in "alternatives to the group work hour controls," "such as individual work hour limits based on a longer term (e.g., monthly or quarterly)" (p. 50617 of [1]).

The intent of the proposed NRC rule is to promote fitness for duty by addressing known fatigue-related safety risks. It is critical to emphasize that individual operators are the ones at risk for sleep and circadian disruption and the associated degradation in performance and alertness. It is the individual operator's sleep need that must be met during the off-duty break period. The fatigue-related safety risks in 24/7 operations are created by individuals with an acute sleep loss, a cumulative sleep debt, an extended period of continuous wakefulness or working and sleeping at a circadian phase contrary to their natural biological programming. These are the physiological fatigue factors addressed by the proposed NRC rule that will have the greatest effect on minimizing the fatigue-related safety risks.

Straightforward mathematics shows that collective or group averages will not reflect the risk contributed by individuals. Some individuals could be working maximum hour schedules, while others are working minimum hour schedules. Though the collective average would put the work hour schedule in the middle, this would not reflect the differential risk associated with the widely disparate individual schedules. This type of calculation and use of average work hours could obscure potential fatigue-related safety risks contributed by individual operators.

In this case, it is recommended that the NRC eliminate the specific policies regarding collective work hour limits, as they are not an effective means to address the known physiological fatigue risks contributed by individual operators.

As stated in its request for alternatives, the NRC is interested in approaches that would address cumulative fatigue, potentially in the form of individual work hour limits based on a longer term (e.g., monthly or quarterly). This is a potentially important conceptual component of an effective work hour policy. Unfortunately, it is also an example where the science regarding fatigue, sleep and circadian rhythms has minimal data to contribute. It also should be noted that other measures in the proposed rule (see section II.a) already address cumulative fatigue, and so alternative approaches involving long-term individual work hour limits are not necessary.

In 1996, NASA published a Technical Memorandum (#110404) entitled, "Principles and Guidelines for Duty and Rest Scheduling in Commercial Aviation." In the guidelines, it specifically addressed cumulative (flight) duty periods (section 2.3.7) and summarized its approach in the overview figure (Figure 1, p. 9 of [33]). It states: "There is not sufficient data to provide specific guidance in this area (monthly, annual limitations); however, cumulative flight duty period limitations should be adjusted downward over increasing time frames."

The state of the science has not changed since the NASA Technical Memorandum was published and there remains insufficient data to guide the establishment of monthly or annual individual work hour limitations. Therefore, the operational settings that have established such limitations have used straightforward mathematical calculations, such as multiplying the weekly limit by four to create a monthly limit and multiplying the monthly limit by 12 to create an annual limit.

The established limitations that do exist vary widely across different industries and work settings and further illustrate the artificial nature of the long-term limits. For example, the ACGME, in establishing Resident Duty Hours, defined a 24-hour limit on a single continuous duty and an 80-hour weekly limit, averaged over four weeks, with no explicit monthly or annual limits. However, the monthly and annual limits could be calculated from the short-term limits (e.g., 320 hr limit for a month). In aviation, the FAA flight, duty and rest regulations define a limit for flight time per month (e.g., 100 hrs for commercial Part 121 flight crew) and an annual limit of 1,000 flight hours (14 CFR Part 121); though no explicit duty time limits are identified. These examples demonstrate the inconsistency and artificial manner in which policies intended to address fatigue-related safety risks have been established.

Therefore, using an individually based approach is conceptually a more sound mechanism than the proposed collective group averages to reflect fatigue-related safety risks contributed by individual operators. However, it will be difficult for the NRC to establish long-term limits that have a scientific basis, given that no scientific data exist to develop those limitations.

III. Education and fatigue assessment

An alertness management approach to addressing fatigue in complex 24/7 operational settings includes a variety of elements (see Section I.e), including education. The NRC proposal includes education and fatigue assessment as complements to the explicit work hour policies that are outlined. This represents a progressive and enlightened approach that acknowledges the complexity of managing fatigue in the nuclear generating electric industry. Some brief comments on these two elements will highlight their importance.

a. Education

Education is a critical foundation for addressing fatigue-related risks in 24/7 operational settings. The NRC proposal extends beyond just requiring education to actually outlining educational content examples of what should be included in these activities (26.29, 26.197 and 26.199). It goes on further to include not only training but also examination requirements to ensure knowledge acquisition. The importance of establishing this knowledge base for individuals and the organizations cannot be overstated. Education and training can have pervasive effects on all aspects of an organization's operations as well as its personnel and their families.

The NRC's charter to ensure safety requires that frontline operational personnel are the regulatory focus for these types of education and training activities. However, all personnel would benefit from the type of educational information recommended in the NRC proposal. By extending this to an organizational effort, there is an opportunity to affect system or culture change regarding fatigue management.

b. Fatigue assessment

This is another element that complements the proposed work hour policies and represents an innovative activity to address an often-overlooked issue. Fatigue assessments are outlined in the NRC proposed rule (26.201) for use in specific situations and according to particular procedures. An effective practice of fatigue assessments will add a significant dimension to overall fatigue management activities and further extends efforts beyond just a work hour limits policy.

It is recommended that the NRC further refine this innovative element prior to its potential implementation. Some aspects are already well defined, such as situations where fatigue assessments would be used and some of the procedures (e.g., done by properly trained personnel, free of bias, and with privacy protections). However, the specific details of what will be assessed, how the information is summarized and analyzed, and the interpretation of findings require further development. For example, the role of observation to identify fatigue-related behaviors can be useful when sleepiness is significant enough to cause overt behavioral change. At other times, observable behavioral indicators may not reflect the underlying physiological state. One approach that may be worthwhile to explore is how fatigue factors are examined in accident investigations [34, 35]. This provides a structured approach to examining the known physiological factors that underlie fatigue and could be extrapolated and tailored for use in the context of the NRC proposed fatigue assessments. This can provide an objective, scientifically grounded approach that is based on the known fatigue factors that can create safety risks in 24/7 operational settings.

V. Conclusions

The societal demand to operate around-the-clock has created fatigue-related safety risks due to the physiological challenges that confront the human operators. Efforts have emerged to directly address the fatigue engendered by 24/7 operations and optimize operators' fitness for duty. A central element of many such efforts involves policies that limit work hours and provide off-duty rest and recovery opportunities. However, addressing fatigue through hours-of-service (HOS) regulations is a complex and contentious endeavor. Very recently, the National Transportation Safety Board reaffirmed the importance of updating the HOS for all transportation modes by keeping fatigue and this task on its Most Wanted List [36]. Transportation is only one example of the many 24/7 operational settings that must contend with this known safety challenge.

The NRC has acknowledged the importance of managing fatigue and its relevance as an operational safety issue for almost 25 years. It is in this historical context that the NRC has now proposed its most comprehensive rule to date to address fatigue through work hour policies, education, and fatigue assessment. The proposed NRC rule has relied heavily on the available scientific knowledge to craft specifics consistent with scientific findings, which are operationally feasible and will be effective in managing the known risks associated with fatigue. Also, the proposed NRC rule acknowledges the complexity of this issue by utilizing multiple approaches to address fatigue. The significant advances represented by this proposed rule, and the tremendous NRC efforts to constructively manage fatigue in the nuclear generating electric industry are to be enthusiastically commended and appreciated.

Engaging in this process also clearly shows where a work hour limits policy and the scientific data available to guide that policy are necessary but not sufficient to fully address the complex factors related to fatigue. The central role for work hour limit policies, and the use of scientific knowledge, must be balanced by appreciating their limitations as well. This document attempts to provide a perspective that acknowledges the physiological factors that underlie fatigue, the complex issues that represent challenges and barriers to effectively managing fatigue and how a comprehensive approach offers great promise in efforts to effectively address the safety risks.

Two specific aspects of the proposed NRC rule are examined in detail from a scientific perspective while two are addressed from an implementation viewpoint. The 10 hr required break and work hour limits are demonstrated to provide an effective means for obtaining sufficient sleep. This eliminates or minimizes the potential for acute sleep loss and a cumulative sleep debt. Therefore, while recovery opportunities remain an important element of managing fatigue in a work hour limits policy, an artificially applied time off (i.e., 24 hrs in 7 days) does not translate into an effective mechanism for providing recovery. However, further refinement of how recovery opportunities are applied to known vulnerabilities, such as cumulative sleep debt situations, would enhance the NRC policies and increase their effectiveness to create the intended outcome.

Also, using collective group averages of work hour limits obscures the risk associated with individual operators and does not represent an effective fatigue management tool. The NRC's interest in alternatives related to individual work hour limits provides a potentially useful approach, though establishing scientifically based limits will be difficult. The method of using long-term work hour limits does not necessarily control the variability of the individual fatigue risk over time, and since cumulative fatigue is already addressed by other portions of the rule, longer term individual work hour limits are not necessary.

The NRC also is to be commended for acknowledging the importance of education and fatigue assessment as activities that will complement work hour limits policies. Further refinement of these efforts will only enhance the effectiveness of the final rule in using multiple approaches to address fatigue in 24/7 operations.

Overall, the NRC has proposed an innovative and progressive rule to address known safety risks associated with fatigue. It is now confronted with the challenges and limitations of policies and scientific knowledge to implement meaningful and effective actions. Serious consideration of the issues raised and modifications that integrate the science with operational factors offer the potential to enhance the final NRC rule.

Effectively managing fatigue in 24/7 operational settings is a shared responsibility among corporations, operators, the NRC, and others. By refining and enhancing its final rule, the NRC will be able to meet its responsibility to address fatigue-related safety risks in the nuclear generating electric industry.

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References

1. Nuclear Regulatory Commission. (2005). Nuclear Regulatory Commission, 10 CFR Part 26, Fitness for Duty Programs; Proposed Rule. *Federal Register 70*(165), 50441-50677.

2. Rosekind, M. R. (2005). *Managing Safety, Alertness and Performance through Federal Hours of Service Regulations: Opportunities and Challenges* (Docket Document No. FMCSA-2004-19608-1134). Washington, DC: U.S. Department of Transportation.

3. Czeisler, C. A., Buxton, O. M., & Khalsa, S. B. S. (2005). The Human Circadian Timing System and Sleep-Wake Regulation. In M. A. Kryger, T. Roth, & W. C. Dement (Eds.), *Principles and Practice of Sleep Medicine* (pp. 375-394). Philadelphia, PA: Elsevier Saunders.

4. Roehrs, T., Carskadon, M. A., Dement, W. C. & Roth, T. (2005). Daytime Sleepiness and Alertness. In M. A. Kryger, T. Roth, & W. C. Dement (Eds.), *Principles and Practice of Sleep Medicine* (pp. 39-50). Philadelphia, PA: Elsevier Saunders.

5. National Sleep Foundation. (2002). *2002 Sleep in America Poll.* Available at: http://www.sleepfoundation.org/_content/hottopics/2002SleepInAmericaPoll.pdf. Accessed December 1, 2005.

6. Wehr, T. A., Moul, D. E., Barbato, G., Giesen, H. A., Seidel, J. A., Barker, C., & Bender, C. (1993). Conservation of photoperiod-responsive mechanisms in humans. *Am J Physiol. 265*(4 Pt 2), R846-57.

7. Carskadon, M.A. & Roth, T. (1991). Sleep restriction. In T. H. Monk (Ed), *Sleep, Sleepiness and Performance* (pp. 155-167). Chichester: Wiley.

8. Roehrs, T., Burduvali, E., Bonahoom, A., Drake, C., & Roth, T. (2003). Ethanol and sleep loss: a "dose" comparison of impairing effects. *Sleep, 26*(8), 981-5.

9. Carskadon, M.A. & Dement, D. C. (1981). Cumulative effects of sleep restriction on daytime sleepiness. *Psychophysiology, 18*(2), 107-13.

10. Carskadon, M. A. & Dement, D. C. (1979). Effects of total sleep loss on sleep tendency. *Percept Mot Skills, 48*(2), 495-506.

11. Belenky, G., Wesensten, N. J., Thorne, D. R., Thomas, M. L., Sing, H. C., Redmond, D. P., Russo, M. B., & Balkin, T. J. (2003). Patterns of performance degradation and restoration during sleep restriction and subsequent recovery: a sleep dose-response study. *J Sleep Res, 12*(1), 1-12.

12. Dinges, D. F., Pack, F., Williams, K., Gillen, K. A., Powell, J. W., Ott, G. E., Aptowicz, C., & Pack, A. I. (1997). Cumulative sleepiness, mood disturbance, and psychomotor vigilance performance decrements during a week of sleep restricted to 4-5 hours per night. *Sleep, 20*(4), 267-77.

13. Kales, A., Tan, T. L., Kollar, E. J., Naitoh, P., Preston, T. A., & Malmstrom, E. J. (1970). Sleep patterns following 205 hours of sleep deprivation. *Psychosom Med, 32*(2), 189-200.

14. Carskadon, M.A. & Dement, W. C. (1985). Sleep loss in elderly volunteers. *Sleep, 8*(3), 207-21.

15. Czeisler, C. A., Duffy, J. F., Shanahan, T. L., Brown, E. N., Mitchell, J. F., Rimmer, D. W., Ronda, J. M., Silva, E. J., Allan, J. S., Emens, J. S., Dijk, D. J., & Kronauer, R. E. (1999). Stability, precision, and near-24-hour period of the human circadian pacemaker. *Science, 284*(5423), 2177-81.

16. Carrier, J. & Monk, T. H. (1999). Effects of Sleep and Circadian Rhythms on Performance. In F.W. Turek & P.C. Zee (Eds), *Regulation of Sleep and Circadian Rhythms* (pp. 527-556). New York: Marcel Dekker.

17. Monk, T. H., Buysse, D. J., Reynolds, C. F., Berga, S. L., Jarrett, D. B., Begley, A. E., & Kupfer, D. J. (1997). Circadian rhythms in human performance and mood under constant conditions. *J Sleep Res, 6*(1), 9-18.

18. Van Dongen, H.P. & Dinges, D. F. (2005). Circadian Rhythms in Sleepiness, Alertness, and Performance, In M. A. Kryger, T. Roth, & W. C. Dement (Eds.), *Principles and Practice of Sleep Medicine* (pp. 435-443). Philadelphia, PA: Elsevier Saunders.

19. Lavie, P. (1986). Ultrashort sleep-waking schedule. III. 'Gates' and 'forbidden zones' for sleep. *Electroencephalogr Clin Neurophysiol, 63*(5), 414-25.

20. Strogatz, S. H., Kronauer, R. E., & Czeisler, C. A. (1987). Circadian pacemaker interferes with sleep onset at specific times each day: role in insomnia. *Am J Physiol, 253*(1 Pt 2), R172-8.

21. Folkard, S., Lombardi, D. A., & Tucker, P. T. (2005). Shiftwork: safety, sleepiness and sleep. *Ind Health, 43*(1), 20-3.

22. Civil Aviation Authority. (2004). *CAP 371. The Avoidance of Fatigue in Aircrews: Guide to Requirements*. West Sussex, UK: Safety Regulation Group, Civil Aviation Authority. Available at: http://www.caa.co.uk/docs/33/CAP371.PDF. Accessed December 1, 2005.

23. Rosekind, M. R. (2005). Managing work schedules: an alertness and safety perspective. In M. A. Kryger, T. Roth, & W. C. Dement (Eds.), *Principles and Practice of Sleep Medicine* (pp. 680-690). Philadelphia, PA: Elsevier Saunders.

24. Van Dongen, H. P., Maislin, G., Mullington, J. M., & Dinges, D. F. (2003). The cumulative cost of additional wakefulness: dose-response effects on neurobehavioral functions and sleep physiology from chronic sleep restriction and total sleep deprivation. *Sleep, 26*(2), 117-26.

25. Baker, T.L., Campbell, S.C., Linder, K.D., & Moore-Ede, M. C. (1990). Control room operator alertness and performance in nuclear power plants. *EPRI Technical Report NP–6748*. Palo Alto, CA: Electric Power Research Institute.

26. National Aeronautics and Space Administration. (2004). *NPR 1800.1 NASA Occupational Health Program Procedures w/Change 2 (8/31/04)*. Available at: http://nodis3.gsfc.nasa.gov/displayDir.cfm?Internal_ID=N_PR_1800_0001_&page_name=main. Accessed December 1, 2005.

27. National Aeronautics and Space Administration. (2002). Interim Procedural Letter Regarding Maximum Work Time, KHB 1710.2. Revision E-1 April 2002 (Includes 2 Interim Changes – Sept 2003). In *Kennedy Space Center Safety Practices Handbook*. Kennedy Space Center, FL: NASA.

28. NASA Langley Research Center. (2004). NASA Langley Research Center (LaRC) Maximum Work Time Policy (Langley Policy Directive 1700.5). Hampton, VA: NASA Langley Research Center.

29. National Aeronautics and Space Administration. (2004). *Marshall Procedural Requirements. Marshall Safety, Health, and Environmental (SHE) Program. Appendix Z: Maximum Work Hour Guidelines*. Available at: http://webpub.nis.nasa.gov/RightSite/getcontent/tempfile.pdf?DMW_FORMAT=pdf&DMW_OBJECTID=090033db801cbb5b. Accessed December 1, 2005.

30. Gander, P. H., Graeber, R. C., Connell, L. J., & Gregory, K. B. (1991). *Crew Factors in Flight Operations VIII: Factors Influencing Sleep Timing and Subjective Sleep Quality in Commercial Long-haul Flight Crews* (Technical Memorandum No. 103852). Moffett Field, CA: NASA Ames Research Center.

31. Monk, T. H. (2005). Shift Work: Basic Principles. In M. H. Kryger, T. Roth, & W. C. Dement (Eds.), *Principles and Practice of Sleep Medicine* (4th ed., pp. 673-679). Philadelphia: Elsevier Saunders.

32. Accreditation Council for Graduate Medical Education. (2003). *Common Program Requirements*. Available at: http://www.acgme.org/acWebsite/dutyHours/dh_Lang703.pdf. Accessed December 1, 2005.

33. Dinges, D. F., Graeber, R. C., Rosekind, M. R., Samuel, A., & Wegmann, H. M. (1996). *Principles and Guidelines for Duty and Rest Scheduling in Commercial Aviation* (Technical Memorandum No. 110404). Moffett Field, CA: NASA Ames Research Center.

34. Rosekind, M. R., Gregory, K. B., Miller, D. L., Co, E. L., & Lebacqz, J. V. (1994) Analysis of Crew Fatigue Factors in AIA Guantanamo Bay Aviation Accident. In National Transportation Safety Board, *Aircraft Accident Report: Uncontrolled Collision with Terrain, American International Airways Flight 808, Douglas DC-8, N814CK, U.S. Naval Air Station, Guantanamo Bay, Cuba, August 18, 1993* (NTSB/AAR-94/04; PB94-910406; pp. 133-144). Washington, DC: National Transportation Safety Board.

35. National Transportation Safety Board. (1994). *Aircraft Accident Report: Uncontrolled Collision with Terrain, American International Airways Flight 808, Douglas DC-8, N814CK, U.S. Naval Air Station, Guantanamo Bay, Cuba, August 18, 1993* (NTSB/AAR-94/04; PB94-910406). Washington, DC: National Transportation Safety Board.

36. National Transportation Safety Board. (2005). *NTSB Most Wanted Transportation Safety Improvements 2006*. Available at: http://www.ntsb.gov/Recs/brochures/MostWanted_2005_06.pdf. Accessed December 1, 2005.

From: Carol Gallagher
To: Evangeline Ngbea
Date: Tue, Dec 20, 2005 12:41 PM
Subject: Comment letter on FFD proposed rule

Attached for docketing is a comment letter on the above noted proposed rule from Mark R. Rosekind that I received via the rulemaking website on 12/19/06.

Carol

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