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“The Lighthouse: Regulatory Stability in a Time of Change”

by

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at the

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I. Introduction

Good afternoon. I am delighted to address once again this annual meeting of the chief executive and senior nuclear officers of the Institute of Nuclear Power Operations' (INPO) member utilities. The contributions that INPO consistently has made to enhance the performance of the nuclear power industry deserve high recognition and high praise. Today, in particular, I would like to note the outstanding leadership and enduring contributions of Dr. Zack Pate during his tenure as INPO President and Chief Executive Officer--and most recently, as Chairman. Dr. Pate has exemplified the highest ideals of service to his country, beginning with 22 years of Naval service--from 1958 to 1980--followed by what will be a total of 18 years here at INPO, where he took over as the successor to Admiral Dennis Wilkinson in 1984. Some of you may not be aware that Dr. Pate and I share an alma mater; we each received our doctoral degrees from the Massachusetts Institute of Technology--only 3 years apart. But we share more than that: I want to express my deep appreciation for all that I learned from Dr. Pate when I served with him, from 1992 to 1995, on the INPO Advisory Council. Zack, I sincerely will miss your insight and experience, and I wish you well in every future endeavor--including your most recently assumed critical role as Chairman of the World Association of Nuclear Operators (WANO). I also would like to extend hearty congratulations to Dr. James T. Rhodes, who will be taking over from Dr. Pate. I look forward to working with you, and I wish you every success in your leadership here.

In my presentation to this forum last year, I focused on several challenges that were facing the nuclear power industry, challenges that affected INPO and the U.S. Nuclear Regulatory Commission (NRC) as well--in particular, electric utility deregulation, the need for increased attention in areas such as licensee self-assessments and design basis control, and issues derived from the NRC Strategic Assessment and Rebaselining. I have entitled my presentation today, "The Lighthouse: Regulatory Stability in a Time of Change." In many ways my focus always is essentially the same, but I have selected a different set of issues to discuss, which include: (1) the NRC effort to develop an integrated facility assessment process; (2) the current status of NRC efforts on 10 CFR 50.59 and related design basis issues; (3) the license renewal process; and (4) recent Commission guidance on safety and compliance. Each of these areas of Commission focus is an illustration of the types of challenges that we face, the progress we have made, and the need to maintain excellence as we position ourselves for change.

II. Integrated Assessment Process

As you are aware, the Commission has been focused for some time on improving the effectiveness of the Senior Management Meeting (SMM) process. Shortly after I began my tenure as Chairman of the NRC, I began to press for improved performance indicators--signals and processes that would facilitate earlier detection of a declining trend in facility performance. The staff was asked to develop more consistency in the performance assessment process among Headquarters and the regions, and to instill more objectivity in the SMM process. To help accomplish this latter task, I asked the staff to bring in outside help. The NRC contracted with Arthur Andersen. The Arthur Andersen study evaluated the SMM process and recommended improvements, including the development of an algorithm for using indicators that could be quantified, weighted, and factored into the SMM evaluation process. In addition, a Performance Evaluation Template is being developed to improve process structure and consistency.

As this scrutiny of the process intensified, the Commission began to see the need for improving other plant assessment processes and regulatory actions, including the use of the Plant Issues Matrix (PIM), the Plant Performance Review process, and the Systematic Assessment of Licensee Performance (SALP) process. The staff also was asked to identify supplemental actions for the NRC to consider when a plant remained on the Watch List for an extended period. Given the degree of Commission interest and the increasing scope and complexity of Commission direction related to various aspects of these assessment processes, it became apparent that a more broad-scope review was in order, that would consider reactor assessment as an overall function. In August of this year, the Commission directed and approved the performance of an integrated review of all reactor-related assessment processes, to achieve a number of outcomes:

- ◆ To clarify the objectives of each assessment method;
- ◆ To eliminate redundancies as much as possible;

- ◆ To define office and individual staff roles and responsibilities;
- ◆ To ensure consistency among the regions;
- ◆ To incorporate, to the extent possible, risk insights and risk assessment methodology;
- ◆ To reduce administrative burden; and
- ◆ To match the processes to available staff resources.

I am aware, from my interactions with some members of the industry, that the ongoing NRC effort to refine the reactor licensee assessment processes is viewed as potentially contributing to “regulatory instability.” However, I would contend that exactly the opposite is true. To the degree that, in past years, NRC changes in this area have created mixed messages or licensee confusion, it has largely been the result of a “piece-meal” approach that addressed each perceived process inadequacy with a new process or a modification to an existing process. The focus of the current effort, however, is to understand the objectives of each process, to identify strategies for achieving those objectives (including the various types of data that feed the process), and to develop a creative alternative that is at once more scrutable, more predictable, more objective, and more efficient--a process in which all constituent parts are consistent with each other, and properly integrated.

In the Spring of next year, the staff will be presenting to the Commission the results of its review, with options for Commission consideration. The staff also will schedule a workshop to obtain comments from stakeholders on the assessment process. I encourage you to participate in the workshop, and to inform us of your views on the assessment process.

III. 10 CFR 50.59 and Related Design Basis Issues

My second area of discussion today bears a resemblance to the first, in that the focus of the Commission has evolved from a series of issues--each related to licensees maintaining the design bases of their facilities--to an awareness of the “big picture” and a commitment to finding an overall solution. Currently, the NRC has multiple methods for dealing with inoperable and/or degraded equipment, each with a different formula for classifying equipment--structures, systems, and components (SSCs). Among these methods are 10 CFR 50.59; Generic Letter 91-18; 10 CFR Part 50, Appendix B, Criterion XVI; Technical Specifications and Final Safety Analysis Reports (FSARs) of varying scope and level of detail; and other guidance--each created at a different point in the evolution of the NRC, and each with a specific purpose and scope. The resultant ambiguity and overlap of these methods, guidance documents, and requirements have created, in some cases, inconsistent application, or gaps in application, that in turn have caused confusion and inefficiency both for the NRC and for licensees.

While the Commission recognizes the value of several actions that have been taken by the staff to provide near-term clarification and guidance, our overall focus has expanded to recognize the need for a unified, consistent overall approach that also is

understandable and risk-informed. Last month, in a paper to the Commission, the staff presented five options that would address, in various ways and to varying degrees: (1) implementation of improvements to 10 CFR 50.59; (2) the proper use and content of the plant SAR; (3) maintenance of the facility design basis; and (4) NRC oversight of licensee commitments and other related internal process improvements. The fifth option draws from certain elements of Options 1-4 to include both small, risk-informed enhancements to selected existing regulatory processes in the near term and, in the longer term, the development of much broader implementation of risk-informed decision-making and oversight for many regulations. Option 5 specifically considers the relationship of 10 CFR 50.59 to other Part 50 requirements.

The Commission currently is weighing the merits of each option. What is clear is the following:

- ◆ The need to define clearly the scope of equipment within the plant that should receive a significant degree of regulatory oversight;
- ◆ Within that scope, the need to establish a consistent, risk-informed method of classifying facility equipment;
- ◆ The need to clarify the degree of regulatory oversight that should be accorded to each class or type of equipment, and the course of licensee and NRC action that should be taken (including an appropriate time limit for resolution) when equipment is inoperable or degraded, when a temporary modification is put into place, or when any other actions are taken that could impact facility adherence to the design basis; and, finally,
- ◆ The need to delineate clearly the relative functions of the Technical Specifications, the FSAR, and less formal licensee commitments. Simply put, what is important is scope, classification/categorization and disposition; as well as delineation of important documents, control of documents and commitment tracking.

IV. License Renewal Process

Let me turn now to the subject of license renewal. By way of background: about 10 percent of the remaining nuclear plant licenses will expire by the end of 2010 (with the first to expire in 2006), and more than 40 percent will expire by 2015. The timely renewal of licenses, where appropriate, may be important to ensuring an adequate energy supply mix for the U.S. during the first half of the 21st century. It could play into the debate over mitigation of global warming. It also may be important to the economic viability of a utility, due to the additional time over which investments can be amortized.

The decision on whether to seek license renewal rests with a licensee. The NRC task is to establish a reasonable process and clear safety standards, so that licensees can make timely decisions about whether to seek license renewal.

For nuclear power plant licensees, license renewal can be a two-edged sword. The benefits of gaining 20 years on the existing investment must be weighed against the uncertainties associated with the cost of renewal, based on a consideration of economic, political, regulatory, and environmental factors. Uncertainties may exist associated with future operation and maintenance costs. The timing of major replacements, such as steam generators--or major maintenance operations such as thermal annealing--may be considered.

For our part, the NRC has created the regulatory structure to support license renewal. As you know, the Commission published an amended license renewal rule, 10 CFR Part 54, in May 1995. The amended rule is based on two key principles. First, the current regulatory process, continued into the extended period of operation, is considered adequate to ensure that the current licensing basis provides and will maintain an acceptable level of safety, with the possible exception of detrimental aging effects for certain systems, structures, and components. The second key principle is that the licensing basis for each plant must be maintained during the renewal term. In other words, the foundation of license renewal hinges on the determination that currently operating plants will continue to maintain adequate levels of safety, and that these levels have been sustained over the life of the plant through maintenance of the licensing basis, with appropriate adjustments to address aging effects identified during the review, and to address relevant operating experience.

In support of license renewal efforts, the NRC staff performed a Generic Environmental Impact Statement (GEIS) that reviewed over 90 possible environmental impacts of license renewal. Out of this group, more than 60 issues were ranked as Category 1 and analyzed generically, based on meeting three criteria: (1) the issue was generic in scope to all licensees; (2) the potential impact, whether high, medium, or low, was the same for all licensees; and (3) no sufficiently beneficial mitigation measures existed which licensees had not already taken. For these issues, covered in the GEIS, license renewal applicants need not perform a site-specific analysis, but simply can adopt the analysis given in the GEIS. For the remaining issues, ranked as Category 2, applicants will need to present plant-specific impact analyses in their environmental reports.

One issue that has caused some potential applicants concern relates to the environmental impact of transporting high-level waste (HLW) to the proposed geologic repository at Yucca Mountain. At the time the GEIS was performed, given the uncertain status of Department of Energy (DOE) activities at Yucca Mountain, this issue was made a Category 2, thus requiring plant-specific environmental impact review. In June 1997, the Commission asked the staff to revisit this issue, and to prepare a set of options, both near-term and long-term, for treating environmental impact analyses related to HLW transportation and disposal for license renewal applications. These options should be presented for Commission review later this month.

The current industry approach to license renewal is to submit for NRC approval plant-specific and Owners' Group technical reports on specific topics, prior to submitting

complete license renewal applications. This approach is intended to establish a foundation of technical information that a licensee can use to evaluate the feasibility of a license renewal application, and to reference that information later in the application itself. The NRC is reviewing technical reports prepared by the Baltimore Gas and Electric Company addressing the Calvert Cliffs units, and technical reports prepared by the Duke Power Company addressing the Oconee units. We also are reviewing generic reports prepared by the Babcock & Wilcox Owners' Group on behalf of five operating B&W plants. The Boiling Water Reactor Owners' Group has submitted a technical report for review, and the Westinghouse Owners' Group has submitted reports on several structures and components. This level of activity on the part of industry clearly reflects a serious interest in license renewal.

However, I also have heard some concerns expressed related to the efficiency of NRC license renewal processes, and in particular the possibility of unnecessarily lengthy hearings. As I am sure you are aware, the Commission always has the authority to exercise its inherent supervisory authority over the conduct of adjudicatory proceedings, and has done so in the past, both to provide guidance to the Licensing Board on novel issues and to direct the use of expedited schedules. When the Commission's adjudicatory review process was revamped several years ago to make the Commission the sole appellate body, it gave the Commission greater opportunity and flexibility to exercise oversight of its adjudicatory processes. In addition, we may be able to modify certain internal NRC procedures in a way that would increase the efficiency of reviews, safety evaluations, or other aspects of the license renewal process. I should mention, however, that in an era of fiscal restraint, the level of staff resources applied to this area must remain commensurate with the degree of foreseen activity and the number of initiatives by potential license renewal applicants. We remain confident that we can meet these challenges, and that a clear and stable regulatory process for license renewal will result.

V. Safety and Compliance

My last topic today concerns a recent Commission action to provide guidance to the NRC staff on the relationship between safety and compliance. Historically, this area has been strewn with misconceptions--as evidenced by discussions of the supposed difference between a safety inspection and a compliance inspection, or implications that safety and compliance represent opposing ends of a continuum of how prescriptive the NRC is in its approach to regulatory oversight. Such ideas not only are misconceptions, they also fuel miscommunication, unpredictable regulation, and an unclear concept of the role of the regulator.

I am reminded of a story that may be familiar to some of you, related to me by a member of my staff:

On a dark night at sea, two lights were approaching each other. As they continued to get closer, the captain of a ship sent out a message:

"Recommend you change course." The immediate reply came back:
 "Recommend you change course!"

The captain, being somewhat miffed, signaled again: "This is CAPTAIN Smith. Again, I recommend you change course!" The reply came back just as quickly: "This is SEAMAN Jones; I recommend you change course!"

By this time the captain was reaching the limits of his patience. He ordered an immediate, uncompromising message: "I am on a U.S. battleship. I order you to change course!!" to which the reply came back: "I am on a lighthouse. I recommend you change course."

I know that, for some of you, your first impression of that story likens the NRC to the battleship, ready to roll over the licensee lighthouses in its path. From my perspective, the NRC is more like the lighthouse, reminding licensees, both large and small, of the importance of safe operation. I would like to discuss the relationship between safety and compliance in this context.

As commonly understood, safety means freedom from exposure to danger, or protection from harm. In a practical sense, an activity is deemed to be safe if the perceived risks are judged to be acceptable. The Atomic Energy Act of 1954, as amended, establishes "adequate protection" as the standard of safety on which NRC regulation is based. In the context of NRC regulation, safety means avoiding undue risk or, stated another way, providing reasonable assurance of adequate protection for the public in connection with the use of source, byproduct and special nuclear materials.

The definition of compliance is much simpler. Compliance simply means meeting applicable regulatory requirements.

What is the nexus between compliance and safety?

- ◆ Safety is the fundamental regulatory objective, and compliance with NRC requirements plays a fundamental role in giving the NRC confidence that safety is being maintained. NRC requirements, including technical specifications, other license conditions, orders, and regulations, have been designed to ensure adequate protection--which corresponds to "no undue risk to public health and safety"--through acceptable design, construction, operation, maintenance, modification, and quality assurance measures. In the context of risk-informed regulation, compliance can play a very important role in ensuring that key assumptions used in underlying risk and engineering analyses remain valid.
- ◆ Adequate protection is presumptively assured by compliance with NRC requirements. Circumstances may arise, however, where new information reveals, for example, that an unforeseen hazard exists or that there is a

substantially greater potential for a known hazard to occur. In such situations, the NRC has the statutory authority to require licensee action above and beyond existing regulations to maintain the level of protection necessary to avoid undue risk to public health and safety.

- ◆ The NRC has the authority to exercise discretion to permit continued operations--despite the existence of a noncompliance--where the noncompliance is not significant from a risk perspective and does not, in the particular circumstances, pose an undue risk to public health and safety. When non-compliances occur, the NRC must evaluate the degree of risk posed by that non-compliance to determine if specific immediate action is required. Where needed to ensure adequate protection of public health and safety, the NRC may demand immediate licensee action, up to and including a shutdown. In addition, in determining the appropriate action to be taken, the NRC must evaluate the non-compliance both in terms of its direct safety and regulatory significance and by assessing whether it is part of a pattern of non-compliance (i.e., the degree of pervasiveness) that can lead to the determination that licensee control processes are no longer adequate to ensure protection of the public health and safety. Based on the NRC's evaluation, the appropriate action could include refraining from taking any action, taking specific enforcement action, issuing orders, or providing input to other regulatory actions or assessments, such as increased oversight (e.g., increased inspection).
- ◆ Where requirements exist that the NRC concludes have no safety benefit, the NRC can and should take action, as appropriate, to modify or remove such requirements from the regulations or licenses. Requirements that are duplicative, unnecessary, or unnecessarily burdensome can actually have a negative safety impact. They also can tend to create an inappropriate NRC and licensee focus on "safety versus compliance" debates. As the Commission states in its Principles of Good Regulation, "There should be a clear nexus between regulations and agency goals and objectives, whether explicitly or implicitly stated."
- ◆ Since some requirements are more important to safety than others, the Commission should use a risk-informed approach wherever possible when adding, removing, or modifying NRC regulations, as well as when applying NRC resources to the oversight of licensed activities (this includes enforcement). Based on the accumulation of operating experience and the increasing sophistication of risk analysis, the NRC should continue to refine its regulatory approach in a manner that enhances and reaffirms our fundamental safety objective.

These principles attempt to describe the nexus between compliance and safety. The misperception that compliance and safety are somehow incompatible or unrelated arises when the principles just outlined are not understood or are wrongly applied.

When understood and applied correctly, the result should be a consistent, credible regulatory approach--as applied to licensing, inspection, enforcement, performance assessment processes, and rulemaking.

This guidance to the NRC staff on safety and compliance represents the consensus of Commission opinion, and, as I said earlier, it attempts to dispel the misconceptions that sometimes arise in this area. It has been codified and issued to NRC staff for use in developing inspection, enforcement, and rulemaking guidance. It is publicly available should you wish to distribute it to your facility managers and employees.

To illustrate our seriousness with respect to how elements of this guidance can and will direct what we do, let me discuss a direct final rulemaking change to 10 CFR 70.24, and provide a brief on our activities related to risk-informed regulation.

10 CFR 70.24 concerns criticality accident requirements, including provisions for criticality monitors and related emergency drills. This requirement is an example of an area in which the NRC has issued a high number of exemptions. In fact, nearly 2 out of 3 reactor plants currently have an exemption to one or more of the requirements of §70.24. As you may have heard me say before, I do not believe in "regulating by exemption." Exemptions should be reserved for unusual, highly specific circumstances. When exemptions become the rule, either the rule or the regulator--or both--are at fault.

At the same time, a number of nuclear plant managers, of plants not subject to the exemption, had complained directly to me of "nitpicking" on the part of the NRC staff, with respect to compliance with the rule. These two sides of the situation were and are untenable. I asked the staff, therefore, to examine how we were implementing and enforcing the rule, and, if 2/3 of the plants were being exempted from the rule, why the rule itself should not be changed to correspond to its implementation in reality.

In August 1997, the Commission directed the staff to proceed with a direct final rulemaking on this issue, and to evaluate the agency's enforcement practices related to this rule. A direct final rulemaking differs from the traditional rulemaking process in that the provisions for public comment are reduced significantly. In this approach, the NRC will publish simultaneously, in the Federal Register, the Proposed Rule and the Final Rule. The Proposed Rule provides for a 30-day public comment period; however, if no comments are received, the Final Rule becomes effective 75 days after the publication date. The Commission will only use a direct final rulemaking when it has reason to believe that no adverse comments would be expected on the rulemaking. The obvious benefit of this approach, when it can be used, is that the streamlined rulemaking process significantly improves timeliness. The Commission expects to review and act on the staff's recommendations by the end of next month. As for enforcement, the NRC staff issued an Enforcement Guidance Memorandum last month to withdraw previously issued violations for power reactor non-compliance with this rule.

Finally, in the area of risk-informed regulation, many of you are aware that we have been conducting a series of pilot applications with the nuclear power industry in the areas of Technical Specifications (TSs), Graded Quality Assurance (QA), In-Service Inspection, and In-Service Testing, using the draft PRA Standard Review Plans and draft PRA Regulatory Guides published earlier this year. The NRC staff has received applications in each of these four topical areas, and we are well into the process of reviewing and issuing the associated Safety Evaluation Reports. As one example, the staff has been working with the Combustion Engineering Owners Group (CEOG) on a joint application that would modify existing CE TSs to allow a degree of risk-informed operating flexibility. This TS change would allow licensees to employ a Configuration Risk Management Program to make decisions on whether or not to enter an extended Allowed Outage Time on specific plant structures, systems, and components, based on incorporating probabilistic risk assessment (PRA) insights into the analysis of the existing or intended plant configuration. A similar TS change was issued for the South Texas plant last year. In May, the Commission reviewed this program and did not object to the issuance of safety evaluations using this rationale. This program is illustrative of the types of enhancements that are being achieved through risk-informed regulation.

VII. Conclusion

In closing, I hope that I have succeeded today in giving you a sense of where I believe we--the NRC and the nuclear industry--are headed, in terms of the challenges and issues presented. In the areas of reactor-related assessment processes and regulatory oversight of licensee design basis issues, I believe that the NRC has plotted a course that will improve regulatory effectiveness and that is directed toward achieving regulatory stability. I also believe that the NRC has created effective, reliable processes that will ensure effectiveness and efficiency in reviewing any license renewal applications that are submitted. I reiterate the Commission's conviction of the complementary relationship between safety and compliance, and I encourage you once again to review the recent Commission guidance in this area. I fully expect that INPO will continue to be a leader and an ally in monitoring and maintaining a high standard of licensee performance. Thank you for your attention.