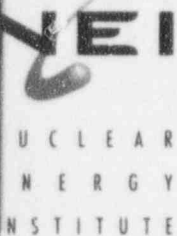


**NEI 96-02 (ORIGINAL)
GUIDELINE FOR IMPLEMENTING A
GRADED APPROACH TO QUALITY**



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NUCLEAR ENERGY INSTITUTE

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GUIDELINE DOCUMENT PROCESS

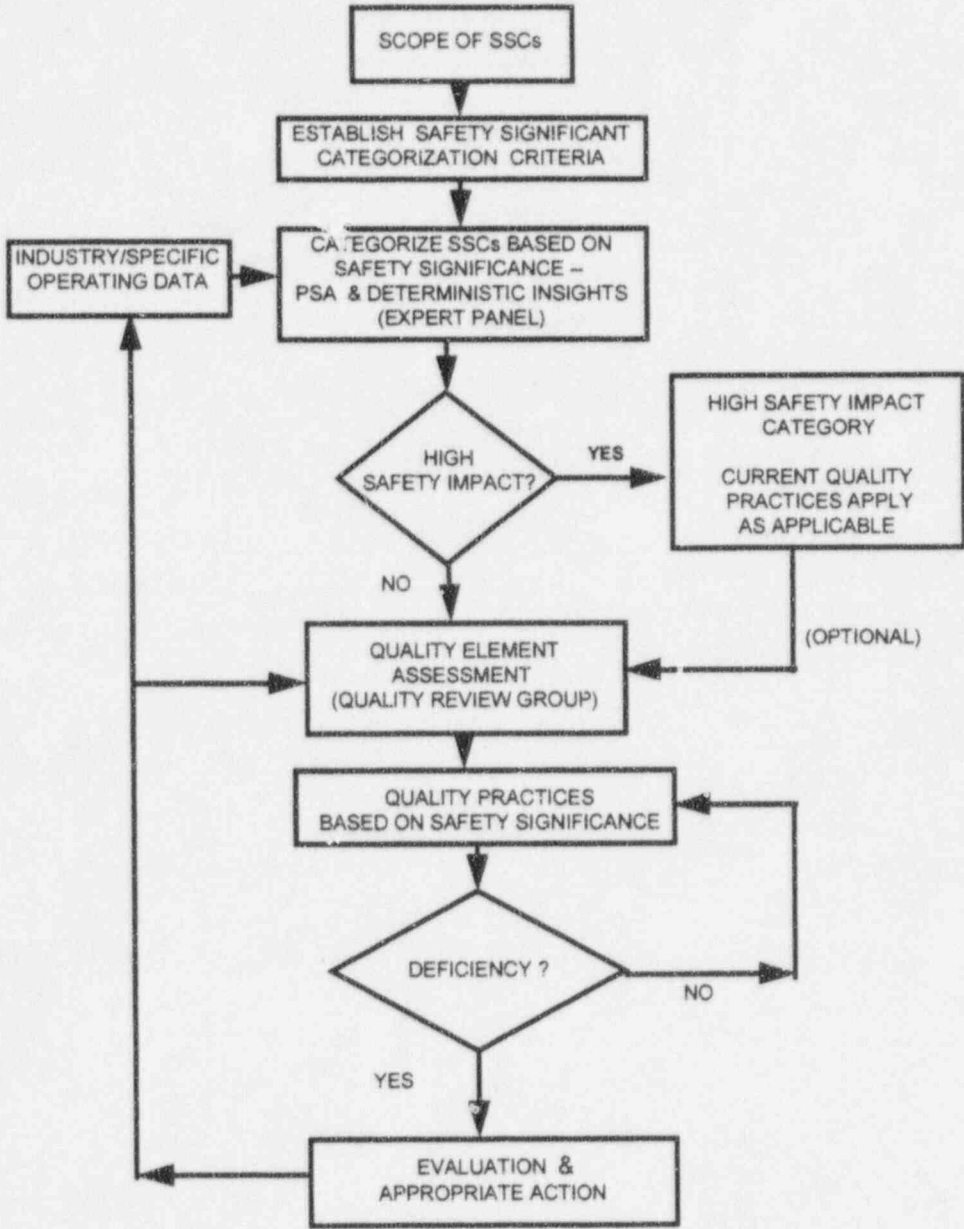


FIGURE 1

EXECUTIVE SUMMARY

This guideline provides the general framework for implementing a graded approach to quality. It is envisioned that companies will base their decision to adopt or enhance their current methods for implementing quality on cost benefit considerations and the additional safety benefits of such activities.

The fundamental regulatory purpose for a graded quality assurance program remains the same; to provide reasonable assurance that the safety functions will be fulfilled. The current regulations permit a graded approach to quality. However, licensees often limit their actions on improving their quality assurance programs because of overly conservative interpretations of statements in their quality program descriptions, or conservative interpretations on what constitutes a reduction in commitment from a regulatory perspective. As a result, licensees sometimes defer potential quality program changes because of the administrative burden associated with processing a change that requires NRC review and approval prior to implementation.

The guideline recommends the use of probabilistic and deterministic insights and analyses to categorize structures, systems and components (SSCs) following a review by an expert panel. Such insights and categorization form the basis for the implementation of graded quality assurance activities. The methodology for categorizing SSCs builds on the processes for implementing the maintenance rule in using probabilistic safety assessment (PSA) insights. As such, this document should be read in conjunction with NUMARC 93-01, Rev. 1, *Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants* (ref. 2), NUMARC 93-02, *A Report on the Verification and Validation of NUMARC 93-01, (Original)*, *Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants* (ref. 3), and the industry's *PSA Applications Guide, EPRI TR-105396, dated August 1995* (ref. 8).

The methodology for the categorization of SSCs described in this document involves assessments and evaluations of safety functional failures, and deviations in the pertinent work functions that could impact a safety function. It is broader than that used in the maintenance rule. It involves the assessment of the pertinent failures, not just those associated with a maintenance preventable failure. It includes, when applicable, an assessment of the potential impact of such aspects as, different plant operating modes, human factors, seismic, fire, and design considerations, including environmental qualification (EQ) that could impact the pertinent safety functions.

The implementation of a graded approach to quality will enable licensees to better identify and focus on those SSCs and activities that are of safety significance. It will improve the implementation of quality processes and practices, improve the effectiveness in implementing the regulations, and could ultimately enhance the protection of public health and safety.

This guideline should not result in the development of an alternative quality assurance program. The intent is to refine and optimize current quality implementation practices, building on industry experiences, and taking advantage of improved technologies and advances in analytical techniques.

The guidance includes the following steps:

- The categorization of SSCs (safety-related and nonsafety-related) based on safety significance, building on the concepts and practices established in implementing the maintenance rule and in developing the Individual Plant Examinations (IPE). This approach involves combining probabilistic safety assessment (PSA) and deterministic evaluations (including a review by an expert panel) to categorize and determine the relative importance to safety of SSCs.
- The grading of applicable quality criteria for SSCs to an extent commensurate with safety significance. A group of technically knowledgeable individuals, i.e., a review group determines or reviews the appropriate application of quality elements (criteria), as well as the depth of implementation.
- The determination of the applicability and need to change the quality program description included or referenced in a licensee's Final Safety Analysis Report (FSAR), and the action to be taken to process the change per the requirements of 10 CFR 50.54(a).

It is anticipated that each licensee will develop additional detailed implementation procedures building on the guidance contained in this document.

Appendix A provides a list of definitions, terms and acronyms to clarify and assist in understanding the concepts and guidance given in this document.

Appendix B provides copies of NRC-NEI correspondence from 1994/5 associated with implementing a graded, performance-based approach to quality. Also included is the NEI disposition of specific comments and suggestions made by the NRC staff on implementing a graded, performance-based approach to quality.

1. INTRODUCTION

The originators of 10 CFR 50, Appendix B, drafted the regulation in a manner that permitted flexibility in its implementation. Further, as stated in the NRC Regulatory Review Group Report (ref. 1), and confirmed in the industry/NRC management interactions, the language in the regulations allows for the quality program to be implemented to an extent that is consistent with the importance to safety (a graded implementation).

Currently, a licensee is permitted to grade its quality elements without prior NRC approval providing the regulatory commitments described in its quality program description included or referenced in its Final Safety Analysis Report (FSAR) are not reduced. Changes to the quality program included or referenced in the FSAR are processed in accordance with the requirements of 10 CFR 50.54(a). The requirements of 10 CFR 50, Appendix B are implemented in a manner that provides reasonable assurance that the safety functions will be performed.

Some licensees have already implemented a graded approach for their quality practices and controls. This guideline describes an option, permitted by the existing regulations, of using PSA insights to assist licensee management in determining whether further grading activities and improvements can be justified and made to existing quality practices. The decisions to implement more extensive grading of quality practices, the extent of such activities, and the time frame of implementation, are based on cost benefit determinations. Naturally, the revised quality practices must continue to provide reasonable assurance that the pertinent safety functions will be satisfactorily performed.

It is not necessary for licensees to establish a rigid schedule for implementing a graded approach to quality unless the cost benefit assessments indicate significant savings from such an exercise. Licensees may wish to implement a graded approach, or enhance their existing graded program on an opportunity basis, as circumstances dictate. For example, cost benefit considerations might suggest that a licensee should immediately grade its design change process. However, additional grading for procurement of spare parts might be performed as the need arises, dependent on the status of warehouse inventory.

The implementation of a graded approach to quality enables licensees to focus their finite resources on the more safety-significant issues and concerns. At present, equal priority is often apportioned to issues irrespective of their true safety significance, increasing the potential for not resolving a significant safety issue in a time frame commensurate with its safety significance. Improved analytical and assessment techniques provide licensees with insights that enable a more efficient application of graded quality assurance. Such a restructured program improves the

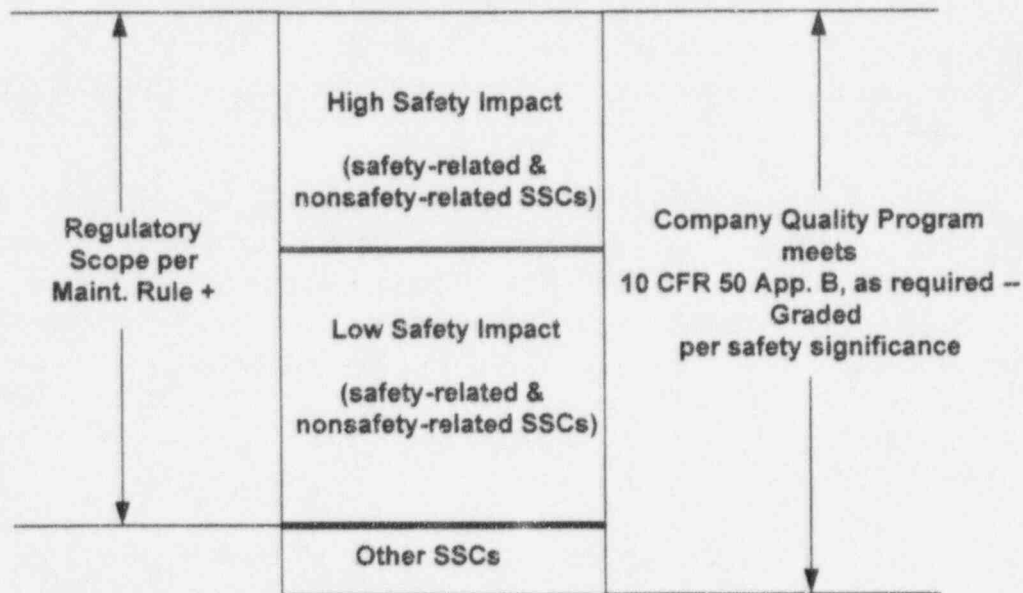
effectiveness of implementing NRC regulations and could ultimately enhance the protection of public health and safety.

Traditionally, SSCs have been categorized into a number of lists, such as nonsafety-related, Q-lists, and augmented quality. In some cases, because of ease of implementation or specific regulatory commitments, the requirements of Appendix B, as defined in the numerous regulatory guides, have been applied to SSCs.

Today, with over twenty five years of operating experience, with new technologies, and improvements in analytical techniques (such as PSAs), supplemental analyses can be performed to provide further insights into identifying and categorizing SSCs based on their safety significance. The application of such techniques to categorize a facility's list of SSCs can then become a basis for a graded approach to implementing quality. Those SSCs identified as having high safety significance are categorized in a group labeled 'high safety impact'.

Figure 1-1 provides a graphical description of the methodology and guidance given in this document.

GRADED APPROACH TO IMPLEMENTING QUALITY



+Reg. Scope = Maint. Rule Scope + Other SSCs from Other Regs.

Figure 1-1

Many companies have a general, very broad company quality program for implementing and controlling work activities. The driving force for such programs is associated with safety and cost effective plant operation in a competitive

electrical generating environment. The elements of a company's quality program that meet 10 CFR 50, Appendix B requirements are a subset of the overall company quality program.

The general methodology for grading quality practices described in this document is based, in part, on two recent industry activities: the IPE project, defined by NRC Generic Letter 88-20, and the implementation of the maintenance rule (10 CFR 50.65) through the industry guidance document NUMARC 93-01, Rev. 1, which has been endorsed by NRC Regulatory Guide 1.160 (ref. 4). However, the methodology for categorizing SSCs for graded QA is broader and includes, when applicable, an assessment of the potential impact of such aspects as, different plant operating modes, human factors, seismic and fire considerations.

Within the scope of this document, SSCs are ranked based on their safety significance and are divided into two main categories: (1) high safety impact and (2) low safety impact. (There is an additional category that is not within the regulatory scope, is not part of the scope of this document, yet is subject to quality practices, as determined by licensee management). The two main groups are a blend of the current regulatory classifications; safety-related and nonsafety-related SSCs. Quality elements (criteria) are applied in a manner and to an extent commensurate with safety significance, as permitted by the regulations.

NOTE: Licensees may wish to grade into more than two major categories. The benefits of grading into more than two major categories must be addressed against the cost and additional complexity of establishing and managing a larger number of categories.

Each licensee should develop its own graded quality implementation plan and associated implementation procedures. Such plans and procedures may vary from licensee to licensee dependent on cost benefit determinations and current licensee quality practices, as described in a licensee's quality assurance program description included or referenced in its FSAR.

A licensee may determine that there is no overall benefit to grading quality requirements for SSCs in one particular segment, e.g. security, or fire protection. In which case, the licensee would not change the quality practices in that area until the benefit of a graded approach is identified.

It should be recognized that individual licensee business plans may place additional emphasis on specific quality elements for SSCs because of their importance (economic or operational aspects). The necessity for the additional emphasis on quality in this area is outside the scope of this document and is based on management, not safety, considerations.

2. PURPOSE

This guidance provides an approach for implementing graded quality measures and is intended for the voluntary use of nuclear power plant licensees. It does not preclude the use of other approaches for implementing a graded approach to quality. This document provides an approach for implementing a graded quality program that meets the quality criteria described in 10 CFR 50, Appendix E, and includes:

- Using PSA and deterministic insights, consistent with NUMARC 93-01, Rev. 1, and the industry's *PSA Applications Guide*, to restructure a Q-list based on safety significance; and
- Applying appropriate quality elements, including Appendix B criteria, to a restructured Q-list in a graded manner.

The development of the methodology to categorize SSCs based on safety significance may facilitate the transition to a performance-based regulatory regime at a later date. Such a performance-based regulatory regime would be similar to the concepts and philosophies established in the NRC's maintenance and training regulations.

3. RESTRUCTURING THE Q-LIST

This section provides guidance for a process to refine a licensee's current Q-list. It begins with the SSCs that are within the general scope of the NRC's regulations and ends with a list of SSCs that are categorized by their safety significance. The restructured Q-list will have at least two categories; high safety impact and low safety impact. In addition, optional guidance is provided on refining the scope of SSCs that reside in the two categories, should a licensee determine that additional categorization and grading are beneficial.

3.1 Defining the Scope of SSCs

The SSCs defined by the Maintenance Rule, 10 CFR 50.65, and SSCs encompassed by other NRC regulations and licensing commitments provide the scope and the starting point for determining which plant SSCs will reside on the restructured Q-list. The initial scope includes safety-related and nonsafety-related SSCs. A licensee may modify the scope based on the extent of graded quality practices that have already been implemented and cost benefit determinations.

The Maintenance Rule, 10 CFR 50.65, defines the scope of SSCs in the following manner:

1. *Safety-related SSCs that are relied upon to remain functional during and following design basis events to ensure the integrity of the reactor coolant pressure boundary, the capability to shut down the reactor and maintain it in a safe shutdown condition, and the capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposure comparable to the 10 CFR Part 100 guidelines.*
2. *Nonsafety-related SSCs:*
 - *That are relied upon to mitigate accidents or transients or are used in plant emergency operating procedures (EOPs);*
 - *Whose failure could prevent safety-related SSCs from fulfilling their safety-related function; or*
 - *Whose failure could cause a reactor scram or actuation of a safety-related system.*

Additional clarification on the scope of the maintenance rule is provided in NUMARC 93-01, Rev. 1. The scope for quality assurance may be larger than the maintenance rule and encompass plant SSCs that are governed by NRC regulations but are exempt from maintenance rule considerations.

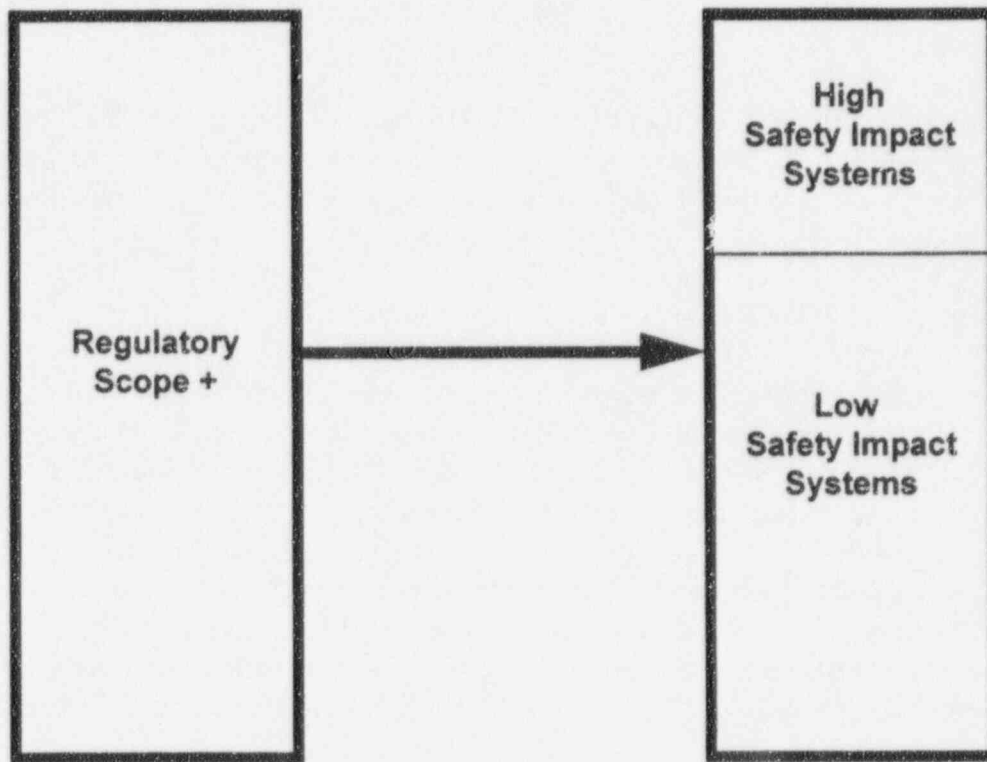
3.2 Establishing the Safety Significance of SSCs

The methodology for categorizing SSCs based on safety significance is based on that developed for implementing the Maintenance Rule, 10 CFR 50.65, and described in NUMARC 93-01, Rev. 1. Section 9.3.1 of NUMARC 93-01, *Establishing Risk Criteria*, provides guidance on establishing the safety significance of SSCs. The guidance involves a blend of both probabilistic and deterministic methods to appropriately identify the safety significance of SSCs. This approach is intended to capitalize on the insights gained from plant-specific PSAs, the operating experience and expertise of plant personnel, and a review of the system safety functions and specific aspects that might not have been modeled in the IPE or in additional PSA evaluations.

As in the implementation of NUMARC 93-01, Rev. 1, a licensee would first establish the criteria for categorizing SSCs based on safety significance. Section 9.3 of NUMARC 93-01, Rev. 1, provides guidance on establishing such criteria based on IPEs, plant-specific PSAs, critical safety functions (e.g., vessel inventory control), system performance reviews, or other documented processes. In regard to the use of

PSA, importance measures¹ can be used to provide quantitative insights into the categorization of SSCs based on safety significance. An expert panel assesses the impact of failure modes that may not be modeled in a licensee's PSA evaluations, e.g., EQ, fire, seismic, different plant operating modes, and unique human factor considerations. Section 3.4 provides additional guidance on the use of the expert panel.

NOTE: There is one important difference regarding the guidance provided in NUMARC 93-01, Rev. 1, to establish the safety significance of SSCs. Appropriately, the guidance in NUMARC 93-01, Rev. 1, only considers the impact of failures that are maintenance related. In regard to an assessment of the effectiveness of quality, maintenance is one of many functions in a quality program. Thus, in using PSA importance measures to gain insights into the safety significance of SSCs from a quality perspective, the pertinent failure modes associated with quality, whether they are maintenance related or not, are considered.



+Regulatory Scope = Maintenance Rule Scope + SSCs from Other NRC Regulations

Figure 3-1

¹ As described in NUMARC 93-01, Rev. 1, risk reduction worth, risk achievement worth, and core damage frequency contribution.

The methods described to identify the safety significance of SSCs using PSA importance measures were employed by several utilities during the development of NUMARC 93-01 and its associated verification and validation report. The results of those efforts were published in NUMARC 93-02. The licensees generally identified the safety significance of SSCs at the system level. In addition, nine NRC maintenance rule inspection module pilot reviews confirmed that licensees had, in general, correctly categorized the safety significance of SSCs. This step serves as the first step. Figure 3-1 illustrates the concepts discussed thus far in this section.

3.3 Initial Categorization at the Component Level

The next step involves a component level categorization. This section discusses the initial breakdown of the systems into two main categories on the restructured Q-list, high safety impact and low safety impact.

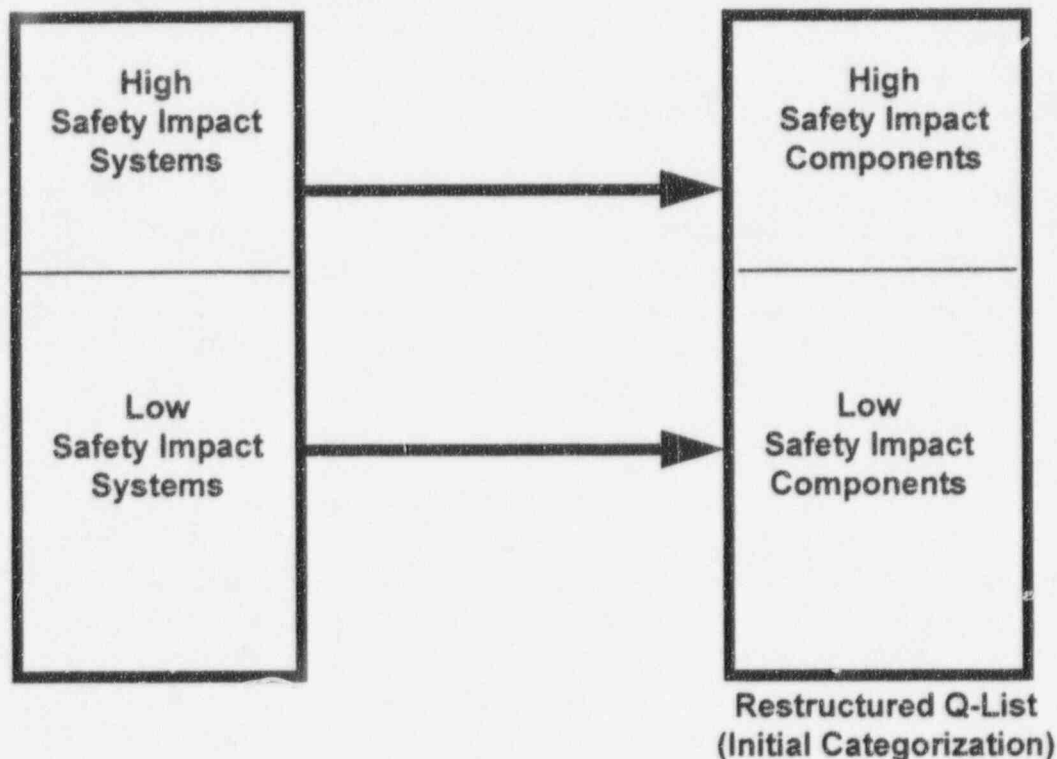


FIGURE 3-2

Components in systems identified as high safety impact should be initially categorized as high safety impact components. If the system is not categorized as

high safety impact, then no components in that system would be placed in the high safety impact category. Figure 3-2 illustrates this concept. One could use this categorization as the foundation for implementing graded quality practices. However, within a system categorized as high safety impact, there may be several components that are not necessary to support the system safety function. The next section addresses this topic, i.e., components that are not necessary to support a safety function should not be placed in the high safety impact category.

3.4 Reviewing the Scope of Components for Categorization as High Safety Impact

This section provides optional guidance that further refines the scope of the components that reside in the two categories. Up to this point, components have been categorized based upon the safety functions and safety significance of the system of which they are a part. The review at this step is intended to provide greater focus on truly safety-significant components by determining the component's contribution to the system's safety function.

There are a number of acceptable methods to determine a component's contribution to its system's safety function. In general, these methods consist of deterministic, or a blend of probabilistic and deterministic approaches to evaluate component safety significance. In either case, a final review by an expert panel, or organizational entity within the utility is performed.

As provided by the industry's *PSA Applications Guide*, a panel of individuals experienced with the pertinent aspects of managing and operating a nuclear generating facility, e.g., operations, maintenance, design, engineering (PSA) etc., should be employed to enhance and assess the categorization of SSCs based on probabilistic results. This expert panel addresses the limitations of the PSA and areas not modeled in the PSA, yet are associated with establishing the safety significance of SSCs.

Licensee management determines the specific composition and level of operational and technical expertise for the panel members from the pertinent disciplines associated with the facility. Licensees may wish to use the same expert panel for this activity as used in the maintenance rule implementation. The expert panel can make the determination as to the categorization, or can function in an oversight and review role. Additional information and guidance is contained in NUREG/CR 5424, *Eliciting and Analyzing Expert Judgment* (ref. 5); NUREG/CR 4962, *Methods for Elicitation and Use of Expert Opinion in Risk Assessment* (ref. 6); NUREG/CR 5695, *A Process for Risk Focused Maintenance* (ref. 7), in NUMARC 93-01, Rev. 1, and NUMARC 93-02.

For a deterministic approach, the identification of the system safety function can be made through a review of documents such as system descriptions, design basis documents, or operating experiences (plant specific or industrywide). The role of a component in supporting the system's safety function could then be determined or reviewed by the expert panel. The expert panel performs an assessment of the ability of a system or structure to achieve its safety function in all operating modes, following specific component failures, including those associated with EQ, fire, seismic, and unique and specific human factor considerations.

The deterministic approach can be enhanced using PSA insights gained from the IPE project, as well as other industrywide operating experiences. The degree of enhancement and influence accorded to the PSA analysis is proportional to the scope and quality of the modeling analyses. Additional guidance on the use of PSA is provided in the industry's *PSA Applications Guide*.

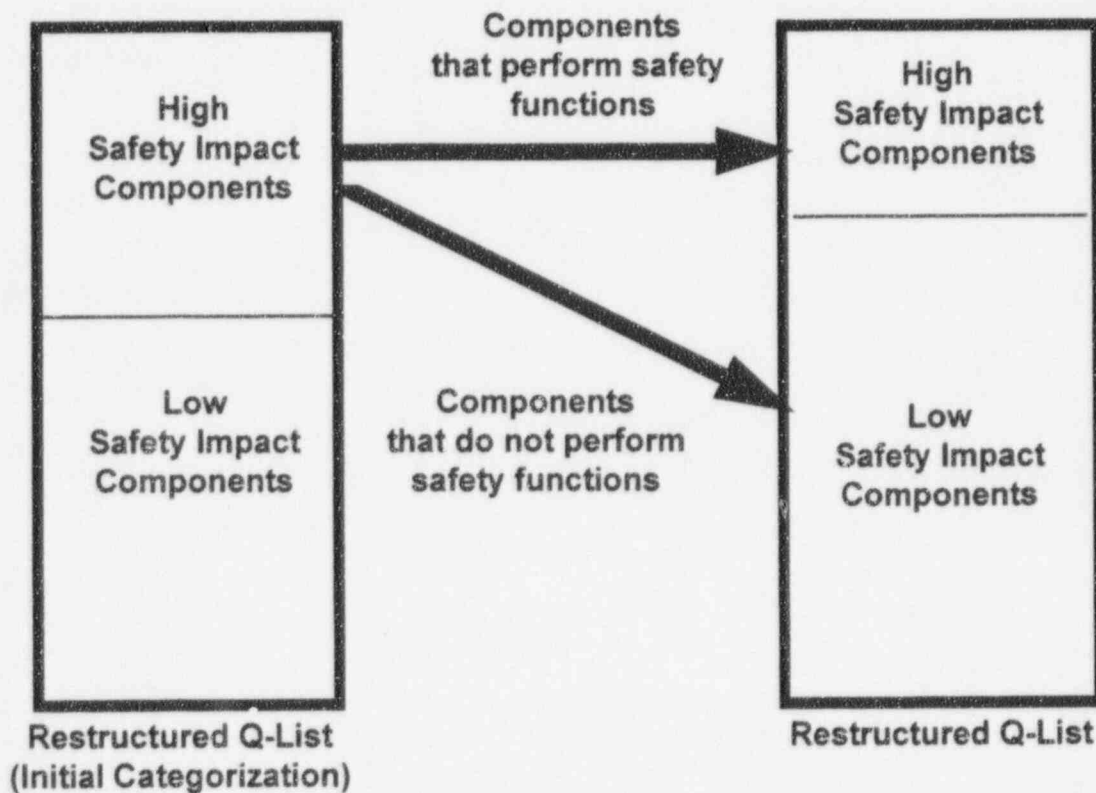


FIGURE 3-3

If the predominant analyses used in the categorization of components is PSA, a licensee still performs a final review by the expert panel. Those components which have been modeled in the IPE, or in the additional assessments associated with the IPE, are reviewed by the expert panel as a final assessment of the sensitivities that could impact the risk significant categorization. A component whose failure has low

or negligible risk, as determined by PSA importance measures with a review by an expert panel, is not included in the high safety impact category.

By employing deterministic, or a blend of deterministic and probabilistic approaches to identify those components that are relied upon to carry out the system safety function, greater emphasis can be applied to those components (categorized as high safety impact) and their associated activities. Figure 3-3 illustrates this concept.

It is recognized that after reaching this step of the categorization, the two groups discussed in this section may contain a mixture of safety-related and nonsafety-related components.

3.5 Additional Categorization of Components Categorized as High Safety Impact

This section provides optional guidance on further subdividing the high safety impact category into additional categories. It is emphasized that a decision to

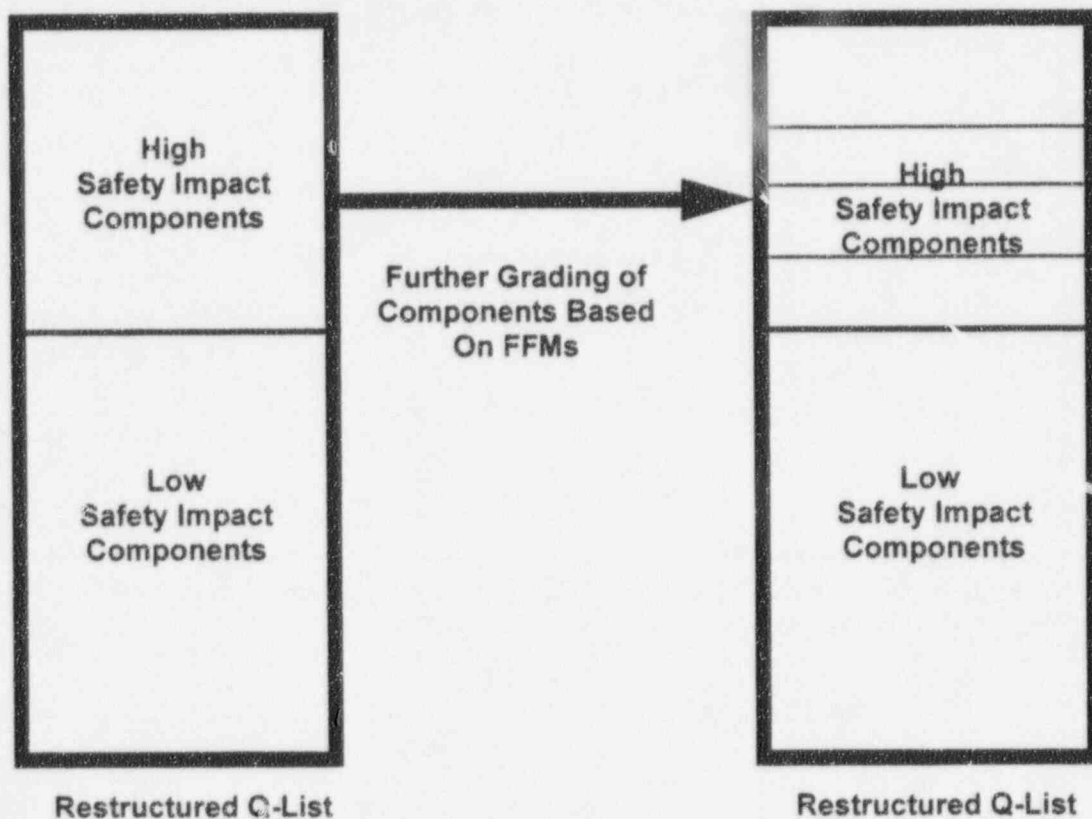


FIGURE 3-4

proceed with implementation of this optional guidance should be based on cost benefit determinations. The decision should be based on whether the savings from implementing a graded approach over the life of the facility outweigh the cost of further categorizing the SSCs plus the cost of managing additional categories of SSCs.

The additional categorization is primarily based on identifying the safety functional failure modes (FFMs) of the applicable trains, sub-systems or components residing in the high safety impact category. This approach would require additional use of the plant-specific PSA and deterministic evaluations to identify and categorize the high safety impact failure mode(s) of the components, sub-systems, or trains. Appropriate quality elements are applied to address the particular failure mode of that category of components. Figure 3-4 illustrates this concept.

4. APPLYING GRADED QUALITY ELEMENTS

The degree and schedule for implementing this section of the guideline is dependent on cost benefit determinations, and the degree to which graded quality activities have already been implemented. The objective is to improve the implementation of quality practices in a manner that improves productivity, reduces costs, yet maintains safety by continuing to provide reasonable assurance that the safety functions will be performed.

The application of graded quality elements (criteria) results in a number of adjustments to current quality processes that are applied to SSCs and their associated activities. For safety-related SSCs, the quality elements and the details of their implementation must meet the requirements described in the language of 10 CFR 50, Appendix B, consistent with safety significance. However, the elements and the details of their implementation do not have to comply with the applicable regulatory guides and associated industry standards.

It should be noted that because of commercial operational considerations, a licensee may impose additional controls above those required for providing reasonable assurance that the safety function will be fulfilled. The selection and application of these commercial operational controls and practices is outside the scope of this document.

4.1 Quality Commitments

Changes to the quality program description, included or referenced in the FSAR are implemented through the 10 CFR 50.54(a) process. In this process, the focus should be whether there is any reduction in commitment with respect to safety.

4.2 Quality Element Assessment

The specific details for adjusting a licensee's existing quality elements, including the extent of refinements to the implementation procedures, practices, and instructions are determined by each licensee. A quality review group, or organizational entity responsible for quality element assignment, conducts a review of any new or revised quality elements.

Each licensee determines whether to use a quality review group, or organizational entity to develop and grade the quality elements and their implementation practices, or only review the final quality element determination. The decision will be based on each licensee's specific business practices and organization, current work practices, and cost benefit considerations. Some licensees may decide that its quality review group makes the determination, with the group interactions replacing the need for a formal review. In some instances, the quality review group could be the same as the expert panel described in Section 3, but the task associated with the assessment, determination and adjustment of quality elements might be undertaken in a different time frame from that of categorizing SSCs.

The group or entity conducting the review consists of technically knowledgeable, multi-disciplined licensee personnel, who determine, or review the applicability and depth of implementation of the appropriate quality elements. Licensee management determines the level and operational expertise of the group or entity from the pertinent disciplines including design, operations, PSA, and assessment (quality) functions. The guidance in this document related to the quality review group can be supplemented by the information in NUREG/CR 5424, *Eliciting and Analyzing Expert Judgment* and NUREG/CR 5695, *A Process for Risk Focused Maintenance*.

The review group should consider a number of factors when developing quality elements or assessing the need to adjust the programs, controls, procedures or instructions associated with SSCs, the functional activity, or the quality element under review. Some of the factors are described below (not in order of priority) and include:

- Existing nonsafety-related and safety-related work practices and instructions
- Support of safety functions, including impact on safety functions
- Industry and plant specific performance history (equipment performance)
- Design specifications and conditions, including EQ, fire and seismic

- Training, professional development and certification programs
- Experience and expertise of the work force (contractors, consultants and licensee personnel)
- Public health and safety implications
- Testing and evaluation options, e.g., final acceptance test versus a series of tests
- Different operating modes, e.g., shutdown, low power operation

The quality review group determines or reviews the applicability of specific elements that provide reasonable assurance the safety function will be fulfilled. The basis for new and revised quality elements is documented. Current documentation associated with licensee programs that include design basis, industry and plant specific operating experience, operating requirements and procurement records should be sufficient basis for any new or revised quality elements, and for supporting the performance of cause determinations, should a deficiency occur. Additional supporting documentation should not have to be developed unless specifically determined to be necessary by the quality review panel.

A licensee may wish to have one program for the SSCs categorized as high safety impact and a separate program for low safety impact SSCs. The number of independent programs, the degree of grading, and the specifics of each program is determined by each licensee by balancing the cost of implementation and management of numerous categories against the economic gain.

It should be noted that similar components might be included in more than one category because of the varying safety significance of their pertinent system, train or sub-system. Currently, many licensees have established management control practices for identifying components in other structures or systems that are the same as a defective or failed component. However, with the implementation of a new and improved safety significant categorization of SSCs through the activities described in this document, licensees should review these practices to ensure that their measures encompass the identification of equipment and material that have the same model/identification number or initial quality specifications, yet are now in different safety significant categories. Such activities should enable licensees to identify and assess whether a failure of a low safety impact SSC has implications for SSCs that are categorized as high safety impact.

Depending on the scope, quality, and level of detail in a licensee's PSA, a licensee could use its PSA to provide a more objective assessment of the impact on safety

(increase in cumulative risk) that adjustments to the quality program may have prior to implementation. Such assessments would be performed only if there is a concern that safety could be negatively impacted. The assessments and conclusions would be based on the guidance provided in the industry's *PSA Applications Guide*.

4.3 High Safety Impact, Safety-Related SSCs

It is unlikely that a licensee would need to adjust the quality elements associated with SSCs in this category.

4.4 High Safety Impact, Nonsafety-Related SSCs

For nonsafety-related SSCs that have been categorized as high safety impact, an assessment is performed to determine whether the current quality elements are appropriate, and are being applied in a manner consistent with the safety significance of the SSC.

Past SSC operating histories, input from plant personnel, and current quality practices provide input into the quality element determination. The basis for any new or revised set of quality elements is documented, and reviewed by the quality review group. Such a review ensures that the degree and level of implementation is commensurate with the safety significance of the SSC, and provides reasonable assurance that the pertinent safety function(s) will be performed.

It is emphasized that the requirements of 10 CFR 50, Appendix B do not apply to this category of SSCs. However, some of the quality elements and their implementation may be consistent with current 10 CFR 50, Appendix B requirements and practices, or with a licensee's "augmented quality" program, if applicable. The determination of whether changes need to be made to include these SSCs in a licensee's established quality program, such as its "augmented quality" program, or even its Appendix B quality program, is an individual licensee decision. It is based on economic, ease of implementation, operational history, and safety considerations.

4.5 Safety-Related SSCs Categorized as Low Safety Impact

Each licensee determines the applicability of the quality elements for this category. Not every criterion of the regulations (10 CFR 50, Appendix B) governing quality assurance is necessarily applicable, and not every segment of those criteria need apply. The depth of implementation and specific details are determined by each licensee based on safety significance.

The selection of the pertinent quality elements, and the degree of implementation is based on the need to provide reasonable assurance that the safety function will be

fulfilled. The quality review group or organizational entity makes this determination or reviews the results of such determinations. The resultant quality elements, and their degree of implementation do not have to be the same as those described in current commitments to regulatory guides or industry standards.

As a minimum, a corrective action program that meets the requirements of 10 CFR 50, Appendix B is applied in a manner commensurate with safety significance. Other quality assurance criteria described in the regulations might be applicable, but are dependent on the determinations or review of the quality review group, and are based on the safety significance of the SSC or activity under consideration. Further, the depth of implementation should be consistent with safety significance, which, for this category, is low. It should be noted that based on the safety significance categorization criteria, SSC failures in this category should have minimal impact on safety.

4.6 Nonsafety-Related SSCs Categorized as Low Safety Impact

A licensee may wish, as part of this project, to review the quality controls and practices associated with these SSCs to determine whether there is any commercial benefit to refining and improving the quality elements associated with this category.

4.7 Discussion on Specific Quality Assurance Elements

The depth of implementation, and the application of quality elements may vary from SSC to SSC dependent on the safety categorization of the SSC under consideration. The two elements described in the subsequent sub-sections are considered to be central to a graded quality program. The extent to which these elements apply and the extent to which other pertinent quality elements apply is reviewed by the quality review panel, and is dependent on safety significance (see Section 4.2).

A number of licensees may consider that their current quality programs in the two areas described below are adequate, fulfill the needs of a graded QA program, and do not require revising.

4.7.1 Quality Assessments

Assessments, including self-assessments, should continue to be performed to an extent determined by each licensee based on plant (equipment, department, or personnel) performance and safety significance. Each licensee should determine the degree of management oversight, independent and technical review, type, frequency and degree of specificity of these assessments based on safety significance, the performance history of the SSCs or work activities, or regulatory requirements. The aim is to assess and assist line departments and line quality functions.

Assessments may be in the form of audits, examinations, inspections, monitoring, surveillances, tests or verifications.

The current assessment functions are expected to be sufficient. Changes to assessment functions and criteria should be based on safety significance and performance, i.e., facility or industrywide operating histories and experiences.

A sub-element of a licensee's assessment program is a periodic assessment of the overall effectiveness of its quality program. The output from licensee monitoring and corrective action programs provide the basis for, and input into, these periodic assessments. Such assessments can be qualitative, quantitative, or a blend of both qualitative or quantitative assessments, as determined by each licensee's current programs.

The scheduling and level of detail of these periodic quality assurance assessments are contingent upon the safety significance of the SSC under review and, when necessary, may be part of a specific corrective action program activity. Licensee management or its designated review group reviews the results of these periodic assessments and determines whether any adjustments are necessary. In many instances, current licensee management self assessment reviews would encompass many features of a periodic review for quality assurance. In such a manner, the overall impact on safety from adjusting quality assurance elements can be assessed, and the need and extent for further adjustments, including changes in SSC categorization, or changes in quality practices can be determined.

Dependent on the scope, quality, and level of detail in a licensee's PSA, a licensee could use its PSA to provide a more objective assessment of any impact on safety that adjustments to the quality program have had during the assessment period. Any changes in PSA results would be assessed using the guidance in the *PSA Applications Guide*.

4.7.2 Corrective Action Program

A corrective action program is the central element of a quality program. It is through this process that deficiencies and deviations that impact safety functions are evaluated and resolved by appropriate licensee actions. The resolution of deficiencies through the implementation of appropriate corrective action is fundamental in assuring safe and reliable operation.

A corrective action program may take many forms, from informal (e.g., front line technician/supervisor/foreman interactions) to formal (e.g., divisional and departmental interactions, with detailed engineering evaluations and specific procedures) assessments and documented actions. Each has its benefits and disadvantages. The most important consideration is that the programs are

structured in a manner that provide reasonable assurance that deviations and deficiencies are resolved in a timely manner commensurate with safety significance.

Deficiencies should be documented to an extent consistent with their safety significance. The documentation of deficiencies is an important element in any operational entity. The degree and extent of documentation may vary dependent on existing practices, historical equipment condition or operating profiles, and the safety significance of the SSC under consideration. The level of documentation can vary from rough defect log books and operator preliminary deficiency reports, to detailed root cause analyses or modification packages with detailed calculations and safety analyses.

The important aspect is that deficiencies are documented in a manner to assure appropriate management attention based on the safety significance of the deficiency. The documentation process for deficiencies should be sufficient to provide input into periodic assessments of the quality program's effectiveness.

APPENDIX A

DEFINITIONS, TERMS AND ACRONYMS

APPENDIX A

DEFINITIONS, TERMS AND ACRONYMS

The following definitions and terms are provided to assist in understanding the terms used in the document.

Assessments: A collective term covering reviews, monitoring, tests, surveillances, inspections, audits or examinations.

Graded quality assurance: Application of quality elements (criteria) to structures, systems or components in a manner commensurate with their safety significance.

Industrywide operating experience: Information included in NRC, industry, and vendor equipment information and monitoring programs that is applicable and available to the nuclear industry with the intent of minimizing adverse plant conditions or situations through shared experiences.

Q-list: The list of structures, systems, components required by Criterion II of 10 CFR 50, Appendix B.

Restructured Q-list: The list of structures, systems, and components required by Criterion II of 10 CFR 50, Appendix B, and other applicable regulations, categorized based on their safety significance.

QA program description: A general report and description of the licensee's Appendix B quality program and the corresponding standards. It constitutes the quality assurance licensing commitments associated with implementing 10 CFR 50, Appendix B.

Quality elements: The quality attributes, controls, criteria, processes, or practices necessary to provide reasonable assurance that a SSC would perform its intended safety function.

Safety functional failure: A failure of a component that results in a determination that the safety function of a structure, system or train cannot be performed on demand.

High safety impact SSCs: A category of safety significance for SSCs that are significant contributors to risk as determined by a combination of deterministic and PSA methods, or other methods as determined by the licensee.

List of Acronyms

CFR	Code of Federal Regulations
EOPs	Emergency Operating Procedures
FFM	Functional Failure Modes
FSAR	Final Safety Analysis Report
IPE	Individual Plant Examination
NRC	Nuclear Regulatory Commission
NEI	Nuclear Energy Institute
NUMARC	Nuclear Management and Resources Council
PSA	Probabilistic Safety Assessment

APPENDIX B

**NRC - NEI MANAGEMENT CORRESPONDENCE ON A GRADED,
PERFORMANCE-BASED APPROACH TO IMPLEMENTING QUALITY**

APPENDIX B

Summary of the NEI Disposition of NRC Suggestions on Implementing Graded Quality Assurance

This appendix provides the basis for positions taken in the *Guideline on Implementing a Graded Approach to Quality* to address the suggestions made by the NRC staff in the interactions on the deferred industry-NRC pilot project on a graded, performance-based approach to quality. It should be noted that the NRC comments and the majority of the industry-NRC interactions were associated with an industry-NRC pilot effort associated with implementing a broader scope of activities than graded quality assurance.

Copies of the significant industry-NRC correspondence and NRC meeting summaries associated with implementing graded and performance-based quality are provided in this appendix for information.

In general, while the specific language of the NRC suggestions may not have been incorporated in the guidance, the general concept and thrust of the NRC comments have been adopted. The subsequent paragraphs summarize NEI positions on NRC suggestions that apply to graded QA.

The NEI letter, dated February 8, 1995, to the NEI Administrative Points of Contact provided the rationale for deferring the pilot project on implementing a graded, performance-based approach to quality. NEI had previously informed the NRC staff of the decision in December 1994 following extensive NEI Appendix B Working Group discussions (NEI letter to James Milhoan, Deputy Executive Director for Nuclear Reactor Regulation, Regional Operations, dated December 21, 1994). In the letter to the NEI Administrative Points of Contact, NEI strongly encouraged utilities to continue their graded QA activities using probabilistic and deterministic insights.

The NEI *Guideline for Implementing a Graded Approach to Quality*, has not been reviewed by the NRC staff. The NRC has acknowledged that licensees can implement a graded approach to quality. Since their introduction, the NRC regulations and a number of the industry's implementation standards have permitted a graded approach to implementing quality assurance. The NRC has stated that the need for guidance on graded QA is based on consistency and resource considerations, not regulatory. NEI believes that it is more appropriate for the industry to develop guidance where there are no regulatory implications, providing the quality assurance measures continue to provide reasonable assurance that the pertinent safety functions will be satisfactorily performed. Although no formal NRC review of the guideline and the industry response to the NRC

suggestions was requested, they have been discussed in general terms during NEI-NRC meetings on other QA matters.

The regulatory boundaries for a graded approach to quality assurance programs are governed by the requirements of 10 CFR 50.54(a). Many standards referenced in a licensee's quality program description, included or referenced in its FSAR, provide for a graded implementation based on safety significance and complexity of the task. The NRC regulations emphasize that each licensee must make its own assessment on the "reduction in commitment" requirement in Section 50.54(a) when considering a change to its quality program description. The specific language in Section 50.54(a) together with the variance between licensees' quality programs preclude a generic interpretation.

Level of detail: Utilities have already implemented a graded approach to quality to a limited degree. Many have enhanced their programs through the additional insights gained from probabilistic safety assessments (PSAs), and the feedback from industrywide and plant specific operating experiences. To provide more detailed implementation guidance presents a high potential for conflict with activities for improving the QA process that already have been accomplished, or that are being implemented within the current regulatory framework. The incorporation of a level of detail, as suggested by the NRC, to promote consistency among licensees is unnecessary. Naturally, each licensee would develop appropriate detailed implementation procedures.

Corrective action and operating experience programs: Current utility programs are adequate. There is minimal discussion in the document on corrective action because it is considered that the current programs are satisfactory. In regard to improvements in operating experience programs, the maintenance rule implementation activities are focusing utility attention in this area, and should identify and implement any necessary improvements, as appropriate. It is not necessary to provide a detailed description of existing programs when they are satisfactory, or where activities are already being pursued to implement any necessary enhancements.

Documentation: Existing documentation, design basis information, plant specific or operating history should be sufficient to support the implementation of new quality criteria for SSCs, where appropriate. The need to determine the appropriate documentation to implement a root cause analysis, should a defect occur, could easily develop into a long term exercise analyzing hypothetical events. Such an approach is unwarranted. If necessary, and in specific instances, utility management, or its designated quality review group or expert panel, should resolve questions associated with the need for additional documentation to support newly identified and unique plant characteristics.

Inform NRC staff prior to start of implementing a graded approach to quality:

Numerous utilities have already implemented, or are in the process of implementing a graded approach to quality. There is no regulatory basis for requiring NRC notification prior to implementation of a graded approach to quality, providing the requirements of 10 CFR 50.54(a) are satisfied.

Methodology and level of detail associated with the safety significant categorization of SSCs: The method for categorizing SSCs described in the draft guideline is based on the general methodology established, noticed for public comment, accepted by the NRC, and used in the implementation of the maintenance rule. The methodology is a combination of deterministic and probabilistic assessments. In the case of the maintenance rule, there has been significant regulatory interaction including pilot studies and pilot NRC inspections. The results have generally been satisfactory. Further, as noted in NRC SECY 95-265, and in the NRC Chairman's letter to NEI dated January 16, 1996, the conceptual four-part determination process described in NUMARC 93-01 provides an acceptable method for grouping structures, systems and components on the basis of risk significance, and could be used in other applications under certain conditions.

The graded QA guideline emphasizes that for QA, the scope is broader because the full spectrum of pertinent failures must be evaluated, not just those associated with maintenance. As such, there may be minor differences in the list of SSCs categorized as high safety impact for quality assurance as compared with the list of SSCs (risk-significant) generated for the maintenance rule implementation activities.

PSA issues: These issues are addressed through use of the industry's *PSA Applications Guide* (EPRI TR-105396, August 1995). The guide seeks to ensure that the plant specific PSA model and accompanying analyses are appropriate for the application, i.e., categorizing SSCs based on safety significance for a graded QA project.



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

January 6, 1994

Mr. Joe Colvin
President and Chief Executive Officer
Nuclear Management and Resources Council
1776 I Street, N.W.
Suite 300
Washington, DC 20006

Dear Mr. Colvin:

On December 16, 1993, the NRC staff met with NUMARC and industry representatives to discuss the graded application of 10 CFR Appendix B, Quality Assurance. As discussed at the meeting, the NRC considers this issue to be extremely important, and, in fact, the Regulatory Review Group identified the development of guidance to address the use of graded quality assurance as one of its most important recommendations.

The benefits to be gained from a graded quality assurance program could be significant. First and foremost, in terms of enhanced public health and safety by focusing both the NRC's reviews and inspections and the industry's resources on the more safety-significant structures, systems and components (SSCs); and, secondly, in terms of cost savings to the industry by avoiding the dilution of resources on less safety-significant issues.

The NRC's regulations (10 CFR Part 50, Appendices A & B) require quality assurance programs that are commensurate (or consistent) with the importance to safety of the functions to be performed. However, the practice that has evolved has not been graded and, generally, has either been a full Appendix B program or none at all.

In the development of guidance for the implementation of the maintenance rule, a methodology to determine the risk significance of SSCs within the scope of the rule was proposed by industry in NUMARC 93-01 and endorsed by the NRC in Regulatory Guide 1.160. During the December 16th meeting, it was suggested that the staff and industry could build on the experience gained with the maintenance rule to develop a policy and criteria for a graded quality assurance program. Once developed, they would then be tested in a pilot program, similar to the V&V effort by industry with NUMARC 93-01. Considering the benefits that could be realized from a parallel and coordinated effort with the maintenance rule implementation, the timing for developing guidance for a graded quality assurance program is important.

In view of the above, the NRC has established a steering group of senior managers to provide guidance to the staff and for the timely resolution of any policy issues. The steering group membership includes myself, Jack Heltemes (RES) and Bill Russell (NRR). The NRC's working level lead on this issue is Gary Zech, Chief of the Performance and Quality Evaluation Branch. Mr. Zech will also be the NRC's day-to-day point of contact for NUMARC and industry on this subject. A schedule has been established that identifies the summer of 1994 for the development of guidance for a graded quality assurance program

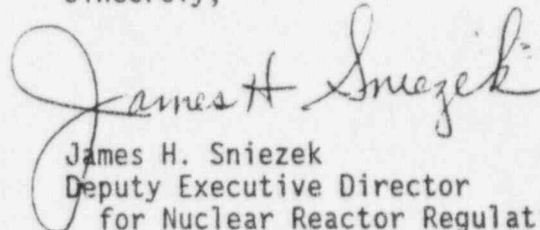
January 6, 1994

that can be pilot-tested at a few utilities, starting in about September 1994. This near-term goal, although ambitious, is important in terms of benefitting from the experience that will be gained by utilities in determining the risk significance of SSCs within the scope of the maintenance rule. Once the pilot program is complete, the longer-term schedule includes the issuance of draft guidance for public comment in the spring of 1995 and a final regulatory guide in the spring of 1996, prior to the effective date of the maintenance rule in July 1996.

If you are in agreement with the views and priorities expressed above and with the approach described for the development of guidance for a graded quality assurance program, I request that you identify a senior level contact to interface with our steering group.

I look forward to your prompt response on this important issue.

Sincerely,

A handwritten signature in cursive script that reads "James H. Sniezek". The signature is written in dark ink and is positioned above the typed name and title.

James H. Sniezek
Deputy Executive Director
for Nuclear Reactor Regulation,
Regional Operations and Research



NUCLEAR MANAGEMENT AND RESOURCES COUNCIL

1776 Eye Street, N.W. • Suite 300 • Washington, D.C. 20006-3706
202) 872-1280

Joe F. Colvin
President & Chief
Executive Officer

January 19, 1994

Mr. James H. Sniezek
Deputy Executive Director for
Nuclear Reactor Regulation,
Regional Operations and Research
U.S. Nuclear Regulatory Commission
Washington, DC 20055

Dear Mr. Sniezek:

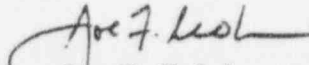
Thank you for your letter dated January 6, 1994, regarding the graded application of 10 CFR 50 Appendix B, Quality Assurance. The industry concurs with your suggestion that we should build upon the experiences and practices developed in the Maintenance Rule implementation projects to develop a performance-based, graded approach to implementing quality assurance.

The subject of graded QA is a topic of consideration by both the Regulatory Threshold Working Group, chaired by Jack Skolds, and the Appendix B Working Group, chaired by Bill Bohlke. Discussions with potential candidates for the pilot projects have already commenced. We believe the outline of a guidance document can be produced, by the March time frame. From our initial review and internal discussions, the schedule proposed in your letter of completing our guidance document by the end of 1994 is achievable.

We agree with the wisdom of establishing a senior steering group. The industry representatives will be Jack Skolds, Bill Bohlke and Bill Rasin. Our routine point of contact for Mr. Zech is Alex Marion.

We look forward to working with you on this promising effort.

Sincerely,


Joe F. Colvin

JFC/WHR/cma



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

May 23, 1994

MEMORANDUM FOR: Charles E. Rossi, Director
Division of Reactor Inspection
and Licensee Performance, NRR

FROM: Gary G. Zech, Chief
Performance and Quality Evaluation Branch
Division of Reactor Inspection
and Licensee Performance, NRR

SUBJECT: SUMMARY OF SECOND MEETING OF THE NRC AND INDUSTRY STEERING
GROUPS ON MAY 12, 1994, ON GRADED QUALITY ASSURANCE

On May 12, 1994, the NRC graded quality assurance (QA) Steering Group met for the second time with their counterparts from the Industry Steering Group, consisting of representatives from the Nuclear Energy Institute (NEI) and the industry.

Mr. James Milhoan, of the NRC Steering Group, provided a summary of the progress to date relative to the development of a graded QA methodology and the associated pilot plant initiatives.

The staff then presented a synopsis of the four major staff concerns related to the proposed NEI draft "Guideline for Industry Pilot Project — Implementation of Graded Performance Based Approach to Quality" dated April 1994 as follows:

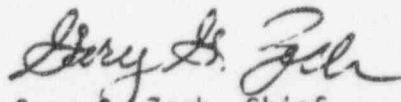
- 1) The NEI guideline contains insufficient specificity and guidance, particularly in the areas of the expert panel activities, the control of QA aspects for the low-safety significant safety-related structures, systems, and components (SSCs), and the feed back process to account for operating history. The present guidelines are not felt to be sufficiently descriptive to allow the initiation of pilot programs and they would not provide a basis for evaluating the success of the pilot programs.
- 2) The NEI guideline only implements a formal corrective action program in conjunction with a performance monitoring program for the low-safety-significant SSCs. This is not consistent with the staff view that the applicability and extent of application of the Appendix B criteria needs to be determined based on both the SSC safety-significance and safety function.
- 3) The NEI guideline proposes to substitute the described methodology in lieu of existing QA commitments and practices for the population of low-safety significant safety-related SSCs. This is not consistent with the staff position that a process is needed to adjust the current practices and commitments in a controlled manner.
- 4) The NEI terminology of "non-safety-significant" is not appropriate for classifying safety-related equipment, the terminology "low-safety-significant" is more appropriate.

A discussion transpired between the NRC and NEI Steering Groups about the points raised by the staff and the rationale behind the draft NEI guideline. NEI participants indicated that the impetus behind the initiative was to identify a way for utilities to streamline their operations and invest their resources in safety-significant SSCs based on probabilistic risk assessment (PRA) technology. They were of the opinion that the proposed methodology would meet the regulatory requirements of Appendix B. The staff cautioned NEI that the use of PRA in the graded QA program needs to consider the PRA limitations and assumptions. NEI agreed that the terminology "non-safety-significant" would be revised to "low-safety-significant" within the guidelines.

The discussions then focused on the set of safety-related SSCs that would be categorized as low-safety-significant. The applicability and depth of implementation of the Appendix B criteria, other than corrective action, was discussed at length. NEI indicated that they envision a performance-based approach for the low-safety-significant SSCs that would be outside of the regulatory purview. The NRC participants clarified that the staff will carry out their regulatory responsibilities regardless of the SSC categorization and that if the graded QA categorization process is performed in a reasonable manner, that it would not normally be questioned during the conduct of NRC inspections. The NRC Steering Group also reinforced the need for a systematic consideration of all Appendix B criteria and associated licensee practices to determine how they should be applied in a graded manner for the low-safety-significant SSCs.

NRC and industry representatives agreed to meet again in early June 1994. There was also agreement that NEI would review their guideline in light of the concerns expressed by the staff. The staff agreed that, for those portions of the NEI-proposed methodology that require more detailed guidance and specificity to support the initiation of the pilot efforts, we would provide NEI "inserts" that reflect what we consider to be an acceptable level of detail.

Enclosure 1 is the staff meeting handouts, including the meeting agenda. Enclosure 2 is a list of meeting participants. NEI did not present any viewgraphs or written information to the staff during the course of the meeting.



Gary G. Zech, Chief
Performance and Quality Evaluation Branch
Division of Reactor Inspection
and Licensee Performance, NRR

cc w/enclosures:
Nuclear Energy Institute
Attn: Alex Marion
Suite 300
Washington, DC 20006-3706

Enclosures:
As stated



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

June 15, 1994

Mr. William Rasin
Nuclear Energy Institute
1776 Eye Street, N.W.
Suite 300
Washington, D.C. 20006

Dear Mr. Rasin:

During the last meeting of the NRC and NEI Graded Quality Assurance (QA) Steering Groups on May 12, 1994, the staff committed to provide you with specific comments on your draft "Guideline for Industry Pilot Project - Implementation of Graded Performance-Based Approach to Quality." However, upon further consideration, the NRC Steering Group believes it would be more appropriate to first ensure that we are in agreement on the fundamental concept for a graded QA program. Therefore, the purpose of this letter is to provide the NRC Steering Group's views on some basic issues such that, if we are not in agreement, we can first address the conceptual differences and then move forward on this important initiative.

First, the purpose, or goal, for developing guidance for a graded QA program is to realize a savings from tailoring QA controls based on the safety significance of the structures, systems, and components (SSC) involved. Such an approach should be possible without any significant impact on plant safety, and would allow both the staff's and licensees' QA resources to be focused on the more safety-significant SSCs. We believe at this point that this fundamental goal may be accomplished by the development of guidance for the implementation of a graded Appendix B QA program. The pilot program should provide a meaningful evaluation of the guideline and allow us to determine if rulemaking may be necessary.

Secondly, the essential elements of any graded QA program should include the following: 1) a process that, with high confidence, will identify the appropriate safety significance of all SSCs in a reasonable and consistent manner, 2) an effective root-cause analysis and corrective action program for safety-significant SSCs, 3) the determination of appropriate QA controls for individual SSCs, or groups of SSCs, based upon safety function and significance, and 4) a means of reassessing SSC safety significance and QA related controls when new information becomes available. Each of these elements is discussed in further detail in the enclosure.

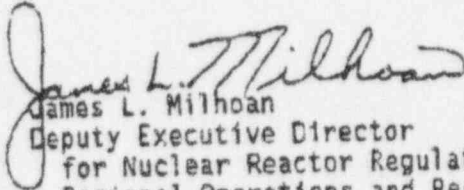
If there is agreement on the goal and elements of such a program, we can then proceed towards implementation of the program. We believe that the goal expressed above and the associated elements need to be specifically identified and discussed in NEI's guidance document. At that point we can provide specific comments on the guidance document.

Mr. William Rasin

- 2 -

Be assured that we continue to strongly support this effort. It is important that our regulatory requirements are effective and efficient and we are committed to working with you towards achieving that end.

The NRC Steering Group looks forward to your timely response to this letter. After receiving your response, we believe a meeting to discuss future activities, especially the upcoming pilot program, would be appropriate.


James L. Milhoan
Deputy Executive Director
for Nuclear Reactor Regulation,
Regional Operations and Research

cc: Jack Skolds c/o NEI
William Bohlke c/o NEI

Enclosure:
As stated

ESSENTIAL ELEMENTS OF A GRADED QUALITY ASSURANCE PROGRAM

1. Establishment of Risk Significance.

The nature and magnitude of an SSC's contribution to plant risk should determine the type and amount of QA controls and practices applied to that SSC. In our discussions, we have agreed that the process developed for implementing the maintenance rule, i.e., NUMARC 93-01, "Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," may offer a practical means for establishing the basis for a graded QA program. The philosophy applied in implementing the maintenance rule, i.e., the establishment of criteria or goals, performance or condition monitoring, and appropriate corrective actions when failures occur, should also be applicable to a graded QA program. For example, those SSCs that are determined to be risk significant within the scope of the maintenance rule are likely to be risk significant within the context of a graded QA program.

The expert panel described in NUMARC 93-01, and further expanded upon in NUMARC 93-02, "A Report on the Verification and Validation of NUMARC 93-01," would appear to have an extremely important role in both the maintenance rule and graded QA applications. The panel's role would be to establish the high, low and no safety-significant categories. In this regard, we understand that SSCs in the high safety-significant category would continue to reflect the Appendix B program as now constituted, and SSCs having no safety significance could be removed from the scope of Appendix B (in accordance with existing regulatory provisions). The real benefit from this activity is in tailoring the specific nature of needed QA controls for SSCs of low safety significance. The expert panel's role is critical to this determination and would be based upon:

- a) The results of risk-significant determination methodologies, and
- b) Deterministic factors associated with the nature and consequences of failure that could affect safety margins for SSCs such as passive pressure boundary components and standby safety systems.

The decision process needs to be described well enough such that it is likely to provide the classification results with reasonable confidence and consistency.

2. Effective Root Cause Analysis and Corrective Action Program.

NEI and the NRC have agreed that graded QA programs need to include an effective root cause analysis and corrective action program. This program would determine whether the failure of any SSC within a low-safety-significant category is acceptable in light of its specified safety significance and QA-related controls. Therefore, the NRC believes that the expert panel would need to pre-identify the necessary

procurement, design, installation, and other records necessary to be able to conduct effective root cause analyses and corrective action determinations. In addition, an adequate corrective action program would require that the locations and applications of SSCs similar to that which failed should also be retrievable.

Consistent with the approach agreed upon for the implementation of the maintenance rule, failures of low safety-significant SSCs would have to be evaluated. If a second failure subsequently occurs that is determined to be QA-preventable and/or is due to inadequate earlier corrective actions, the need for augmented QA controls should be considered until corrective actions are shown to be effective.

3. Determination of Appropriate QA Controls.

Once the expert panel has determined the safety significance of an SSC to be low, the panel would then determine the specific nature and extent of the QA controls and practices to be applied to the SSC to, among other things, support an effective root cause analysis and corrective action program as discussed in Item 2 above. This determination would include the consideration of the safety function of the SSC and non-maintenance related factors such as design, procurement, fabrication, construction, installation, testing, and human factor issues. This "grading" of QA controls is critical in order to assure that the margin of safety continues to be adequate and yet unnecessary economic burdens are minimized.

4. Incorporation of New Information and Operational Experience.

The final element would be a mechanism for the timely reevaluation of an earlier safety-significance determination and related lessening of QA controls when new information is obtained. This information could be the result of a change to the plant's IPE, an equipment or system modification, adverse performance monitoring results, or operating experience from other plants. The NRC believes that a graded QA program should be a dynamic process and that the consideration of new information needs to be an inherent part of the program.



NUCLEAR ENERGY INSTITUTE

July 14, 1994

Mr. James L. Milhoan
Deputy Executive Director for Nuclear Reactor Regulation,
Regional Operations and Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Milhoan:

Industry's Senior Management Steering Committee for Implementing a Graded, Performance-Based Approach to Quality, has reviewed your letter dated June 15, 1994. We are encouraged that the NRC staff shares many conceptual views with industry that could lead to an improved quality regime. However, we believe that additional dialogue is necessary regarding how these views should be implemented.

The concepts described in your letter appear to reflect much of the current quality practices for implementing 10 CFR 50, Appendix B. We agree with the four essential elements of a graded QA program identified in your letter. However, we believe an additional element relating to performance-based regulatory assessment, consistent with the practices established in the Maintenance Rule implementation, is needed to supplement the list of essential elements described in your letter. A fundamental change in culture is necessary to achieve a more efficient and effective quality infrastructure. The absence of a performance basis for the implementation of graded quality assurance will preclude the significant historical record of plant performance that should be used to achieve a more efficient and effective quality regime with the attendant safety benefits.

We agree that the purpose, or goal, for developing a graded QA program is to realize a savings from QA controls based on the safety significance of the systems, structures, and components (SSCs) involved. A graded, performance-based approach to implementing quality would provide both licensees and NRC staff flexibility to allocate resources based on safety significance. Licensees would establish appropriate quality elements, including appropriate 10 CFR 50, Appendix B criteria, that would be graded based on historical performance and consistent with safety significance.

Effectiveness of quality criteria and activities for those SSCs that are categorized as safety significant would be assessed in the same manner as they are in the current quality assessment regime.

Mr. James L. Milhoan

July 14, 1994

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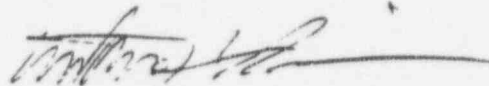
For those SSCs that do not warrant inclusion in a safety significant group, effectiveness of quality criteria and activities would be assessed through monitoring performance against a predetermined set of licensee established performance criteria. Such an approach is based on the NRC endorsed implementation concepts of the Maintenance Rule, 10 CFR 50.65.

The Maintenance Rule requires licensees to monitor performance of pertinent SSCs against licensee established performance criteria to provide reasonable assurance that the safety function will be fulfilled. We believe the purpose and requirements of 10 CFR 50, Appendix B can be satisfied by monitoring performance and meeting the licensee established performance criteria. We concur with NRC senior management statements in December 1993 that the implementation of a new quality regime should be initially implemented for SSCs that do not warrant inclusion in the safety significant group.

We believe that licensees can implement a graded, performance-based quality regime within the current regulatory framework of 10 CFR 50.54(a). Alternative and equivalent performance-based regulatory commitments can be substituted for the existing set of quality commitments. Additional details are provided in the enclosure.

The enclosure provides additional comments on the processes described in your letter and further amplification on our approach to a performance-based quality regime. We look forward to discussing these matters with you at our meeting on July 21, 1994. Should you have any questions before then, please call Bill Bohlke, Jack Skolds or myself.

Sincerely,



William H. Rasin
Vice President
Technical/Regulatory

WHR/APH/cma
Enclosure

c: Mr. J. L. Skolds, South Carolina Power & Light Company
Mr. W.H. Bohlke, Florida Power & Light Company

Enclosure to NEI Letter to NRC dated July 15, 1994 on Graded, Performance-Based Quality Assurance

A. Specific NEI Comments on NRC Letter to NEI (Milhoan/Rasin) dated June 15, 1994

We agree that the mutual objective of the NRC and industry is to develop a more efficient and effective approach for implementing 10 CFR 50, Appendix B (Quality Assurance). A graded, performance-based approach, using the concepts and practices established for implementing the Maintenance Rule as the principal cornerstones, should significantly support the achievement of our objective. Such an approach would provide increased licensee and NRC flexibility in the allocation of resources based on safety significance. Furthermore, such an approach will enhance public health and safety by focusing the licensee's finite resources and the NRC's regulatory emphasis on those structures, systems, components (SSCs) and activities that are truly safety significant.

We agree that the process for identifying the safety significance of SSCs developed for implementing the Maintenance Rule, as endorsed in Regulatory Guide 1.160, can be applied to a graded, performance-based implementation of 10 CFR 50, Appendix B.

We further agree general guidance should be developed for determining the appropriate quality elements, including 10 CFR 50, Appendix B criteria, that provide reasonable assurance that the pertinent SSCs are capable of performing their safety function. Specific examples of quality criteria for various SSCs would be developed through a pilot project and included as a supplement to the industry guidance, to assist other licensees in implementing a reasonable and consistent graded, performance-based approach for 10 CFR 50, Appendix B.

Adequacy of the quality criteria for the safety significant set of SSCs and associated activities would be determined through the current practices.

For those SSCs that do not warrant inclusion in the safety significant group, adequacy of the quality processes and practices would be assessed through monitoring performance against a set of predetermined, licensee established performance criteria. A licensee would establish appropriate quality criteria and associated processes, retaining the flexibility to adjust these quality criteria and processes to permit more efficient use of resources while ensuring safety, as demonstrated by meeting the performance criteria. The performance criteria would be predominantly plant level, such as unplanned scrams per 7,000 hours critical, unplanned safety system actuations or unplanned capability loss factors. In those circumstances where it is inappropriate for plant level criteria to monitor

performance, criteria proposed in the Maintenance Rule implementation, such as at the system level (reliability, availability or condition monitoring) would be set. Furthermore, specific system performance criteria would be established for SSCs that are in a standby (not normally operating) mode.

Failure to meet performance criteria would result in cause determination and appropriate corrective action for failures that not only include those which are maintenance preventable. We believe that such an approach is an enhanced implementation of the concepts embedded in the Maintenance Rule and, if adopted, would supersede the existing prescriptive procedural compliance approach for assessing the adequacy of a quality program.

We agree that assessment (including self assessment and cause determination) and corrective action programs are essential elements in any quality program. We consider that current licensee corrective action and assessment are adequate for use in a performance-based approach for implementation of 10 CFR 50, Appendix B. We do not understand the need for enhancing current programs, or developing new programs. The necessity of compiling supplemental documentation, beyond that already collated by licensees, as a basis to implement new or existing corrective action or assessment programs, is counter to the objective of improved efficiency and effectiveness.

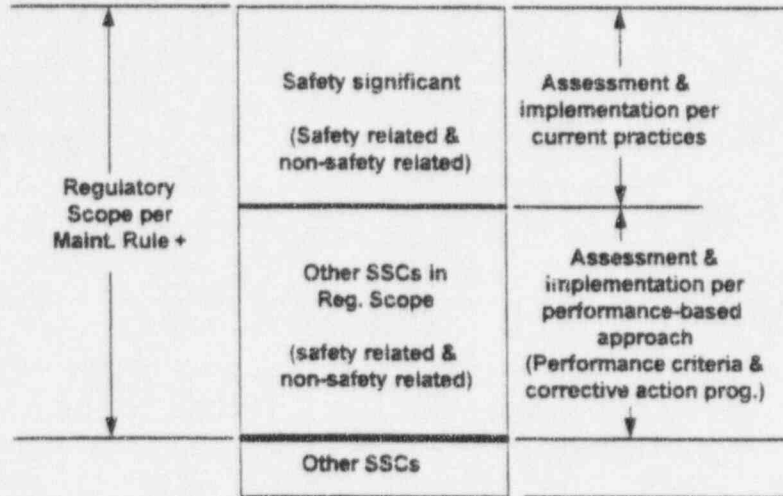
Licensees already consider and assess feedback from operational experiences and general industry information in the daily management of plant activities. In a performance-based approach, plant specific and industry operating experience would be reviewed as part of a periodic performance assessment activity, similar to that which is conducted in implementation of the Maintenance Rule.

B. Performance-Based Approach for Implementing Quality

We believe a more effective and efficient method of implementing 10 CFR 50, Appendix B is attainable through a performance-based approach, building on the concepts and implementation practices established for the Maintenance Rule.

The purpose of 10 CFR 50, Appendix B and its associated commitments is to provide reasonable assurance that the plant SSCs will perform their intended safety functions. Under the Maintenance Rule, performance criteria are established, and the performance of SSCs is monitored, to provide reasonable assurance that specific SSCs are capable of fulfilling their intended safety functions. Thus, we believe a determination of quality program adequacy can be made through meeting a set of predetermined performance criteria. The attached figures summarize the approach described in the draft industry guidance document for implementing graded, performance-based quality.

**GRADED, PERFORMANCE-BASED APPROACH TO
IMPLEMENTING QUALITY**



+Reg. Scope = Maint. Rule Scope + Other SSCs from Other Regulations & Licensing Commitments

Figure 1

GRADED, PERFORMANCE-BASED QUALITY IMPLEMENTATION PROCESS

	SAFETY SIGNIFICANT	OTHER SSCs WITHIN SCOPE
Scope	As per Maintenance Rule + Other SSCs & activities within NRC regulations.	As per Maintenance Rule + Other SSCs & activities within NRC regulations.
Categorization of SSCs	As per Maintenance Rule Implementation Guidance & Graded, Performance-Based Quality Guidance, Section 3	As per Maintenance Rule Implementation Guidance & Graded, Performance-Based Quality Guidance, Section 3
Grading and delineation of quality controls	Per current practices, Section 4.2 of Graded, Performance-Based Guidance	Per expert panel determinations based on Graded, Performance-Based Guidance, Sections 4.0, 4.1 & 4.3
Application & review of quality commitments, & the associated commitment change process	Current regulatory process. Licensees consider the need to change quality commitments on a case by case basis, per Section 50.54(a) process.	Existing quality commitments substituted by a commitment to implement & assess quality per Section 50.54(a) process through NEI Guidance Document. NRC endorsement of industry guidance document provides mechanism for generic approval — individual licensee procedural submittal required to amend each docket, referencing industry guidance document.
Quality process adequacy assessment	Per current practices	Per performance-based concepts, by meeting a set of predetermined, licensee established performance criteria

Figure 2

C. Commitments

In the NRC staff - NEI working level interactions over the past six months on a graded, performance-based approach to quality, the issue of existing commitments associated with the group of SSCs that do not warrant inclusion in the safety significant group has been discussed. We believe this issue can be resolved generically through the existing Section 50.54(a) process, by substituting the following commitments for the current set of quality commitments for this group of SSCs:

- a) Implement the requirements of 10 CFR 50 Appendix B through a graded, performance-based approach as described in an industry guidance document;
- b) Monitor and meet a predetermined set of licensee established performance criteria (predominantly plant and system level criteria); and
- c) Implement corrective action and assessment processes to resolve deficiencies and deviations, and monitor performance.

The purpose of quality assurance commitments, described in the NRC approved program description, is to assist in assuring that 10 CFR 50, Appendix B is implemented properly. The objective of 10 CFR 50, Appendix B is to provide adequate assurance that SSCs that prevent or mitigate the consequences of postulated accidents will perform their safety-related functions. Furthermore, 10 CFR 50, Appendix B permits quality controls to be applied in a manner consistent with the importance to safety. The Maintenance Rule (10 CFR 50.65) requires licensees to establish performance criteria, sufficient to provide reasonable assurance, that applicable SSCs are capable of fulfilling their intended function. Therefore, we believe that the quality commitments associated with a graded, performance-based approach to implementing the regulations are equivalent to the current set of quality commitments for the group of SSCs and associated activities that do not warrant inclusion in the safety significant group. They can replace the existing quality commitments described in the NRC approved quality program description for those SSCs not included in the safety significant group.

NEI believes that such a change is not a reduction in commitment, as described in the NRC approved quality program description. It is substituting an alternative and equivalent commitment to achieve the same objective as existing regulatory commitments. The objective of providing reasonable assurance that the pertinent set of SSCs are capable of performing their intended safety function is accomplished through a different methodology (e.g., a graded, performance-based approach). Such a change is

permitted under the requirements of 10 CFR 50.54(a). We consider that because of its generic applicability, the proposed improvement in implementing 10 CFR 50 Appendix B, should be pursued on a generic basis. Each licensee that wishes to pursue the option of implementing a performance-based quality assurance regime, modeled on the concepts and practices established in implementing the Maintenance Rule, would file a change to the quality program commitments under Section 50.54(a) as a procedural matter for documentation. The change would not be submitted for NRC approval because such a change is viewed as implementation of a previous generically approved approach to meet the regulation.



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

AUG 01 1994

MEMORANDUM FOR: R. Lee Spessard, Director
Division of Reactor Inspection and
Licensee Performance, NRR

FROM: Suzanne C. Black, Chief
Performance and Quality Evaluation Branch
Division of Reactor Inspection and
Licensee Performance, NRR

SUBJECT: SUMMARY OF THIRD MEETING OF THE NRC AND INDUSTRY STEERING
GROUPS ON GRADED QUALITY ASSURANCE CONDUCTED ON JULY 21,
1994

On July 21, 1994, the NRC Graded Quality Assurance (QA) Steering Group met for the third time with their counterparts from the Nuclear Energy Institute (NEI) Steering Group, comprised of representatives from NEI and the industry.

The purpose of the meeting was to discuss the Steering Groups' respective positions regarding the essential elements that should be incorporated in a graded approach toward the implementation of 10 CFR 50 Appendix B and to gather additional information about NEI's letter to the NRC dated July 14, 1994.

Recent management changes within the Office of Nuclear Reactor Regulation were identified by Mr. James Milhoan of the NRC's Steering Group. These changes involved the replacement of Mr. Gary Zech with Ms. Suzanne Black as the Branch Chief of the Performance and Quality Evaluation Branch. In this capacity Ms. Black will serve as the new Chairperson for the NRC's Graded QA Working Group. It was also noted that as a result of the retirement of Mr. Jack Heltemes, Mr. John Craig, Deputy Director, Division of Engineering, Office of Nuclear Reactor Research, had been named as the interim replacement for Mr. Heltemes on the NRC Graded QA Steering Group.

Mr. Milhoan, also provided a summary of developments to date which included reference to the NRC Steering Group letter to NEI dated June 15, 1994 outlining the goals and expectations for the development of a graded QA methodology. Mr. Milhoan also discussed NEI's response letter from Mr. Rasin, dated July 14, 1994 which articulated areas of agreement and apparent disagreement with the NRC's expectations for the graded QA initiative.

The staff presented its goal for the graded QA program, which would involve the tailoring of QA controls based on the safety significance of structures, systems, and components (SSCs). By establishing the relative safety significance, a process could be implemented which would focus quality resources on the more safety significant SSC's. The staff stated that the proposed methodology would be implemented during a pilot program to validate

its effectiveness. At the conclusion of the pilot program an evaluation will be performed to incorporate the lessons learned to enhance the initial concepts. In response, NEI acknowledged their endorsement of the stated goal.

The staff then discussed the process necessary to identify, with high confidence and consistency, the appropriate safety significance of SSCs. The staff reaffirmed its position that NUMARC 93-01, "Industry Guidelines for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants" and the companion document 93-02, "A Report on the Verification and Validation of NUMARC 93-01" offer a process that can be used for a graded QA program. However, the staff indicated that 93-01 would have to be modified for use in a graded QA program to account for other than maintenance related unavailabilities. NEI generally concurred with the staff's position that 93-02 be formally recognized as part of the graded QA program process, but indicated that they would need to review the document in more detail in order to endorse the application of all of the report's findings and conclusions. Both the staff and NEI recognized the need for a multi-disciplinary panel of experts to provide a balanced perspective considering both probabilistic risk assessment (PRA) and deterministic factors to establish safety significance.

The staff also discussed the need for an effective root cause analysis and corrective action program such that potential failures of other SSCs (e.g., generic and common cause failures) could be appropriately evaluated, particularly if equipment failures are attributable to the reduction in QA controls. The staff indicated that it does not envision the need for new types of records to be generated, rather it expects that sufficient documentation regarding failures would continue to be generated and that the guidance document would address the need for the expert panel to consider failure data in the context of common mode failures across system boundaries. NEI indicated that necessary records would be a subset of existing QA documentation. Both the staff and NEI acknowledge the need for adequate records as an essential ingredient to an effective root cause and corrective action program. The staff also indicated that the pilot program would provide feedback regarding this issue.

Additionally the staff discussed the need for incorporation of appropriate QA controls for SSCs or groups of SSCs based on safety function and safety significance. The staff indicated that the expert panel, or other technically knowledgeable part of the licensee's organization, would designate the extent of QA controls that would be appropriate for SSCs, including the records needed to support the root cause and corrective action program. Specifically, the panel would need to consider the application of appropriate elements from Appendix B in a graded fashion.

Although NEI's July 14 letter to the NRC concurs with this position, clarification of Figure 1 in the letter, which implied that for low safety significant SSCs only performance monitoring and corrective actions would apply, was requested by the staff. In response to this issue NEI stated that performance monitoring does not mean that other QA criteria do not apply. The adequacy of the QA criteria applied would be evaluated by the performance

monitoring program, according to NEI representatives. NEI concurred with the staff's position, as delineated on Slide 7 (Enclosure 1) of the presentation, and agreed to incorporate these elements into their revised guidance document.

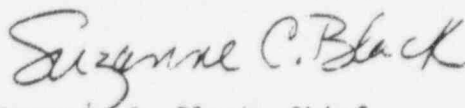
NEI raised a concern regarding the issue of NRC enforcement and whether or not the graded QA program for low safety significant SSCs would fall outside the enforcement umbrella based on satisfactory results from the planned performance monitoring program. The staff agreed that enforcement matters in this area would be examined, but at a later date and that this effort would be separate from the development of the graded QA program elements.

With respect to providing a means of assessing SSC safety significance and QA controls based on new information, both NRC and NEI indicated that timely reevaluation based on plant experience and industry feedback is an essential element of the graded QA program. Accordingly, NEI stated their intention to include this element in its revised guidance document.

Relative to the manner in which licensee commitments would be modified to adopt a graded QA program, the staff indicated that the type of changes under discussion would involve a reduction in commitment requiring a licensing submittal. However, resolution of the specific options associated with the modification of existing commitments in licensee's QA program descriptions remained an open item for future staff interaction with NEI.

The staff also presented the results of three site visits to plants that are developing graded QA programs: North Anna, Palo Verde, and Grand Gulf. While the programs developed at North Anna and Palo Verde appeared to be consistent with the staff's position on graded QA, the proposed process at Grand Gulf had not appeared, at the time of the staff visit, to adequately consider deterministic analysis when evaluating SSC safety significance.

NEI stated in their concluding remarks, that they expected to submit a revised guidance document to the staff by the third week in August 1994, after the pilot plants had reviewed the changes. The staff expressed the desire to review the guide prior to the next working group meeting which is tentatively planned for the late August time frame.



Suzanne C. Black, Chief
Performance and Quality Evaluation Branch,
Division of Reactor Inspection and
Licensee Performance, NRR

cc: R. Ng, NEI

Enclosures:

1. Staff meeting handout
2. Meeting attendees
3. NRC letter to NEI dated June 15, 1994
4. NEI letter to NRC dated July 14, 1994



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D. C. 20555-0001

September 21, 1994

MEMORANDUM TO: Suzanne C. Black, Chief
Performance and Quality Evaluation Branch
Division of Reactor Inspection
and Licensee Performance, NRR

FROM: Robert A. Gramm, Chief *RG*
Quality Assurance Section
Performance and Quality Evaluation Branch
Division of Reactor Inspection
and Licensee Performance, NRR

SUBJECT: SUMMARY OF NRC WORKING GROUP MEETING WITH NEI AND PILOT
PLANT PARTICIPANTS ON SEPTEMBER 14, 1994, ON GRADED QUALITY
ASSURANCE

On September 14, 1994, the NRC Graded Quality Assurance (QA) Working Group met for the seventh time with the Nuclear Energy Institute (NEI) Working Group and representatives from the industry involved with the graded QA pilot initiative.

The purpose of the meeting was for the NRC to provide their comments on the recently revised NEI guidance document for graded QA and to outline the NRC expectations for the pilot program implementation. The staff opened the meeting by stating that they, and NEI, would be providing their relative positions on graded QA and would be exchanging information related to the implementation of a graded QA program.

The staff indicated that the revised NEI guidance document (Attachment 3) had been received on September 2, 1994. Based on the staff review performed to date, a number of comments had been generated. The staff expressed the position that the document still did not contain sufficient details to fully address the essential elements of an acceptable graded QA program. Specific details on these elements had been previously articulated during a meeting of the NRC and NEI Graded QA Steering Groups on July 21, 1994. Issues associated with Graded QA were also discussed in a letter dated June 15, 1994 from the NRC to NEI. The staff further stated that an overall assessment was that the quality and level of detail of the NEI document had degraded since the last version.

The staff discussed their specific comments on the NEI guidance document (Attachment 1) in relation to the essential elements of a graded QA program.

The staff reiterated that the topics of inspection and enforcement are not appropriate for inclusion in the NEI guidance document. The staff indicated that inspection activities would focus on the more safety significant issues. However, the staff would not be precluded, for example, from examining the determination of component safety significance and assignment of performance monitoring criteria for low safety significant structures, systems, and

components (SSCs). Because of the unique considerations of the pilot program, the staff indicated that a special NRC review panel would be convened to review any proposed enforcement actions prior to issuance.

The staff stated that while it was disappointed with the content and level of detail contained in the NEI document, the NRC remains committed to the graded QA project and that it desires to move ahead with pilot plant implementation in a controlled fashion so as to not impact plant safety. However, the schedule the staff had originally envisioned for moving through the pilot program phase is no longer feasible. In order to expeditiously bring the discussions to a plant specific basis and to work out details in the guidance, the staff stated that it will be providing a letter to NEI in the near future that will provide supplemental guidance to the NEI document. In some cases the NRC supplement will augment the NEI document and in a few cases it will supersede the information contained in the NEI document. The staff indicated its desire to move ahead at that point with two lead pilot plants to assess how the guidance will be utilized and to evaluate whether it is sufficient for application to the graded QA task.

At a point when confidence has been obtained from the two lead plants that sufficient guidance is available, the remaining 5 pilot plants would then proceed to implement the program. At the conclusion of the second phase of the pilot program, lessons learned would be incorporated into the guidance document and the staff would develop a draft regulatory guide for public comment.

NEI and the pilot participants expressed concerns as to how the provisions of 10 CFR 50.54(a) would be applied to QA program changes that may occur during the pilot program. The staff outlined several options dependent upon a decision reached by each individual pilot licensee as to whether the QA program change would constitute a reduction in commitment. The staff indicated that it would expect to receive detailed letters from each pilot plant identifying the intended scope of graded QA application.

There was a brief intermission for NEI to caucus to discuss the information presented by the staff. Upon their return, NEI indicated that they were disappointed with the staff's reaction to the NEI document and they expressed the opinion that the staff was not properly evaluating the graded QA proposal in a manner consistent with respect to other staff activities in the area of applying probabilistic risk assessment techniques. Several utilities indicated that their desire to continue in the pilot program would be contingent upon the type of information contained in the supplemental staff document.

A concern was expressed by the licensees that the supplemental staff document would constitute a regulatory burden that would limit the flexibility they had hoped to have available under the graded QA approach. NEI expressed the opinion that NUMARC 93-01, written for implementing the Maintenance Rule, had been previously found acceptable by the staff and questioned why additional detail would be needed for a graded QA application.

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September 21, 1994

The staff indicated that NUMARC 93-01, as endorsed by Regulatory Guide 1.160, was developed as an option which, if followed by licensees, would satisfy the Maintenance Rule requirements. While that process conceptually may provide the initial foundation for the graded QA framework, it does not encompass the broader spectrum of plant activities within the purview of graded QA.

In its closing comments the staff pointed out to NEI and the industry representatives that implementation of a graded QA program is already permitted by the regulations. If a licensee concludes that changes to its QA program would not result in a reduction in commitment, the staff suggested that they could proceed independently of the pilot program. However, the staff added that the purpose of the NEI and NRC Working Group efforts was to develop a common understanding of what would be an acceptable approach to a graded QA program so that the industry would proceed in a relatively consistent manner and the staff would not have to review multiple approaches to graded QA.

The meeting concluded with the NRC committing to provide NEI with the supplemental document in the near future.

The staff provided the opportunity for members of the public in attendance to provide additional comments on graded QA. None were provided.

cc: R. Ng, NEI

Attachments:

1. Staff meeting handout
2. Meeting attendees
3. NEI letter to NRC dated September 1, 1994 transmitting NEI guidance on graded QA



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

October 14, 1994

Mr. Thomas Tipton
Nuclear Energy Institute
1776 Eye Street, N. W.
Washington, D.C. 20006

Dear Mr. Tipton:

I am writing you this letter to address some of the issues that emerged during the last meeting of the NRC and NEI Graded Quality Assurance (QA) Working Groups on September 14, 1994.

Both the NRC and industry have made a substantial resource investment in trying to develop a workable approach to implement graded QA. After our Steering Group meeting of July 21, 1994, it appeared that the major obstacles had been overcome for moving ahead with the generation of a sufficiently detailed guidance document for use in conducting the pilot project. However, your revised guidance document, "Draft Pilot Project Guideline for Implementation of a Graded, Performance-Based Approach to Quality" dated September 1, 1994 was still lacking adequate detail in several areas. During the meeting of the NRC and NEI Working Groups on September 14, our major concerns with the document were articulated. The staff also committed to provide you with supplemental guidance for implementing the graded QA pilot initiative.

Enclosure 1 identifies certain portions of the NEI guide that are not appropriate for inclusion in the guide. For example, the topic of regulatory assessment (i.e., inspection and enforcement) is an NRC function that is not subject to restrictions by the NEI guide. Though we intend to perform inspections focused on the relatively risk significant issues, the NRC would not be precluded, for example, from examining the determination of component safety significance as low-risk significant and evaluating the graded QA treatment that the low-risk significant plant equipment receives. Because some uncertainties exist about the appropriateness of some potential violations under graded QA, the staff will establish a peer panel to review proposed Notices of Violations (NOVs) during the pilot effort.

Enclosure 2 provides supplemental information to the NEI guidance document in the areas of the Expert Panel function, the appropriateness of performance monitoring in-lieu of product quality monitoring, activities that should be accomplished as part of the plant corrective action program, and QA commitments. This information is intended to augment that contained in the NEI guidance document and supersede the NEI information if they are dissimilar.

Additionally, the staff will be providing you with a comprehensive set of comments on your guide in the near future. These comments are of less significance and should not detract from the use of the guide during the pilot phase. However, we will hold further discussions with you regarding these comments as the pilot project progresses.

In addition to the level of detail provided by the NEI guidance document, there are several other issues related to implementing the pilot program that are worth noting. The NEI guidance document attempts to generically replace existing QA plan commitments without having each licensee properly evaluating whether the individual pilot plant QA plan changes would constitute a reduction in commitment as required by 10CFR50.54(a). Each pilot licensee will be responsible to assess the intended QA program changes and arrive at their own determination in this regard. The staff review of the revised NEI guidance document also noted that the terminology "non-risk significant" continues to be used when referring to safety-related low-risk significant components. As we stated in the July 21, 1994 meeting, the term non-risk significant is inappropriate.

Prior to receipt of the September 1, 1994, version of the NEI guidance document, the staff had understood that for high-risk significant plant equipment the current quality program provisions would continue to be applied. Your most current version of the graded QA guidance implies that the graded approach could be readily expanded at the option of the pilot plant licensees to include the high-risk-significant equipment and functional areas beyond those examined during the pilot phase. The purpose of performing the pilot project is to establish the adequacy of the graded QA methodology. Until the lessons learned from the pilot phase are analyzed and necessary revisions are made to the guidance, it would be premature for pilot licensees to extend the application beyond that agreed upon for the pilot project. The staff recognizes that licensees have flexibility to implement a graded approach in an alternative manner that would necessitate additional interaction with the staff.

The staff agrees that the NUMARC 93-01 methodology provides a starting point for guidance in the graded QA area. However, we see that given the broader scope and complexity of activities covered under graded QA, NUMARC 93-01 would be built upon and supplemented accordingly. We feel that Probabilistic Risk Assessment (PRA) insights can play an important role and that they should complement, and not replace, deterministic evaluations to identify the risk significance of structures, systems, and components (SSCs). In graded QA, the Expert Panel will play a critical role in determining SSC risk significance based on PRA insights and will compensate for PRA limitations.

Originally, we had envisioned that several licensees could initiate the pilot project simultaneously. Given the level of staff resources available to support this task, we propose that two lead pilot plants use the supplemented methodology to implement the project initially. If the lead pilot plants desire to implement an alternative approach from the supplemented guidance, the staff and pilot plant licensee would need to discuss those alternative approaches to assure a common understanding and acceptability of the planned licensee project. The lead pilot plants would then proceed with their project. After the staff has gained confidence that the supplemented guidance is acceptable, and after some revisions to the supplemented guidance that may be necessary based on insights from the initial implementation phases of the lead pilot plants, the remainder of the pilot plants could proceed at that time. In this manner, the supplemented guidance will be verified and refined in stages to ensure that it contains the requisite level of detail. At the conclusion of the pilot phase,

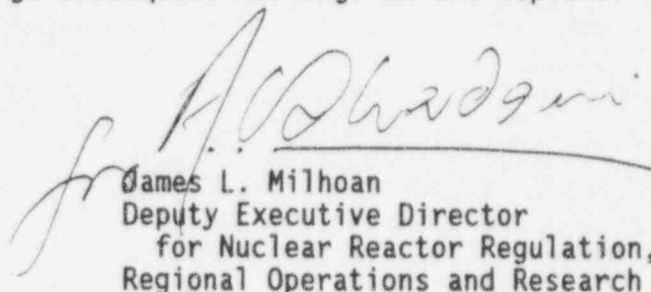
T. Tipton

- 3 -

Lessons learned from the seven pilot plant applications would be incorporated into the guidance. The staff would develop a draft regulatory guide endorsing the guidance for public comment.

The correct determination of high and low-risk significant SSCs is vital to the effective implementation of the graded QA program. For example, at one plant we understand that the reactor protection system (RPS) is considered to be low risk significant. This causes us great concern, because the PRA results are predicated on a highly reliable RPS and that high reliability is, in large part, the result of the QA program. Therefore, in the near-term, if requested by any pilot plant, the staff would agree to review the process for determining risk significance.

The staff is committed to the graded QA project. We hope that the pilot plant licensees continue to see the mutual benefits that can be derived from implementing the concept. We remain optimistic that discussions can be initiated in the near future with the lead pilot plants to start the practical application of the supplemented guidance for graded QA. Please contact Suzanne Black, the NRC Graded QA Working Group Chairwoman at (301) 504-1017 if you have any questions and to arrange subsequent meetings on the topic of graded QA.


James L. Milhoan
Deputy Executive Director
for Nuclear Reactor Regulation,
Regional Operations and Research

Enclosures
As Stated

cc:

Jack Skolds, South Carolina Electric and Gas, Inc.
William Bohlke, Florida Power and Light
Daryl Prisby, Commonwealth Edison - Byron
Roger O. Anderson, Northern States Power
Mike Meisner, Entergy Operations - Grand Gulf
Edwin Froats, Florida Power Corporation
Carter Rogers, Arizona Public Service Company
Stephen Eisenhart, Virginia Power
Ed Rogers, Entergy Operations - ANO

I. Regulatory Assessment - NRC enforcement policy and the inspection program jurisdiction discussed in the 5th bullet item on page 6 are not suitable topics for inclusion in the graded QA guidance document. For low-risk significant SSCs, inspectors could legitimately pursue a notice of violation (NOV) if the circumstances warrant. In recognition that some uncertainties may exist about the appropriateness of some potential violations under the graded QA project, the staff will form a panel comprised of representatives from the Office of Enforcement, Office of Nuclear Reactor Regulation, and regional staff to convene on a periodic basis to review proposed NOV's issued under the graded QA effort.

This review will be done prior to issuance of the NOV to ensure proper consideration has been given to: safety significance, degree to which the licensee has implemented the graded approach in a technically sound manner, the degree to which existing regulations and license requirements are fulfilled, and a consideration of ramifications on plant performance. The panel review may also be re-initiated should a licensee contest an issued NOV. The scope of the panel review will be limited to functional areas/systems addressed under the graded QA pilot. At the conclusion of the pilot project, more specific guidance will be developed for inclusion in the NRC inspection and NRC enforcement manuals.

Reference to regulatory assessment should be deleted from NEI's draft graded QA guidance document.

II. 10 CFR 50.54(a) - The assertion on page 23 that the graded QA effort for the pilot plant implementation will not constitute a reduction in commitments is not appropriate for NEI to make. Each licensee must make that determination dependent upon their unique QA plan provisions. The regulatory requirements associated with QA plan changes are contained in 10 CFR 50.54(a). A pilot plant licensee may currently have language embodied in its QA plan that allows for a graded application and no QA plan changes may be needed to implement its pilot effort. However, we request pilot plant licensees that do not envision the need to amend their QA program, to inform the NRC in writing of their intention to employ the supplemented NEI guidance, or alternate approach, to implement their graded QA project, and of the scope of application, either on a functional area (e.g., procurement) or system basis.

Licensees that need to revise their current QA program must evaluate the extent of the changes to ascertain whether they constitute a reduction in commitment. If they do not, then 10 CFR 50.54(a) does not require an advance NRC review of the changes. However, as indicated above, we request that the licensees participating in the pilot project inform the NRC in writing of their intention to employ the supplemented NEI guidance, or alternate approach, to implement their graded QA project and describe the scope of application.

If a licensee concludes that the change is a reduction in commitment, there appear to be two options available. The first option would be for the licensees to submit a normal QA program change in accordance with 10 CFR 50.54(a) that delineates what elements of the program will be revised

and a justification for concluding the program will continue to meet the requirements of Appendix B. As outlined above, the licensee should also describe the scope of application for the pilot effort. This submittal would receive an expedited NRC review to ensure that the start date of the pilot effort is not impacted. If the changes are found acceptable, the NRC would approve the changes for the pilot effort. Following completion of the pilot project, the NRC would expect the licensee to eventually conform with the revised NEI guidance which will incorporate lessons learned from the pilot project. Licensee programs may need to be revised to account for changes in the NEI guidance.

The second option would be for a pilot project licensee to request a temporary exemption, in accordance with 10 CFR 50.12, to the reporting requirements of 50.54(a). As a basis for requesting the exemption, the licensee would indicate that the supplemented NEI guidance, or alternate approach, would be utilized in-lieu of the current QA commitments for low-risk significant SSCs. The licensee should define the scope of application, either on a functional area (e.g., procurement) or system basis. If the NRC can make a finding that the supplemented NEI guidance, or alternate approach provides an acceptable way to meet the requirements of 10 CFR 50, Appendix B, the NRC would grant a temporary exemption from the requirements of 50.54(a) for a time period limited to the pilot project on the ground that compliance with the explicit requirements of 10 CFR 50.54(a) is not necessary to achieve the underlying purpose of the rule. At the conclusion of the pilot project, the NRC would expect the licensee to conform with the revised NEI guidance which incorporates lessons learned from the pilot project phase. Licensee programs may need to be revised to account for changes in the NEI guidance.

Reference to an advance determination that a generic substitution of existing commitments would not constitute a reduction in commitment should be deleted from NEI's draft graded QA guidance document.

III. Non-Risk Significant - The use of the term "non-risk significant" to describe safety related SSCs is misleading. References to risk-significant and non-risk significant (safety-related) SSCs in NEI's draft graded QA guideline should be replaced with the terminology "high-risk significant" or "low-risk significant" respectively.

SUPPLEMENTAL GUIDANCE FOR NEI GRADED QA DOCUMENT

I. Expert Panel Evaluation

The nature and magnitude of an SSC's contribution to plant risk should determine the type and amount of QA controls and practices applied to that SSC. An essential element of the graded QA process involves the thorough evaluation of SSC safety functions and risk significance to discern the aspects that should be taken into account when determining what quality elements in 10 CFR 50, Appendix B, to apply in a graded manner. The Expert Panel described in NUMARC 93-01, and further expanded upon in NUMARC 93-02, "A Report on the Verification and Validation of NUMARC 93-01," would have a central role in this process. The panel's role would be two-fold: first, to establish the high-risk significant and low-risk significant SSC categories; and second, to determine the appropriate application of QA controls for the SSC or activity under consideration.

A. Expert Panel Composition

The utilization of the Expert Panel, as described in the previously referenced NUMARC documents, provides a basic framework and valuable insights that can be applied to the process of evaluating SSC risk significance for the graded QA process. Based on the lessons learned documented in NUMARC 93-02, the panel would nominally include experienced representatives from each of the following disciplines:

- Operations
- Maintenance
- Engineering
- PRA

Additionally, given the emphasis on quality considerations in the graded QA process, the following two disciplines should also be included on the panel:

- Quality Assurance
- Procurement

B. Risk Significance Determination

The initial function of the Expert Panel would be to evaluate both probabilistic and deterministic information available regarding each SSC (or broad classes of functionally similar SSCs) within the defined scope to reach a conclusion as to the risk significance of SSCs. The Expert Panel would need to carefully weigh the PRA insights, including the associated limitations of PRAs, as part of its process to categorize each SSC by risk significance.

PRA results should be viewed as a screening mechanism to provide insights about the relative risk significance of SSCs. The output from the PRA and/or IPE should be augmented with other critical information, such as SSC outage configuration experience, for the panel to reach its conclusions regarding risk significance. Other sources of input information that the Expert Panel

may feel appropriate to consider include: design bases documents, design specifications, failure modes and effects analyses, plant operating procedures, normal and abnormal plant configurations and alignments, and plant licensing bases documents.

Risk significance should be determined using a methodology similar to that described in NUMARC 93-01, section 9.3.1, revised to account for non-maintenance related failure modes that will be of importance when applying the PRA approach in the QA area. NUMARC 93-01 defines risk significance in terms of prevention or mitigation of core damage, containment integrity, or a reduction in the release probability or consequence to the public, as determined by the PRA/IPE and Expert Panel process. NUMARC 93-01 also provides quantitative guidance, including the application of Risk Reduction Worth, to determine which SSCs should be considered risk significant. Factors such as potential common-mode failures, human errors of omissions and commissions, defense-in-depth, and the maintenance of safety margins would also be considered. Both high-risk significant and low-risk significant categories could include safety-related and non-safety related SSCs.

In some cases, a deterministically important SSC, one whose failure is important from a standpoint of design, operations, and maintenance considerations might not make a significant contribution to plant risk as modeled by the PRA. In addition, some of those SSCs may not be explicitly modeled in the PRA, or the PRA boundary assumptions may be constructed to assume that they do not fail. Thus, a change in QA practices could have significant impact on the continued validity of the boundary assumption. The risk significance of plant features such as containment and the containment isolation function should be thoroughly evaluated because a strict PRA assessment with respect to core damage frequency would not be representative. The Expert Panel should assess these factors during its deliberations and document the results.

Some important limitations of PRA that would have to be considered during the Expert Panel deliberations are outlined below:

- Plant systems are modeled to varying degrees (explicitly, implicitly, or not at all) in the PRA. For example, systems such as the nuclear boiler system and remote shutdown may not be explicitly evaluated in typical PRAs. The fact that an SSC is not modeled does not provide sufficient basis to amend the QA treatment of that SSC. Further Expert Panel evaluation would be warranted.
- The scope of plant PRAs and IPEs may be at the Level 1 analysis that provides estimates of core damage frequency and identifies core damage contributors. Consideration of external events such as seismic, fire, smoke and soot effects, toxic gas dispersion, high winds and tornadoes, flooding, and core damage mitigation (e.g., recovery factors, etc.) should also be addressed.

- The level of PRA performance is a determining factor with respect to the degree the results can be utilized. If the PRA was performed at the system level, then graded QA insights would be derived at the system level.
- The failure modes modeled by the PRA may not be all inclusive.
- The type of data for equipment failure rates, unavailabilities, and initiating event frequencies may be either plant specific or generic. If generic data is utilized, an evaluation is warranted to assure the appropriateness of extrapolating the data to the plant specific QA realm.
- The modeling of human activities and human errors, including cognitive and comprehension errors, is subject to considerable uncertainties in the PRA. These can affect dominant accident sequences and dominant contributors to core damage.
- Truncated low probability events (below approximately 95 percent of core damage frequency) may affect results from the PRA. For example, the reactor pressure vessel is not normally included after truncation yet the reactor pressure vessel obviously plays an important role in assuring plant safety.
- Plant specific PRA modeling practices (in contrast to actual design differences) that could skew the plant specific PRA results when compared to the generic population of similar plant PRA results. Some baseline validation to assure consistency of insights would be warranted.
- The treatment of software driven solid-state control and protection devices are not readily amenable to being analyzed by PRA. Quantitative results should be treated with considerable caution in this area.
- PRAs normally address only 100% power operation. The effects of partial or low power, shutdown, and refueling modes, on plant safety will also need to be considered by the Expert Panel.
- Generally, fault trees are not developed and generic event data is used for modeling the switchyard and emergency diesel generator. The Expert Panel should exercise caution when extrapolating PRA insights in this area.
- Containment performance provisions including containment isolation functions may not be fully modeled. The Expert Panel should consider this limitation during their deliberations.
- Potential influences of aging on component reliability are not evaluated by the PRA. This may warrant additional evaluation by the Expert Panel.

- Low-risk significant components not required to support safety function but whose failure could adversely impact safety function performance (i.e., seismic II/I system interaction) may not appropriately evaluated by the PRA. The Expert Panel evaluation will have to make appropriate compensations in this area.

Before an SSC would be categorized as low-risk significant, the following screening criteria needs to be reviewed by the Expert Panel:

- If a failure of the SSC would not be detectable through performance monitoring methods, it would not be categorized as low-risk significant.
- If the SSC is used in multiple applications in the plant and is susceptible to generic or common mode failure that could impair redundant or diverse safety systems/trains, it should be carefully considered before being categorized as low-risk significant. In addition, if a failure should occur, the root cause analysis must determine whether the failure was random or common mode. In the case of a generic or common mode failure, the location of other affected components must be known, the importance of the potential failure mode must be evaluated, and appropriate corrective action must be taken.
- Other regulatory requirements, such as seismic qualification, environmental qualification, applicable codes, e.g., ASME, etc., would not be affected by the implementation of the graded QA program.

C. Quality Element Assessment

The following information supplements section 4.1.2 of the NEI guide.

Subsequent to the determination of SSC risk significance using a methodology similar to that described in NUMARC 93-01, the selection of appropriate quality assurance (QA) requirements for the low-risk significant SSCs is a critical aspect of achieving an improved utilization of resources and enhanced safety margins.

The appropriate identification of QA requirements is based on plant specific considerations, in particular, the safety analysis which identifies design basis safety functions and operational parameters.

1. High-Risk Significant SSCs

In a two-tier categorization system (i.e., high-risk significant and low-risk significant), the current QA practices would be retained by licensees for safety-related high-risk significant SSCs.

It is likely that a certain number of SSCs currently classified as non-safety related will fall into the high-risk significant category. For these SSCs,

the licensee would institute more rigorous quality practices than would normally be done for those risk-significant non-safety-related SSCs. This would entail the application of augmented quality practices for those SSCs in recognition of their relative importance to plant safety.

2. Low-Risk Significant SSCs

The pilot plant licensee would determine the specific nature and extent of the QA controls and practices to be applied to the SSC to, among other things, support an effective root cause analysis and corrective action program. This determination would include consideration of the safety function of the SSC and non-maintenance related factors such as design, procurement, fabrication, construction, installation, testing, and human factors issues. As previously noted, all failures would have to be considered for their potential generic or common mode effect on other plant equipment. The licensee must be able to locate similar equipment that is susceptible to the failure mechanism and consider the effect of these failures on redundant trains or systems. Adequate corrective actions must be taken.

The pilot plant licensee would ensure that regulatory requirements beyond Appendix B germane to the SSC would not be revised by the graded QA program. Technical provisions of the regulations (e.g., seismic qualification, code requirements) would be maintained while the quality assurance implementation practices would be adjusted.

3. Consideration of Additional Quality Assurance Requirements for Non-Safety Related SSCs

In the past, the NRC has determined that certain categories of non-safety related SSCs warrant some QA program treatment. This has included station blackout equipment, Anticipated Transient Without Scram (ATWS) equipment, and fire protection equipment. These decisions did not result in re-classifying these SSCs as safety-related; however, they recognized the increased importance of these SSCs to plant safety. These additional QA measures should be considered, as appropriate, during the Expert Panel determination of graded QA treatment.

D. Documentation

The licensee should establish adequate documentation with respect to the assignment of risk significance that integrates with existing QA program documentation and includes:

- the qualifications and composition of the Expert Panel performing the risk significance determinations;
- the basis for these determinations;
- adequate explanation regarding the application of graded elements such that failures of SSCs can be evaluated to determine if a lessening of administrative controls for QA activities was the cause or contributing factor; and

- provisions for revising these determinations based on feedback from performance monitoring and corrective action programs.

II. Performance Monitoring vs. Product Quality

The following information supplements section 4.4.2 of the NEI guide.

The guidelines in NUMARC 93-01 describe a performance monitoring program. The practices identified in this document could be extended into the graded QA efforts to validate, with respect to some observable parameters, that plant SSCs continue to be able to perform their safety function. Benefits should be derived from providing operational feedback from a performance monitoring program to ensure the effective implementation of the quality program provisions for safety-significant SSCs.

For the low-risk significant SSCs, a performance monitoring system similar to that described in NUMARC 93-01 would yield beneficial feedback by providing a measure of confidence of the effectiveness of the graded QA provisions. With respect to graded QA, the performance criteria would take into account all failure modes, not just those associated with maintenance preventable failures. It would be appropriate for an Expert Panel to delineate the performance criteria based on the SSC (or broad classes of functionally similar SSCs) risk significance and safety function. For aspects not amenable to verification by testing, performance criteria could be met by condition monitoring (e.g., nondestructive examination, visual inspection, vibration, deflection, thickness, corrosion, or other monitoring methods as appropriate). In other cases component, train, system, or plant level criteria could be considered by the panel depending upon the particular SSC under evaluation.

The QA program is designed to assure that SSCs will function when called upon to do so. There will be human issues, such as design and operating plant staff activities, and process controls that would warrant other types of criteria to judge the success of the program rather than relying on plant performance level criteria. These types of criteria would be selected more in the vein of assuring product quality (e.g., sampling technical integrity of design output documents).

III. Corrective Action Program Activities

The following information supplements section 4.6 of the NEI guide.

With respect to corrective action, the Expert Panel would identify the information and records necessary to conduct effective root cause determinations and corrective action activities for low-risk significant SSCs. These records should include applicable design, procurement, installation, maintenance, and other information germane to the identification of material characteristics related to potential SSC failure modes. The records should be sufficient to evaluate the locations of similar SSCs, or SSCs that perform corresponding functions, that may be included in the scope of necessary corrective actions. The records would support the ability to perform an in-depth root cause analysis of low-risk significant SSCs and to institute the

requisite corrective actions to minimize the potential for repetitive failures.

It would not be appropriate to limit corrective actions for low-risk significant items to only those cases where there is a failure to meet a performance criteria or where there has been a safety system functional failure. Oversight of plant activities could identify a design related issue that has not yet manifested itself in a functional failure. In this type of situation the expectation would be that appropriate corrective actions be initiated as determined necessary prior to the occurrence of a failure. Nor will it be appropriate to have repetitive failures prior to performing a root cause analysis and corrective action implementation. Operational feedback may well demonstrate that performance criteria have been inappropriately set. In that case, the corrective action would be to adjust the performance criteria to be consistent with the operational feedback insights.

In the event that the specified performance criteria are not met, then the appropriate corrective actions would be implemented, including a sufficient root cause analysis. The analysis should consider whether the specified quality treatment (either graded or full quality program implementation) is adequate. The licensee would need to maintain the capability to trend adverse equipment conditions to provide a mechanism for elevating SSCs from low-risk significant to the high-risk significant classification based on repetitive failures (see NUMARC 93-01, Section 9.4.4).

IV. QA Commitments

The following information clarifies the third bullet on page 6 of the NEI guide.

For the purposes of the pilot project, existing QA commitments for low-risk significant SSCs could be replaced by the graded QA methodology that relies upon an Expert Panel to determine the appropriate quality elements that will be applied to the SSCs. The provisions of 10 CFR 50.54(a) related to QA plan changes will continue to be applicable unless a temporary exemption is granted by the NRC. Adjustments under the graded QA project would be limited to the following Regulatory Guides:

<u>REGULATORY GUIDE</u>	<u>TITLE</u>
1.28	Quality Assurance Program Requirements (Design and Construction)
1.30	Quality Assurance Requirements for the Installation, Inspections, and Testing of Instruments and Electrical Equipment
1.33	Quality Assurance Program Requirements (Operational)

- 1.37 Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components of Water-Cooled Nuclear Power Plants
- NOTE: The technical provisions for Reg Guide 1.37, Section 3 - which establish water quality requirements remain in effect
- 1.38 Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants
- NOTE: The technical provisions of Reg Guide 1.38 Section 3.2 which define levels of packaging remain in effect.
- 1.39 Housekeeping Requirements for Water Cooled Nuclear Power Plants
- 1.58 Qualification of Nuclear Power Plant Inspection, Examination, and Testing Personnel
- 1.64 Quality Assurance Requirements for the Design of Nuclear Power Plants
- 1.74 Quality Assurance Terms and Definitions
- 1.88 Collection, Storage, and Maintenance of Nuclear Power Plant Quality Assurance Records
- 1.94 Quality Assurance Requirements for Installation, Inspection and Testing of Structural Concrete and Structural Steel During the Construction Phase of Nuclear Power Plants
- 1.116 Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems
- 1.123 Quality Assurance Requirements for Control of Procurement of Items and Services for Nuclear Power Plants
- 1.144 Auditing of Quality Assurance Programs for Nuclear Power Plants
- 1.146 Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants

V. Definitions

The following information supplements the definitions in Appendix A of the NEI guide.

Assessments: A wide spectrum of methods for plant personnel to gain input relative to plant activities, processes, and equipment. Assessments include design reviews, monitoring, surveillances, inspections, audits, and testing.

Expert Panel: A group of experienced and knowledgeable facility personnel that determine the safety significance of SSCs based on PRA and deterministic evaluations involving operations, maintenance, engineering, and quality assurance insights. They, or a technically equivalent group, are also responsible for establishing the appropriate graded QA provisions which apply to SSCs and for determining the necessary performance monitoring criteria.

Graded Quality Assurance: The proportionate application of quality verification to SSCs and/or activities, commensurate with their risk significance.

Low Risk Significant SSCs: The set of SSCs (safety related and non-safety related) that is determined by an Expert Panel through evaluation of both PRA and deterministic approaches to have relatively low risk significance.

Quality Element: Quality attributes, controls, criteria, processes, or practices necessary to provide reasonable assurance that an SSC would be able to perform its intended safety function.

Safety-Related SSC: From 10 CFR Part 100 and 50.49/50.65: A structure, system, component, or part necessary to assure: (1) The integrity of the reactor coolant pressure boundary; or (2) The capability to shut down the reactor and maintain it in a safe shutdown condition; or (3) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite radiation exposures comparable to the 10 CFR part 100 guidelines.

High-Risk Significant SSC: The set of plant equipment that is determined by an Expert Panel, through evaluation of both PRA and deterministic approaches, to have a relatively high risk significance.



NUCLEAR ENERGY INSTITUTE

Thomas E. Tipton

VICE PRESIDENT
OPERATIONS AND RESEARCH

December 21, 1994

Mr. James L. Milhoan
Deputy Executive Director for Nuclear Reactor Regulation
Regional Operations and Research
U.S. Nuclear Regulatory Commission
Washington, DC 20555

Dear Mr. Milhoan:

The NEI Appendix B Working Group, the pilot project participants for implementing a graded, performance-based approach to quality, and the NEI Nuclear Strategic Issues Advisory Committee Steering Group have assessed the status of the pilot project, including your letter dated October 14, 1994. These groups, encompassing utilities with over 65 operating units, NSSS vendors and architect-engineers, believe that it would be appropriate to adjust our overall approach for implementing a performance-based quality regime modeled after the concepts established by 10 CFR 50.65 (maintenance rule). Our future activities to address this issue are to:

- Actively encourage licensees to grade their quality programs and practices using probabilistic and deterministic insights. Each licensee would determine when appropriate action prescribed in 10 CFR 50.54(a) is necessary.
- Defer the pilot project for implementing a graded, performance-based approach to quality.
- Forward a petition for expedited rulemaking to amend 10 CFR 50.54(a) to allow licensees to change their quality programs as described or referenced in the Safety Analysis Report, providing that the regulations continue to be met and the change does not involve an unreviewed safety question.
- Develop a petition for rulemaking in 1995 for an alternative to 10 CFR 50, Appendix B. Such a rule would provide licensees the option to adopt a performance-based quality assurance regime modeled on the concepts of the maintenance rule, 10 CFR 50.65.
- In parallel with the rulemaking petition for a performance-based option to 10 CFR 50, Appendix B, prepare an industry guidance document for NRC endorsement on implementing the alternative quality assurance regulation. A pilot demonstration study of the industry's implementation guide would be conducted once the initial rulemaking proceedings have commenced.

The general rationale for pursuing these activities is provided in Enclosure 1 to this letter.

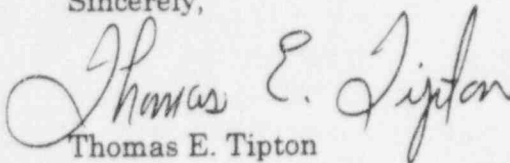
Mr. James L. Milhoan
December 21, 1994
Page 2

The substantial interactions of the past 12 months have been extremely beneficial. They have provided the basis for future activities and have assisted the NRC staff and the industry in focusing on the key 10 CFR 50, Appendix B, issues. Also, from these interactions, a better understanding of the urgent need to develop a more efficient and less burdensome quality regime has been attained.

New regulations should provide the impetus necessary to ensure a timely, predictable, and efficient implementation of a performance-based quality regime. A significant benefit of such new regulations should be enhanced public health and safety resulting from a more effective and efficient application of both NRC and licensee finite resources.

Should you have any questions, please call me.

Sincerely,

A handwritten signature in cursive script that reads "Thomas E. Tipton". The signature is written in dark ink and is positioned above the printed name.

Thomas E. Tipton

TET/acm
Enclosure

c: Jack Skolds, South Carolina Electric & Gas
Bill Bohlke, Florida Power & Light

Enclosure 1 to NEI Letter dated December 21, 1994

The rationale for the industry's decision to modify the strategy for implementing a performance-based quality regime is described in this enclosure.

It is evident from the interactions over the past 12 months that both the industry and NRC staff need additional time to fully embrace a performance-based regulatory regime, modeled on the implementation concepts established for 10 CFR 50.65 (maintenance rule). In view of this, we believe it is appropriate to defer the pilot project activities associated with implementing a performance-based quality regime.

It is widely acknowledged that the current regulations permit a graded approach to implementing quality based on safety significance. The NRC staff statement in the September 14, 1994, meeting that a licensee could proceed independent of a pilot project if the licensee concludes that changes to its QA program would not result in a reduction in commitment, was an appropriate and timely reminder. NEI will urge licensees to implement the NRC staff's suggestion and grade their quality elements, using a combination of probabilistic and deterministic insights gained through operating experiences and the Individual Plant Examination (IPE). Each licensee will make its own determination in regard to the impact on its quality commitments and, where necessary and appropriate, take action, as required in 10 CFR 50.54(a).

It was recognized and acknowledged in December 1993 that the pilot project might result in the need to amend several regulations, including 10 CFR 50, Appendix B, because of potentially inappropriate and inconsistent interpretations. Further, the NRC Regulatory Review Group Report (Volume 2) recommended specific rulemaking activities to improve the consistency of the regulations. These recommendations included a change to 10 CFR 50.54(a).

The substantial activities and interactions of the past 12 months support one of the conclusions of the NRC Regulatory Review Group Report. A significant change in both NRC staff and industry thinking needs to occur to enable quality assurance to be transformed from a prescriptive system to a performance-based regime.

It is evident from the pilot project interactions that 10 CFR 50.54(a) should be amended to reduce the potential for misinterpretation and to enhance the effectiveness and efficiency of implementing the regulations pertaining to quality. As a result, NEI intends to submit a petition for rulemaking to modify 10 CFR 50.54(a).

Recent Commission meetings support moving towards a performance-based regulatory regime, based in part on probabilistic safety assessment (PSA) concepts, and modeled after the philosophies and implementation concepts established under the maintenance rule. Further, at the start of the discussions on the pilot project for implementing a graded, performance-based approach to quality, it was considered that the associated regulatory and industry interactions would assist in resolving the question on the need to invoke rulemaking activities for 10 CFR 50, Appendix B. NEI believes that question has been answered. The discussions over the last 12 months provide an indication of the need to pursue rulemaking activities to introduce an alternative performance-based regulatory

option for licensees' quality assurance programs. We believe that such a rule should be modeled on the concepts and language of 10 CFR 50.65 (maintenance rule).

In 1995, NEI intends to develop the basis and language to support a petition to provide an alternative regulation for quality assurance. Such a rulemaking would promote consistency in the regulations through the enactment of performance-based regulation for an important area, quality assurance.

Such a performance-based alternative to 10 CFR 50, Appendix B, would be optional and could be adopted at each licensee's discretion. A licensee would choose whether to implement quality practices in accordance with the existing or newly promulgated regulatory requirements. Such a rulemaking will assure consistency in the future regulatory (performance-based) regime, improve the effectiveness and efficiency of the regulations, improve the implementation of quality processes and practices, and ultimately, enhance the public health and safety.

The concept of an optional, alternative 10 CFR 50, Appendix B, rule is the same as that proposed for the 10 CFR 50, Appendix J, regulation. It is expected that the language for a performance-based quality regulation would be similar to that of the maintenance rule which codified NRC acceptance of performance-based regulatory concepts. Additionally, the industry will develop a guideline for implementation of the optional performance-based Appendix B rule. As with the maintenance rule, we envision that such a guideline will be verified by a pilot demonstration and subsequently endorsed by an NRC regulatory guide.

This pilot effort will proceed once the initial rulemaking procedural aspects and interactions have been satisfied. NEI believes that such activities will significantly improve the communication and understandings that are fundamental to achieving our mutual objectives.



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

February 9, 1995

Mr. Thomas Tipton
Nuclear Energy Institute
1776 I Street, N. W.
Washington, DC 20006-3708

Dear Mr. Tipton:

In your recent letter dated December 21, 1994, you identified the Nuclear Energy Institute's (NEI's) future approach to performance-based graded quality assurance (QA). Specifically, you indicated that NEI will actively encourage licensees to grade their quality programs using probabilistic and deterministic insights and that the industry believes it would be appropriate at this time to defer the graded QA pilot project effort. Furthermore, you stated that NEI plans to forward rulemaking petitions to amend 10 CFR 50.54(a) and to enact a performance-based option to 10 CFR 50, Appendix B.

The staff looks forward to reviewing any rulemaking petitions that are submitted by NEI related to 10 CFR 50.54(a) or 10 CFR Part 50, Appendix B. With respect to your concept of proposing an alternative performance-based Appendix B regulation that parallels the maintenance rule, the staff would like to have further discussions with you on the concept of performance-based quality assurance. The staff continues to believe that the effectiveness of QA programs cannot be gauged solely on the basis of plant performance monitoring because the implementation of QA program controls provides assurance that plant equipment will function not only during routine operations, but also during design-basis events.

During the past year the staff has expressed a continued willingness and commitment to work with industry to formulate a methodology to implement graded QA. The staff is available to continue its dialogue with the industry to address practical ways to improve the manner in which present QA controls are implemented. More importantly, the staff is receptive to working with either individual volunteer licensees, or groups of licensees, to test and evaluate the implementation of graded QA concepts that would more efficiently focus resources on safety-significant aspects of plant activities and hardware.

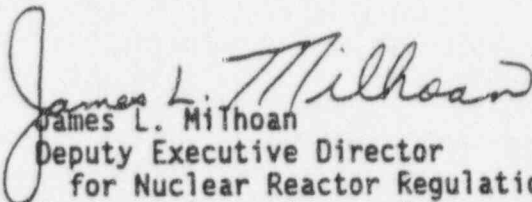
We both appreciate the potential benefits from tailoring QA controls commensurate with safety significance and I agree with your approach of encouraging licensees to utilize both deterministic and probabilistic insights to grade their QA programs. However, if the industry moves forward with implementation of graded QA on an individual licensee basis, I believe it should take into consideration the lessons learned from the staff's review of the NEI graded QA guidance document. On June 14, 1994, I provided a description of the four essential elements that should be embodied in a graded QA program. These essential elements include a reasonable and consistent process to identify the safety significance of plant equipment, an effective root cause analysis and corrective action program, the determination of QA

controls based on safety significance, and a means to adjust equipment safety significance and QA controls as new information becomes available. The staff continues to have reservations about the completeness of the existing NEI guidance as previously documented in our letters of October 14, 1994 and January 31, 1995. We consider the NEI guidance document to be preliminary guidance that would be applicable for use in a pilot plant environment. Though it has received extensive scrutiny by the staff, the guidance document has not gone through a formal staff review and approval process. Thus, it is our opinion that near-term licensee implementation approaches should not rely solely on the NEI guidance document. The staff's comments on your graded QA guidance document should be considered by licensees if they utilize this guidance for revising their programs.

As I indicated previously, the staff remains committed to working with individual licensees as practical approaches are developed for implementing graded QA. Individual licensees who plan on pursuing this approach should interact with the staff as they develop their graded QA programs. The staff will continue to inspect and evaluate the implementation of graded QA programs as part of its normal licensee oversight activities. It is my expectation that the industry and the staff will evaluate lessons learned from developing a graded approach to QA, even as industry develops QA rulemaking initiatives. It should be noted that the NRC's PRA Implementation Plan addresses the application of risk based concepts to graded QA activities. It is anticipated that the execution of this plan will result in the development of NRC guidelines for ranking plant equipment according to risk importance which will be applicable to the graded QA initiative. As the process for implementing graded QA evolves, the staff intends to conduct periodic workshops to share individual licensee experiences with the rest of the industry.

If you should have any questions, please contact me or Suzanne Black.

Sincerely,


James L. Milhoan
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cc: Jack Skolds, South Carolina Electric and Gas, Inc.
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Daryl Prisby, Commonwealth Edison - Bryon
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POLICY ISSUE
(Information)

March 10, 1995

SECY-95-059

FOR: The Commissioners
FROM: James M. Taylor
Executive Director for Operations
SUBJECT: DEVELOPMENT OF GRADED QUALITY ASSURANCE METHODOLOGY

PURPOSE:

To inform the Commission of the current status of the graded Quality Assurance (QA) initiative.

BACKGROUND:

On January 4, 1993, the Executive Director for Operations (EDO) established the Regulatory Review Group (RRG). The RRG conducted a disciplined review of power reactor regulations and related processes, placing special emphasis on the potential application of performance-based regulations and the use of risk insights.

In the area of QA, the RRG determined that the existing regulations were performance based and that 10 CFR Part 50, Appendix B contains provisions for the graded application of QA controls over activities affecting the quality of structures, systems, or components (SSCs) to an extent consistent with their importance to safety. However, the RRG noted that licensees had not availed themselves of the intended flexibility of 10 CFR Part 50, Appendix B. The RRG concluded that some of the implementing documents and guidance would need to be revised in order to implement Appendix B in a more performance-based and graded manner.

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NOTE: TO BE MADE PUBLICLY AVAILABLE IN 5
WORKING DAYS FROM THE DATE OF THIS
PAPER.

On December 16, 1993, members of the NRC staff met with representatives of the industry and the Nuclear Utilities Management and Resources Council (NUMARC) to initiate an effort to develop a consensus on a conceptual approach toward the graded application of 10 CFR Part 50, Appendix B, quality provisions. This meeting culminated with the general understanding that the current regulations allow adequate flexibility to accommodate the graded implementation of QA in a manner commensurate with the safety significance of SSCs. NUMARC proposed to develop a guidance document for implementing QA programs in a graded, performance-based manner. Specifically, the process envisioned would build upon the Maintenance Rule implementation guidance contained in NUMARC 93-01, "Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants." The Maintenance Rule implementation process, endorsed by Regulatory Guide 1.160, includes the use of an expert panel to evaluate both probabilistic risk assessment (PRA) and deterministic insights to gauge the relative safety significance of SSCs.

DISCUSSION:

Subsequent to the meeting on December 16, 1993, the staff developed a plan that identified project milestones for the graded QA project. A goal was established for implementing a pilot graded QA program in the fall of 1994. Attachment 1 contains the initial schedule that was developed by the staff.

The graded QA approach envisioned by the staff would separate SSCs into high-safety significant and low-safety significant categories with quality verification activities applied commensurate with the safety significance or safety functions of the SSCs. The scope of the SSCs covered under the proposed graded approach was considered equivalent to the Maintenance Rule (10 CFR 50.65) which includes both safety-related and non-safety-related SSCs.

The safety benefit derived from the proposed graded QA methodology would be that licensees and the NRC could apply the majority of the available quality verification and inspection resources to the equipment where the greatest safety benefit could be achieved.

A chronology of events for the graded QA project is depicted in Attachment 2. Following the public meeting on December 16, 1993, the staff conducted seven meetings of the Working Groups and three meetings of the Steering Groups with the Nuclear Energy Institute (NEI, previously NUMARC) and industry representatives. These meetings were open to the public. The primary objective of the Working Group meetings was to define a sufficiently detailed methodology for the graded application of quality provisions contained in 10 CFR Part 50, Appendix B, commensurate with the safety significance and function of SSCs. This methodology was envisioned to then be implemented in a pilot program environment. During the meetings of the Steering Groups, NRC and NEI representatives discussed conceptual aspects related to the positions and approaches developed by the NRC and NEI Working Groups.

Additionally, to facilitate the development of the graded QA methodology, the staff performed information gathering visits to three of the seven plants proposed for the pilot study. During these visits to North Anna (Virginia Power), Grand Gulf (Entergy), and Palo Verde (Arizona Public Service Company), the staff interacted with utility representatives to gain additional insights into the proposed graded QA implementation process. The four other plants proposed by NEI for participation in the pilot study to develop a graded QA methodology were Arkansas Nuclear One (Entergy), Byron (Commonwealth Edison), Crystal River (Florida Power Corporation) and Monticello (Northern States Power).

NEI provided the staff a copy of their draft "Guideline for Industry Pilot Project - Implementation of Graded Performance-Based Approach to Quality" on April 11, 1994. On April 20, 1994, the staff sent NEI comments on the draft guideline, emphasizing that the document needed additional details. During a meeting of the Steering Groups on May 12, 1994, NEI requested that the staff provide specific comments to their draft guideline. However, after further consideration, the NRC Steering Group noted that it would be more appropriate to ensure that the staff and NEI were in agreement on the fundamental concept for a graded QA program. The NRC goals and expectations for the graded QA project were conveyed to NEI on June 15, 1994 (see Attachment 3). In that letter, the staff identified the following four essential elements that a graded QA program should include:

- (1) A process that, with high confidence, will identify the appropriate safety significance of all SSCs in a reasonable and consistent manner.
- (2) An effective root-cause analysis and corrective action program.
- (3) The determination of appropriate QA controls for individual SSCs, or groups of SSCs, based upon safety function and [safety] significance.
- (4) A means of reassessing SSCs safety significance and QA related controls when new information becomes available.

Subsequently, NEI submitted a revision to its draft guidance document (see Attachment 4) on September 2, 1994. After the staff had evaluated the revised NEI guidance, the staff responded to NEI on October 14, 1994 (see Attachment 5). The staff continued to be concerned that the NEI revised draft document lacked specificity with respect to the four essential elements of graded QA that were envisioned by the staff.

The major issues identified by the staff with regard to the NEI guidance document included:

- (1) There was insufficient detail regarding the expert panel composition and function, including the associated quality element assessment process.

- (2) There was insufficient detail with respect to a corrective action program to ensure that sufficient information is maintained to conduct effective root-cause determinations and corrective action for low-safety significant SSCs. Also, an inappropriate threshold was established to initiate corrective action (e.g., a safety system functional failure).
- (3) There was insufficient justification for the proposal to conduct performance monitoring in lieu of ensuring product quality.
- (4) The guidance attempted to circumvent the applicable controls for changing QA commitments specified in 10 CFR 50.54(a).

Based on a commitment made to NEI during a meeting of the Steering Groups, the staff prepared detailed comments on NEI's guidance document and transmitted these to NEI on January 31, 1995 (see Attachment 6).

Because the NEI guidance document did not contain the requisite level of detail, the staff envisioned that two licensees would initiate a pilot project following the incorporation of fundamental staff concepts into the guidance document. The staff was prepared to actively monitor this phase of the pilot project implementation. After (1) gaining confidence in the NEI guidance document, based on the implementation results at the two lead pilot plants, and (2) supplementing the guidance document to reflect the initial lessons learned, the remainder of the pilot plants could then proceed with implementing the methodology. The staff planned to continue to actively monitor and verify the adequacy of the pilot program at the associated facilities. At the conclusion of the pilot phase, lessons learned from application of the guidance at all seven sites would be incorporated into the guidance document. The staff would then develop a draft regulatory guide endorsing the guidance and issue it for public comment.

By letter dated December 21, 1994 (see Attachment 7) NEI identified their future approach to achieve a performance-based graded QA regime. Specifically, NEI stated that it would actively encourage licensees to grade their quality programs using a blend of probabilistic and deterministic insights and that the graded QA pilot project would be deferred. Furthermore, NEI indicated their plans to forward rulemaking petitions to amend 10 CFR 50.54(a) and to enact a performance-based option to 10 CFR Part 50, Appendix B.

On February 9, 1995, the NRC responded to NEI's proposal for the future approach to a graded QA methodology. In this letter (see Attachment 8), the staff indicated its willingness to review any rulemaking petitions submitted by NEI relative to 10 CFR 50.54(a) or 10 CFR Part 50 Appendix B. The staff also stated its availability to conduct further discussions with NEI related to the concept of a performance-based Appendix B regulation that parallels the Maintenance Rule, 10 CFR 50.55. Relative to this performance-based approach, the staff stated that it continues to believe that the effectiveness of established QA programs cannot be gauged solely on the basis of plant

performance monitoring, in that the implementation of QA program controls provides assurance that plant equipment will function reliably during routine operations and during design-basis events.

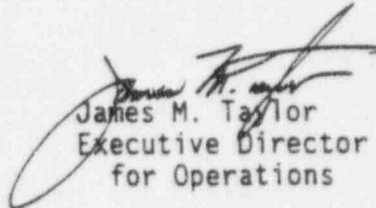
The staff indicated its willingness to continue a dialogue with the industry to address practical ways to improve the manner in which present QA controls are implemented. More importantly, the staff expressed its receptiveness to working with either individual volunteer licensees or groups of licensees to test and evaluate the implementation of graded QA concepts that would more efficiently focus resources on safety-significant aspects of plant activities and equipment.

Given that both the industry and the NRC recognize the potential benefits of implementing QA controls commensurate with safety significance, the staff agrees with NEI's recommendation to licensees to utilize both deterministic and probabilistic insights to grade their QA programs. However, if the industry moves forward with the implementation of a graded QA process on an individual licensee basis, the staff recommends that the individual licensees consider the staff's comments on the NEI graded QA guidance document. As indicated in the NRC's correspondence to NEI dated October 14, 1994, and January 31, 1995, the staff continues to have reservations regarding the completeness of NEI's guidance document. The staff considers that the NEI guidance document constitutes preliminary information applicable for use in a pilot plant environment. Accordingly, the staff comments on NEI's graded QA guidance should be considered by licensees if they utilize this information for revising their programs.

The staff recognizes that the industry's priorities have shifted since the inception of the graded QA initiative. Rather than expending resources to develop a practical methodology and demonstrate the process during a pilot program, the industry has chosen to expand its efforts into the rulemaking arena. Nonetheless, the staff considers that a significant safety benefit can be derived from continuing with the original concept of developing a workable guidance document. To that end, the staff has communicated with several licensees to ascertain their willingness to serve as a volunteer plant during the development of graded QA guidance. Although the NEI guidance document, as provided by the NRC's correspondence to NEI dated October 14, 1994, and January 31, 1995, could be used as appropriate, it is anticipated that each volunteer licensee will adjust the program to suit their individual needs and apply their efforts to different functional areas. The staff would then actively monitor the development and implementation of these volunteer plant programs. Lessons learned during these efforts would be integrated into a more generic guidance document that would then be made available to the rest of the industry. Thus, the guidance would be tested in a sequential manner to validate its completeness and workability. It is also anticipated that this pilot effort will facilitate the development of an integrated and dynamic risk management system in conjunction with NRC's PRA Implementation Plan. At present, several licensees have expressed an interest in participating in the volunteer plant process and the staff is optimistic that this effort will be initiated in the near future.

CONCLUSION:

The staff remains committed to working with individual licensees as practical approaches are developed for implementing a graded QA methodology. Individual licensees who plan on pursuing this approach are encouraged to interact with the staff as they develop their graded QA programs. The staff will continue to inspect and evaluate the implementation of graded QA programs as part of the NRC's normal safety oversight activities. It is expected that the industry and the staff will evaluate the lessons learned from developing a graded approach to QA and that these concepts will be factored into an integrated and dynamic risk management system. Additionally, as the process for implementing graded QA concepts evolves, the staff anticipates conducting periodic workshops to share individual licensee experiences with the rest of the industry. These efforts are intended to culminate in the NRC's endorsement of an industry developed guidance document or the development of a staff directive describing an acceptable graded QA methodology by the end of 1996. The staff will evaluate NEI's proposal for a performance-based QA program through rulemaking following its submittal, scheduled for this fall.


James M. Taylor
Executive Director
for Operations

- Attachments:
1. Initial Graded QA Implementation Schedule
 2. Chronology of Events for the Graded QA Initiative
 3. Letter, J.L. Milhoan to W.H. Rasin, June 15, 1994
 4. NEI Revised "Draft Pilot Project Guideline for Implementation of a Graded, Performance-Based Approach to Quality," September 1, 1994
 5. Letter, J.L. Milhoan to T.E. Tipton, October 14, 1994
 6. Letter, S.C. Black to R. Ng, January 31, 1995, Forwarding NRC Line-in/Line-out Version of NEI Revised Draft Guidance, September 1, 1994
 7. Letter, T.E. Tipton to J.L. Milhoan, December 21, 1994
 8. Letter, J.L. Milhoan to T.E. Tipton, February 9, 1995

DISTRIBUTION:

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REFERENCES

1. NRC Regulatory Review Group Report, August 1993
2. NUMARC 93-01, Rev. 1, October 1995, *Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants*
3. NUMARC 93-02, May 1993, *A Report on the Verification and Validation of NUMARC 93-01, Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants*
4. NRC Regulatory Guide 1.160, June 1993, *Monitoring the Effectiveness of Maintenance at Nuclear Power Plants*
5. NUREG/CR 5424, *Eliciting and Analyzing Expert Judgment*
6. NUREG/CR 4962, *Methods for Elicitation and Use of Expert Opinion*
7. NUREG/CR 5695, *A Process for Risk Focused Maintenance*
8. EPRI TR-105396, August 1995, *PSA Applications Guide*