



UNITED STATES  
NUCLEAR REGULATORY COMMISSION  
WASHINGTON, D.C. 20555-0001

January 24, 1996

Mr. C. Randy Hutchinson  
Vice President, Operations GGNS  
Entergy Operations, Inc.  
Post Office Box 756  
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SUBJECT: GRADED QUALITY ASSURANCE INITIATIVE

Dear Mr. Hutchinson:

The staff and industry have been interacting on the Graded Quality Assurance (QA) initiative for almost 2 years. The staff's primary objective was, and continues to be, to develop and document NRC guidelines for a graded QA program. During previous interactions with the staff, you volunteered to work with us as graded QA programs were developed at Grand Gulf. The initial interactions with the Nuclear Energy Institute (NEI) and subsequent interactions with the volunteer utilities have been valuable to the NRC staff in our attempts to develop regulatory positions and insights into the practical applications of graded QA. It has become apparent, however, that additional structure and planning on our part is necessary to successfully meet our objectives. The NRC staff recently prepared an action plan that established important activities and schedules related to the graded QA initiative. This is, therefore, an opportune time to revisit the processes related to the staff's review of graded QA programs and our interactions with licensees for the purpose of developing regulatory guidance.

The primary objectives of NRC efforts related to the graded QA initiative are to:

1. Provide a safety benefit by allowing licensees and NRC to preferentially allocate resources to higher safety significant items and provide cost savings by reducing the resources expended on lesser safety significant items.
2. Gain lessons learned from volunteer utilities and prepare internal staff guidance and regulatory guidance for wider industry implementation.

To facilitate meeting these objectives, we envision the following process:

1. The NRC staff issues NRR Draft Evaluation Guide for the Development of Graded Quality Assurance Programs (enclosed).

2. Licensees submit program changes, if required by 10 CFR 50.54(a), and NRC staff issues plant-specific responses.
3. NRC staff and volunteer licensees conduct pilot interactions.
4. NRC staff documents lessons learned (Graded QA Pilot Applications Lessons Learned Report).
5. NRC develops draft regulatory guidance (e.g., Regulatory Guide, Inspection Procedure).
6. NRC issues regulatory guidance (close-out of NRR Action Plan).
7. NRC staff and industry gain additional insights through use of the regulatory guidance and through follow-on site visits and reviews. Regulatory guidance revised, as necessary, based on additional experiences and planned evaluation of regulatory guidance effectiveness.

The four essential elements of a graded QA program, previously included in correspondence to NEI and individual licensees, are expected to remain the cornerstone of our regulatory positions and future guidance. These essential elements are:

1. A process that identifies the appropriate safety significance of structures, systems, and components (SSCs) in a reasonable and consistent manner.
2. The implementation of appropriate QA controls for SSCs, or groups of SSCs, based on safety function and safety significance.
3. An effective root cause analysis and corrective action program.
4. A means for reassessing SSC safety significance and QA controls when new information becomes available.

In recognition of the programs being implemented at Grand Gulf, as well as the grading of quality assurance controls being initiated, proposed, or implemented at other utilities, the staff has developed the enclosed draft guidance to clarify our expectations regarding graded QA programs. Although this guidance is generally consistent with our comments on the draft NEI guidance document (January 31, 1995, letter to NEI), several aspects have been revised or clarified as a result of insights gained during the last several months. For the first essential element, determination of risk significance, the staff will confirm that the process is scrutable, repeatable, and provides reasonable results related to the categorization of SSCs based on safety significance. For the second essential element, establishing quality

assurance controls, the staff expects that QA requirements for low-safety-significant safety-related SSCs will continue to satisfy the applicable criteria of Appendix B. It is recognized, however, that the inherent flexibility of the regulations will be utilized and that deviations from past commitments, industry standards, and regulatory guides will be part of graded QA programs. To ensure that a program adequately addresses the third element, corrective actions, the ability to identify and address degraded equipment performance resulting from application of graded QA controls should be apparent. To address the fourth element, operational feedback, existing or modified licensee programs should evaluate additional information as it becomes available (e.g., plant modifications or changes in operating procedures and practices such as rolling on-line maintenance schedules, system/component reliability data, identification of new risk vulnerabilities) and assess its potential implications in regard to the graded QA program. This initial guidance, combined with lessons learned from the pilot plants and early follow-on plants, is expected to form the basis for the staff's final review guidance (e.g., Regulatory Guide and inspection procedures).

In order to support the NRC and industry desires to prepare generic guidance related to graded QA, the staff wishes to continue our interactions with personnel at Grand Gulf. In regard to our current interactions with your personnel, it would be beneficial to clarify the areas in which you would like to interact with the staff (all or selected elements of your graded QA program) and reach an agreement on the nature, extent, and schedule for the interactions and information to be exchanged. For those areas that you choose to voluntarily interact with us in support of our preparation of generic guidance, we believe that selected sets of information need to be shared with, and evaluated by the NRC staff.

For example, in order to gain insights into the placement of SSCs into safety significance categories, the staff needs information to assess the impact of the following issues on the process:

- Scope of the PRA Analysis
- Level of Detail
- Use of Risk Metrics
- PRA Quality
- Process for Assuring PRA Quality
- Role of Expert Panel and its decision criteria
- Deterministic Considerations
- Integration of PRA Insights with Deterministic Considerations

Licensees would provide information such as: detailed descriptions of the PRA model; sensitivity studies regarding the impact of operating practices such as rolling on-line maintenance schedules and plant configurations, failures of combinations of SSCs, and choice of importance measures used in safety significance classifications; expert panel charter and procedures; interviews with expert panel members; and final documentation regarding the classification of SSCs into safety significance categories.

In order to understand the actual grading of QA controls, the staff would likely request information regarding the delineation of the QA controls for the various safety significance categories. Requested documentation would include procedures for implementing reduced QA controls and actual work packages related to activities performed for SSCs in different safety significance categories. Interviews with plant personnel performing the affected activities would be performed. Particular attention would be given to the area of grading controls related to commercial grade dedication activities.

Information related to the third and fourth essential elements, corrective actions and operational feedback, would include procedures and programs related to proposed corrective action processes, performance monitoring, plant and industry operational experience reviews, and related mechanisms for reconsideration of safety significance categorizations or QA controls.

During the course of these interactions with Grand Gulf personnel, the staff would evaluate aspects of your program in order to determine that pertinent regulatory expectations are satisfied. The criteria to be used for this determination are discussed above and in the enclosed draft staff evaluation guidance document. However, the staff may identify issues or raise questions that go beyond these criteria. If such matters are identified, we would communicate them to you during meetings and as part of our routine trip reports or meeting summaries. Periodic status review meetings between NRC and licensee management could also be used to help resolve issues identified during the pilot interactions.

The staff's plans following the preparation of final staff guidance and regulatory guidance for wider industry implementation will include:

1. Evaluation of other graded QA programs (non-volunteers) using the general guidance described above to determine that reasonable safety significance classifications and QA controls have been established.
2. Development of a reactive inspection procedure for instances where graded QA practices may have contributed to operational problems warranting NRC follow-up.
3. Revision of staff guidance and regulatory guidance, as necessary, based on additional experiences and planned evaluation of regulatory guidance effectiveness.

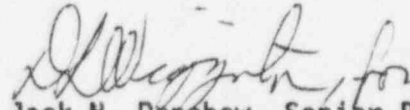
We acknowledge your support and cooperation to date during your interactions with the staff in the developmental phases of the graded QA effort.

Mr. C. Randy Hutchinson

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We would appreciate your comments on the conceptual framework for our continued interaction in the volunteer implementation phase of graded QA. The NRC remains committed to devoting the necessary level of resources to support these interactions and we are more than willing to meet with you to discuss your reaction and thoughts on our proposal.

Sincerely,



Jack N. Donohew, Senior Project Manager  
Project Directorate IV-1  
Division of Reactor Projects III/IV  
Office of Nuclear Reactor Regulation

Docket No. 50-416

Enclosure: Draft Staff Evaluation Guide

cc w/encl: See next page

Mr. C. Randy Hutchinson

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ORIGINAL SIGNED BY: D. Wigginton for

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Office of Nuclear Reactor Regulation

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cc w/encl: See next page

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