NUCLEAR ENERGY INSTITUTE

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November 28, 1995

Mr. John C. Hoyle
Secretary
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

ATTENTION: Docketing and Services Branch

SUBJECT: NEI 10 CFR 50.54(a) Petition for Rulemaking – Response to NRC Request for Additional Information and Comment (60 Fed. Reg. 47716 – September 14, 1995)

Dear Mr. Hoyle:

These comments are submitted on behalf of the nuclear energy industry by the Nuclear Energy Institute (NEI)[1] in response to the subject *Federal Register* notice of the NEI petition on 10 CFR 50.54(a) and the request for additional information and comment on eight specific issues described in the notice.

General Comment:

(1) In the eight issues described in the *Federal Register* notice, comments were requested on suggested alternatives to the petition. The industry has significant reservations regarding two of these suggested alternatives.

(a) The use of a "departure from commitment" standard as the threshold for requesting NRC approval prior to implementation. The industry believes that the adoption of such a threshold would be a regressive step in regard to the protection of public health and safety. Licensee and

[1] NEI is the organization responsible for establishing unified nuclear industry policy on matters affecting the nuclear energy industry, including regulatory aspects of generic operational and technical issues. NEI's members include all utilities licensed to operate commercial nuclear power plants in the United States, nuclear power plant designers, major architect /engineering firms, fuel fabrication facilities, materials licensees, and other organizations and individuals involved in the nuclear energy issue.

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NRC management would be required to address all matters described in a licensee's quality assurance program description, whether or not there is a nexus to safety. This has the potential of diverting licensee and NRC attention and resources from safety-significant matters, increasing the probability of not identifying a safety-significant issue.

(b) Separate change process and mechanism for review and audit functions is suggested in Issue 3. The industry believes that such a measure would further decrease the coherency and consistency of the regulatory process that was a recommendation in the NRC's 1993 Regulatory Review Group Report. The process of implementing the regulations would become more complex, increasing the potential for confusion, misunderstanding and misinterpretation. There would be two different change processes for matters described in the same licensee-controlled document, the quality assurance program description, implementing a common NRC regulation, 10 CFR 50 Appendix B.

In both these instances, the licensee and NRC administrative and regulatory burden would be increased without any corresponding increase in safety. Such a change would be contrary to the recent Administration and Congressional initiatives for improving the federal regulatory process, and contrary to the recommendations in the 1993 NRC Regulatory Review Group Report. Enclosure 1 provides additional amplification on these two issues, and on the other issues described in the *Federal Register* notice.

(2) The notice suggested that the petition had not addressed the impact or provided the rationale for deleting 10 CFR 50.4(b)(7)(i) from the NRC regulations. The NEI petition submitted on June 8, 1995, included the following statement:

"10 CFR 50.4(b)(7), *Quality assurance related submittals (i)* :

This paragraph has been deleted. There is no reason for requiring a separate administrative reporting requirement for changes to the quality assurance program description included or referenced in the Safety Analysis Report. Administrative reporting requirements for changes to the facility, its programs, procedures, tests or experiments

that are described in the Safety Analysis Report should be treated in a consistent manner. The administration of the regulatory process should be as efficient and as consistent as possible through the optimization of the administrative process.

Sub-paragraph (ii) of 10 CFR 50.4(b)(7) is not amended because the requirement is unique to nonlicensees (i.e., architect/engineers, NSSS suppliers, fuel suppliers, constructors, etc.)."

Section 10 CFR 50.4(b)(6) addresses written communication requirements associated with updating a licensee's Final Safety Analysis Report. A licensee's quality assurance program description is included or referenced in its (Final) Safety Analysis Report (SAR). The petition proposes a change process for a licensee's quality assurance program description based on the same change process as for other matters, including programs, described in a licensee's SAR. There is no reason to have different change mechanisms, or different reporting requirements, for matters described or referenced in a licensee's SAR. A common set of update and reporting requirements for all matters described in a licensee's SAR would improve regulatory coherency, consistency and efficiency.

The petition requires a licensee to inform the NRC of changes made to its quality assurance program description during the periodic updates of its SAR. The impact of deleting the Section 50.4(b)(7)(i) requirement is that it will improve the regulations. The estimated cost savings associated with the deletion of the Section 50.4(b)(7)(i) requirement are included in the estimates provided in the petition, and amplified in the industry responses to the eight issues described in the *Federal Register* notice.

Enclosure 1 provides NEI's response to the request for input and additional comment. A draft industry guideline with examples to assist licensees in implementing and interpreting the petition is included as part of the NEI response to the *Federal Register* notice. Naturally, the guideline would not be issued until the rule is finalized and NRC comments have been addressed.
NEI would be pleased to discuss with the NRC staff the NEI response to the request for additional information and comment on the 10 CFR 50.54(a) petition, and the draft guideline, with the intent of improving the regulatory process and interface associated with changes to a licensee's quality assurance program descriptions.

If you have any questions or comments, please contact Steve Floyd (202) 739-8078 or Adrian Heymer (202) 739-8094 of the NEI staff.

Sincerely,

Thomas E. Tipton

TET/ljw
Enclosures

c: Mr. William T. Russell (Director, NRR, NRC)
Ms. Karen D. Cyr (General Counsel, NRC)

Enclosure 1
Response to NRC Requests for Comment on NEI's Petition on 10 CFR 50.54(a)

Issue 1: 10 CFR 50.54(a) was issued on January 10, 1983, to correct instances where licensees had changed their programs that resulted in some unacceptable programs without informing the NRC. What assurances exist to prevent a similar situation from recurring if the petition and the revised threshold for reporting QA program changes is adopted? Is it necessary that such situations be prevented from occurring by adoption of a regulatory approval system?

Comment

As stated in the NEI petition, the original concern of the Commission which prompted the issuance of 10 CFR 50.54(a) in 1983 is still being addressed. The NRC had become concerned that some licensees were making changes to their quality assurance programs that were unacceptable and could increase the risk to the public health and safety.

> ".....some licensees have been changing their quality programs without informing the Commission. In a few cases this has resulted in QA programs which were not acceptable to the NRC staff and which did not conform to all aspects of the NRC regulations. The primary concern with the current situation is that unreported changes to the QA program might diminish the scope of the program permitting significant deficiencies to arise in the design, fabrication, construction, or operation of the facility. This could increase the risk to the public health and safety" (48 Fed. Reg. 1026, January 10, 1983).

The Commission's main concern was that changes could be occurring that presented the potential to degrade public health and safety. The language in the regulation addressed the potential safety degradation issue by linking it to a reduction in commitment as described in the quality assurance program description previously accepted by the Commission. Since its issuance in 1983, there has been significant, and often unnecessary, regulatory and intra-industry discussion on the interpretation of Section 50.54(a) with respect to the term, "...does not reduce the commitments...", even for matters that have no, or minimal safety significance.

In contrast, the use of the Section 50.59 change process for matters described or referenced in the SAR has been relatively free from the debates that are sometimes associated with Section 50.54(a) changes. Licensees routinely use the Section 50.59 criteria to evaluate equipment and non-hardware related changes to procedures and programs described in the SAR. In general, the implementation of the Section

50.59 change process has been successful and acceptable from a regulatory perspective.

The NEI petition builds on the experiences of the past twelve years in attempting to interpret and implement the regulation from a perspective of its impact on public health and safety. The petition addresses the concerns described in the Statements of Consideration for the original rule in a more effective and efficient manner by providing a greater emphasis and focus on safety. The petition basis is a well proven regulatory process, the Section 50.59 process. It requires a licensee to inform the NRC of all changes to its quality assurance program description, included or referenced in its Safety Analysis Report. In addition, for changes that present a potential to degrade safety, as determined by an evaluation against the criteria described in the petition (as amplified in the guideline attachment to these comments), or that result in a change to the Technical Specifications, the petition requires a licensee to seek NRC approval prior to implementation. Such requirements still ensure that the concerns which caused the Commission to issue the initial rule in 1983 do not recur.

Currently, when considering changes to its quality assurance program, a licensee is uncertain of the resource burden associated with processing and implementing the change, even for simple changes that have no, or minimal safety significance. This uncertainty is because of the variance in interpretations on the term "reduction in commitment". Such uncertainties discourage licensees from pursuing more significant improvements to their quality assurance program descriptions that could benefit public health and safety.

The industry recognizes the importance of an effective and efficient quality assurance program in respect to safety. Further, experiences in the global non-nuclear industries, as well as the U.S. nuclear sector adequately demonstrate the importance of effective quality programs in the commercial marketplace. In general, facilities with good quality programs and practices have good safety assessment reports, high capacity factors and low operating costs. It is not in a licensee's interest to implement changes that only are focused on improving efficiency and productivity, and not on improving quality. In a competitive generating marketplace, there is significant financial incentive for licensees to have superior quality programs that assure safety and economic performance.

The only difference in the proposed petition and the existing regulation is that the petition appropriately places emphasis on safety rather than a reduction in commitment. The petition provides added impetus for licensees to pursue improvements to their quality programs and eliminates the uncertainty over resources associated with implementing improvements to their quality assurance programs. As such, the petition, when implemented, would enable licensee and NRC attention and resources to be more appropriately focused on safety significant matters, enhancing the protection of public health and safety.

Issue 2: **Traditionally, the NRC staff has used a variety of documents such as the NRC Standard Review Plan, NRC Regulatory Guides, and associated industry consensus standards to delineate what QA program elements are necessary to meet Appendix B. Should these standards continue to be used to define acceptable QA programs? Should a licensee QA program change that constitutes a departure from a commitment to comply with a specific regulatory position be considered of sufficient importance that the NRC should be notified in advance of implementation? How would such changes be evaluated under the petitioner's proposed criterion?**

Comment

The NRC regulations provide for the protection of public health and safety. The NRC's quality assurance regulations, when implemented, provide reasonable assurance that the pertinent safety functions will be satisfactorily accomplished, thus assuring the protection of public health and safety.

The NRC Standard Review Plan, regulatory guides and the associated industry consensus standards are general guidance on approaches to satisfy the NRC regulations. It is acknowledged that other implementation methodologies and practices also can satisfy the regulations. Licensees must meet the requirements of Appendix B regardless of implementation strategy. The focus of licensee reviews and submittals, NRC reviews, and regulatory interactions should be on safety and satisfying the regulations, not a departure from an existing regulatory commitment, or on a departure from an NRC accepted industry standard or generic guidance document in an area that may be of no, or minimal safety significance.

When assessing any change, a licensee's first and most important task is to assure safety. As a result, the petition places emphasis on the safety implications of a change. It ensures that the NRC is informed of all changes to a licensee's quality assurance program description, with NRC approval being required prior to implementation for changes that could have implications to safety (i.e., present an unreviewed safety question or result in a change to the Technical Specifications incorporated in a license).

The benefits of making a change in accordance with an NRC accepted industry standard or guidance document are associated with implementation resources and the management of the regulatory interface. In the case of implementing NRC accepted industry standards or guidance documents, the regulatory costs (both industry and NRC) should be minimal, because the standard or plan has already been reviewed and endorsed. The decision on whether to adopt an NRC accepted industry standard or guidance document, or the degree to which that standard or

guidance is implemented, are predominantly economic and ease of implementation decisions. Naturally this assumes that the alternative approach accomplishes the same function, output, or result from a safety perspective.

Licensees should be afforded the regulatory flexibility to deviate from existing guidance to improve their quality programs, without prior NRC approval providing they continue to meet the regulations. Such a regime will encourage licensees to seek ways to further improve their programs without the resource uncertainties of the current change process.

Since its issuance in 1983, the industry and the NRC staff have struggled to reach a consistent understanding on the term "provided the change does not reduce the commitments". There have been numerous instances of rigid interpretation by the industry and the NRC staff that have throttled the drive for improvement in quality programs or safety (see response to Issue 1).

A "departure from commitment" threshold for seeking NRC approval prior to implementation is inappropriate. Its adoption would be a regressive step with respect to the protection of public health and safety. It increases the potential for distracting licensee and NRC management attention from matters of safety significance as they are obligated to address all matters described in a licensee's quality assurance program description, even for those where there is no nexus to safety.

Recently, the industry and the NRC reached a general understanding on a process for licensees to use in managing licensee commitments to the NRC. In this process, potential safety impact is the determining factor in seeking prior NRC review and approval. The change process for regulatory commitments should be consistent, no matter the topic, whether associated with design, operations, or quality assurance. Such an approach, as defined in the industry *Guideline for Managing NRC Commitments*, enhances regulatory coherence and provides an appropriate and consistent focus on matters that could impact the protection of public health and safety. The important regulatory measure is whether safety is impacted, not whether there has been a departure from, or reduction in, a regulatory commitment.

The petition places a different emphasis on the change process than currently prescribed in Section 50.54(a). The emphasis is similar to that used in the process for managing NRC commitments and for performing Section 50.59 changes, one of safety and meeting the regulations, not a reduction in commitment. It focuses on the differences in the program description element being changed, as it relates to safety. A licensee determines whether the differences in the program description result in a decrease in public health and safety, as measured by potential equipment malfunctions and general qualitative or quantitative risk evaluations

that are assessed to be beyond those analyzed in its Safety Analysis Report, or result in a change to the Technical Specifications incorporated in its license. The process is described in the attached draft guideline.

Issue 3: **The NRC has allowed licensees to relocate administrative controls for review and audit functions from the Technical Specifications. Examples include details on safety review committees, audits, and technical review functions. These have been relocated to the QA program based on the existing change control provisions in § 50.54(a). Would it be appropriate for activities such as safety review committees, independent technical review groups, and audits to be controlled so that only licensee changes exceeding the threshold of an unreviewed safety question (USQ) be reported to the NRC for pre-review before implementation? What kind of changes to a licensee's QA program would constitute a USQ? Assuming that the USQ should/could be applied, does not the use of § 50.59 effectively negate the administrative and regulatory advantage of removing this information from Technical Specifications (because both Technical Specification changes and USQs are subject to an opportunity for hearing)? If the revised QA change control mechanism is adopted, should aspects of the review and audit functions remain in the QA program or be relocated elsewhere to ensure appropriate NRC review of changes prior to implementation?**

Comment

The 1993 NRC Regulatory Review Group Report emphasized the need for consistency and coherence in the NRC regulations and identified 10 CFR 50.54(a) as an example of incoherency and inconsistency in the regulations and their implementation. For a number of licensees, the administrative controls for review and audit functions are described in their SAR, and in some cases these controls are duplicated in the Technical Specifications of their licenses.

Through the Technical Specification Improvement Program, the NRC allowed licensees to relocate these administrative controls from the Technical Specifications to "....other licensee documents for which changes to those provisions are adequately controlled by other regulatory requirements" (*NRC Letter to Owners' Groups Chairpersons,* dated October 25, 1993). As such, the NRC is assured that a licensee's change process for these administrative controls will continue to ensure that safety is maintained at a level that provides for the protection of public health and safety. The NRC reaffirmed its position in a letter to the Owners' Groups Chairpersons on January 17, 1995,

"The Owners' Groups submitted proposed changes to the standard technical specifications (STS), ... by relocating many of the provisions to licensee-controlled documents, in accordance with the letter from W. Russell dated October 25, 1993. Several of the provisions previously included in the administrative controls would be allowed to be relocated to licensee-controlled documents, such as the Quality Assurance Program (QAP)...".

Licensees routinely use the criteria of Section 50.59 to evaluate non-hardware related changes to procedures and programs described in the SAR. Some licensees may wish to include these controls in their quality assurance programs; others may wish to simplify the process and keep them in existing SAR sections, for which there is a satisfactory and well proven regulatory change process, the Section 50.59 process. In either case, changes are subject to regulatory controls that assure the protection of public health and safety.

The QA program is the only SAR described program not evaluated under Section 50.59. The petition remedies this inconsistency.

The petition requires licensees to inform the NRC staff of all changes to its quality assurance program description, and for changes that have the potential to degrade safety, (i.e., present an unreviewed safety question, seek NRC approval prior to implementation). The proposed change process, when approved by the Commission, would become a regulatory controlled change process that improves the focus on safety. As such, the process would be consistent with the understanding reached in the Technical Specification Improvement Program interactions.

The Section 50.54(a) petition improves the coherence and consistency of the NRC's regulations and their implementation. It provides for a similar change process to the Section 50.59 change process. The Section 50.59 process has been proven over time, with the NRC staff being notified of changes to matters described in the SAR, and with the requirement for an NRC approval prior to implementation for changes that present an unreviewed safety question, or result in a change to the Technical Specifications. Also, the amendment is consistent with the concepts and understandings recently discussed in the regulatory interactions on managing NRC commitments, one of focusing on safety.

The 1993 NRC Regulatory Review Group Report recommended an approach similar to Section 50.59 for managing licensee commitments to the NRC. Such an approach would be based on an evaluation of whether an unreviewed safety question is involved. The industry's *Guideline for Managing NRC Commitments* reflects such an methodology. The NEI petition is consistent with the approach and concepts described in the industry's *Guideline for Managing NRC Commitments.* There should be no distinction in the method or focus for assessing a change to a commitment, be it a QA commitment or any other commitment. It should be

associated with the potential to degrade safety, i.e., present an unreviewed safety question.

Since the issuance of 10 CFR 50.59 in 1974, there have been only a few instances of licensees requesting approval for changes that involve unreviewed safety questions. In general, licensees withdraw changes that involve an unreviewed safety question, or amend the change so that it no longer presents an unreviewed safety question before making the decision to proceed with implementation. Should a licensee decide to proceed with a change that involves an unreviewed safety question, then in accordance with the requirements of Section 50.59, the change is processed as a license amendment per the requirements of 10 CFR 50.90. In such cases, there is an opportunity for a hearing. The potential for a hearing under Section 50.59 is not increased until the licensee decides to pursue a change through a license amendment, per the requirements of Section 50.90.

Experience with implementing the Section 50.59 process indicate that the benefits of a more predictable and stable regulatory environment, the resulting improvements in the efficiency of managing the regulatory interface, and the benefits of increased regulatory flexibility significantly outweigh any burden associated with the opportunity for a hearing for changes that constitute an unreviewed safety question, or require a change to the Technical Specifications.

Regulatory consistency and efficiency would be increased by reducing the number of different types of change processes for similar regulatory practices, regulations and matters described in the SAR. Review and audit functions are fundamental components of any quality assurance program. More importantly, for a particular regulation, viz., 10 CFR 50, Appendix B, there should be one change control process. To invoke a different change process for different elements within an existing program or regulation, e.g., the quality assurance program (10 CFR 50, Appendix B), adds unnecessary complexity to the regulatory process, increasing the potential for confusion and misinterpretation. It will result in a fragmented regulatory process, increased regulatory inconsistency and incoherency, and reduced regulatory predictability and stability.

The adoption of a different change mechanism for review and audit functions would be a regressive regulatory step, increasing the administrative and regulatory burden on licensees and the NRC. As such, the proposal to introduce a different change mechanism for review and audit functions would be contrary to the recent Administration and Congressional initiatives for improving the regulations.

The attached guidance document for implementing the petition provides examples of changes that could constitute an unreviewed safety question.

Issue 4: Are there alternative thresholds for determining whether a licensee must submit their QA program changes for advance review in lieu of the USQ threshold? Provide a technical and/or policy explanation as to why this or any other threshold would be more appropriate.

Comment

Alternative thresholds for determining when a licensee should submit changes to its quality assurance program description for NRC review and approval prior to implementation include: (1) the adoption of the same standard as described in Sections 50.54(p) and (q), one of decreased effectiveness, and (2) the deletion of Section 50.54(a), with the change process for quality assurance program commitments being incorporated into the process described in the industry's *Guideline for Managing NRC Commitments.*

Industry discussions, NRC briefings and the NRC 1993 Regulatory Review Group Report have emphasized the need for increased consistency in the regulatory process. These comments reinforce the need for simplifying the regulations by reducing the number of change processes for specific regulations, or matters described in the SAR, to a single process.

The threshold for the proposed change process described the NEI petition includes an element that relates to assessing the impact of a decrease in program effectiveness with respect to safety (also see comments on Issue 5 and the attached guidance document). The petition proposes a threshold for seeking NRC approval prior to implementation as being an unreviewed safety question, or a change to the Technical Specifications. Such a process is consistent with the process developed for managing NRC commitments and the Section 50.59 change process.

The change process for matters described in the SAR (the Section 50.59 process) is understood and well established. A consistent change process should be used for all matters described in the SAR, with the focus for seeking NRC approval prior to implementation being one of possible safety degradation. The use of different change processes for different subjects described in the SAR (i.e., QA program description) unnecessarily complicates regulatory regime. Such complexities present the potential for distracting and diverting licensee and NRC attention and resources from matters of safety significance that could present the potential for degrading public health and safety.

The NRC is notified of changes made pursuant to the Section 50.59 process, with NRC approval being required for changes that involve a change to the Technical Specifications or an unreviewed safety question. Its implementation process is

documented in established industry guidance documents that are generally acceptable to the NRC. The process is understood by the industry and the NRC, and has been proven over time.

The industry believes that the optimum approach for making changes to a licensee's quality assurance program description is through a process that is similar to Section 50.59. Such a change builds on a well proven process, improves the consistency and coherency of the regulations, enhances regulatory predictability and improves safety. Additional draft guidance with examples has been developed to assist licensees in implementing programmatic changes, and is attached to these comments.

Issue 5: **The NRC Regulatory Review Group (RRG) examined change control mechanisms in § 50.54 for control of licensee plans and programs (quality assurance, security, and emergency preparedness). The RRG recommended that licensees should have greater flexibility to make changes in their programs without having to receive prior NRC approval. Currently, QA program changes that "reduce the commitments in the program" are submitted for NRC staff review before implementation. Similarly, security plan changes that "decrease the effectiveness" are submitted for staff review before implementation. Should the staff consider a revision to § 50.54(a) to set the threshold for reporting QA program changes for NRC pre-review that constitute a decrease in effectiveness? Would a "decrease in effectiveness" standard in § 50.54(a) provide a sufficiently flexible and technically reasonable criteria for licensees to report QA program changes to the staff before implementation?**

Comment

As described in the comments on Issue 4, above, the industry discussed a "decrease in effectiveness" option during its deliberations on the petition prior to its submittal. The industry's conclusions are documented in the petition: the optimum change process for amending a licensee's quality assurance program description is a process modeled on the Section 50.59 process.

For a "decrease in effectiveness" threshold to be effective, the following criteria are essential:

(1) Does the changed quality assurance program description meet the requirements described in 10 CFR 50, Appendix B, consistent with the importance to safety?
(2) Does this change contradict any regulatory requirement?

(3) Would this change result in a change to the function(s) described in a licensee's quality assurance program description that would impact the ability of the safety significant structures, systems and components to satisfactorily perform their safety functions, or inhibit licensee personnel from making a safety determination?
(4) Does this change any licensee commitment to an extent that safety is potentially degraded?

In assessing the above criteria, a licensee would focus on whether the proposed change could cause a decrease in program effectiveness with respect to safety; i.e., does the change produce an unreviewed safety question. These are the same issues that are evaluated when considering a change to the SAR using the Section 50.59 process, and the same issues as described in the industry's *Guideline for Managing NRC Commitments*. As such, the implementation process should be the same as for the Section 50.59 process; the process described in the proposed petition, and the associated guideline (Attachment 1). However, these criteria and the associated implementation regime are significantly different to those established for assessing a "decrease in effectiveness" threshold for requiring NRC approval that was recently established by NRC Generic Letter 95-08 dated October 31, 1995, *10 CFR 50.54(p) Process for Changes to Security Plans without prior NRC Approval.*

In 1994 and 1995 the NRC staff and industry discussed the development of a change process for a licensee's security plan based on Section 50.59 concepts. The industry concluded that a security plan, while ultimately associated with plant safety, is focused on the prevention of unwanted substances and personnel from entering the facility and taking actions that could result in an event that ultimately endangers public health and safety. In addition, the security plan is not included as part of a licensee's SAR. As such, it was considered that the use of a Section 50.59 process would not be appropriate.

NRC Generic Letter 95-08 provides a clarification of the term "decrease in effectiveness" as used in Section 50.54(p) in the form of two screening criteria: (1) a change in any of the three security plans is deemed not to decrease the effectiveness of the plan if the change does not decrease the ability of the onsite physical protection system and security organization, as described in paragraphs (b) through (h) of 10 CFR 73.55, or equivalent measures approved under 10 CFR 73.55(a), to protect with high assurance against design basis threat as stated in 10 CFR 73.1(a); and (2) a change that increases the effectiveness of any plan.

In addition to the above criteria, the generic letter includes three questions to assess the impact on the effectiveness of a security plan. (1) Does this change delete or contradict any regulatory requirement? (2) Would the change decrease the overall level of security system performance as described in paragraphs (b) through (h) of 10 CFR 73.55 to protect with the objective of high assurance against the

design basis threat of radiological sabotage as stated in 10 CFR 73.1(a)? (3) For any licensee that has NRC approved security plan commitments of 10 CFR 73.55(b) through (h): does this change decrease the overall level of security system performance needed to protect with the objective of high assurance against the design basis threat of radiological sabotage as stated in 10 CFR 73.1(a)?

The purpose of 10 CFR 50, Appendix B is to provide reasonable assurance that safety related SSCs will satisfactorily perform their intended safety functions. The criteria of Section 50.59 are directly applicable to this purpose. The EP and security regulations are not directly related to ensuring that the safety related functions of the plant are satisfactorily accomplished. Therefore, it could be appropriate to have different criteria, i.e., a "decrease in effectiveness" criteria for the EP and security regulations.

As indicated in the preceding paragraphs, the imposition of a "decrease in effectiveness" threshold for QA program description changes would result in three different interpretations for the same term in a single NRC regulation (10 CFR 50.54). It would introduce additional complexity and incoherency into the regulations by establishing yet another, different interpretation of a term that is already used in Section 50.54 for security and emergency preparedness. As such, the imposition of such a term for QA increases the administrative and regulatory burden on the licensee and NRC staff. The imposition of such a threshold would further reduce the coherency and consistency of the regulations in an area that was identified in the 1993 NRC Regulatory Review Group Report as being an example of incoherency and inconsistency in the regulations.

A "decrease in effectiveness" threshold increases the potential for the diversion of resources from matters of safety significance to matters of regulatory, administrative significance. Such a regime would increase the potential for degrading the protection of the public health and safety.

Currently, there are Congressional and Administration initiatives to improve the efficiency of federal regulations and their implementation. In addition, the industry is striving to improve productivity as it faces the increasing competitive demands of the electrical generation marketplace. With these ongoing initiatives, it is important to increase the focus of regulatory activities on matters that have safety significance. In such a changing and dynamic environment, it is important that licensee and NRC staff not become distracted by protracted discussions on matters that have minimal, or no safety significance, increasing the potential for not properly focusing on, and identifying issues of, significant safety significance.

The change process described in the industry's petition provides a licensee with increased, yet bounded, regulatory flexibility that will engender further licensee initiated improvements to quality assurance program descriptions. As such, the petition is consistent with another recommendation in the 1993 NRC Regulatory

Review Group Report for increased licensee flexibility in regard to making changes to its quality assurance program description without the need for NRC approval prior to implementation for matters that do not present an unreviewed safety question or change the Technical Specifications.

Issue 6: **Should the NRC staff consider retaining the current language of § 50.54(a) and to define explicit guidance or identify examples on what types of QA program changes would be considered to "reduce the commitments in the program"? By developing this guidance could sufficient flexibility be afforded to licensees to make changes in their QA program without having to undergo a pre-review by the staff?**

Comment

The purpose of the NRC regulations is to provide adequate protection of public health and safety. The focus of implementing the regulations should be on safety, not on whether the change reduces a commitment which may have no nexus to safety.

As stated in the petition, since the issuance of 10 CFR 50.54(a) in 1983, licensees and the NRC have struggled over the interpretation of the term "provided the change does not reduce commitments". There have been numerous instances of rigid interpretation of the regulation by industry and NRC staff for changes that have no nexus to safety. The regulation needs to be changed to eliminate ambiguity, uncertainty and inconsistency of the current regime for implementing Section 50.54(a) (also see responses to Issue 1 and Issue 2).

The development of additional NRC guidance would not address the root cause of the problems experienced over the past twelve years in implementing the regulation. The recommendations of the 1993 NRC Regulatory Review Group Report, and the Congressional and Administration initiatives to improve the efficiency and effectiveness of the federal regulations, support the intent of the industry's petition: the introduction of a regulation that would improve the consistency, efficiency and effectiveness of regulatory process, improving productivity, yet ensuring the maintenance of public health and safety.

The term "provided the change does not reduce commitments" continues to result in misinterpretation, miscommunication, and misunderstandings. It increases the unpredictability in the regulatory regime, thereby reducing regulatory efficiency and effectiveness. The industry experiences over the past twelve years indicate that the regulation needs to be amended to refocus licensee and NRC attention on matters of safety significance.

Issue 7: **The petition proposes to apply a § 50.59 process to evaluate QA program changes to determine the necessity for pre-review by the staff. Industry guidance for § 50.59 exists within NSAC-125 "Guidelines for § 50.59 Safety Evaluations." NSAC-125 appears to contain little relevant guidance that would be helpful for determining whether QA programmatic changes would constitute a USQ that requires NRC pre-review of the change. In particular, Section 4.2 of NSAC-125 deals principally with evaluating changes associated with nuclear plant equipment and not programmatic controls. Is existing guidance for processing 10 CFR 50.59 evaluations sufficient for evaluating QA program changes? What factors or aspects of the existing industry guidance would need to be supplemented? What types of QA program changes would be necessary to report to the NRC if the current § 50.59 criteria were applied to QA program changes? What are examples of QA program changes that should be considered as meeting the USQ threshold?**

Comment

The petition proposes the use of a 50.59 type change process. The general concepts and implementation of such an approach are described in established industry guidance documents. The NRC staff has acknowledged that licensees implement Section 50.59 requirements in an acceptable manner. Attached to these comments is additional guidance that, when read in conjunction with the established industry guidance on implementing Section 50.59 safety evaluations, will further assist a licensee in assessing and implementing programmatic changes using a Section 50.59 type process. The guidance also includes examples of changes that would be sent to the NRC for review and approval prior to implementation.

Additionally, Section 50.59 applies to changes to the facility, programs and procedures, as described in the SAR. Licensees routinely use the criteria of Section 50.59 to evaluate non-hardware related changes to procedures and programs. The QA program is the only SAR described program not evaluated under Section 50.59. The petition remedies this inconsistency.

The petition proposes that all changes to a licensee's quality assurance program description are reported to the NRC. For changes that would result in a Technical Specification change or present an unreviewed safety question, as defined in the attached guidance document, the proposed change is submitted to the NRC for approval prior to implementation.

Issue 8: Would the protection of public health and safety be enhanced if the petition were granted, and if so, in what way? What licensee and NRC costs would be reduced, or increased, if the petition were granted?

Comment

The petition, when implemented, will improve the focus of licensee and NRC attention and resources on matters that present the potential for degrading safety, rather than on a myriad of issues that are associated with a reduction in commitment, yet have no, or minimal safety significance. As such, the protection of public health and safety will be improved by increasing licensee and NRC attention and resources on matters of safety significance.

The majority of changes to a licensee's quality assurance program description are administrative. In general, under the change process described in the petition, and as amplified in the attached draft guideline, the cost of making changes to a licensee's quality assurance program description would be reduced. It is acknowledged that even under the proposed change process described in the petition there are implementation costs. Yet, because the majority of changes would be classified as administrative, or be assessed as achieving the same intent as the existing program description, in a more effective and efficient manner (see Attachment 1), the savings in licensee and NRC resources utilized in processing changes could be significant.

In preparation of the petition, cost benefit estimates on implementing the change process described in the petition were developed and compared with the estimated costs of the current process. There was significant variance in the estimated savings that were, in general, approximations based on the resources expended in implementing Section 50.54(a) changes over the past five years. The estimated savings ranged from $3,000/unit/year, to $45,000/unit/year, which translate into industry wide savings of between $330,000/year to $4.9 million/year.

It should be noted that not all licensees capture costs in the same manner. In several instances, licensee management costs associated with specific regulatory or licensing interactions were not included because these licensees do not use unique accounting entries for specific regulatory interactions. In other cases, estimates were made on the licensee management costs and included in the estimates used in the petition. Naturally, these estimates only reflect the savings from implementing the new change process.

None of the cost estimates included NRC costs. The industry believes that the NRC resource burden would also be reduced through the approval of the petition. The NRC resource burden for assessing changes to a licensee's quality assurance

program would be reduced because of a decrease in the number of licensee submittals for NRC approval prior to implementation. The reduction in NRC resources would increase the estimated savings for processing changes to licensees' quality assurance program descriptions because of the 100% licensee fee recovery structure for NRC expenditures.

It is acknowledged that there are costs associated with processing a change per the process described in the petition. These implementation costs increase as a licensee proceeds through the process. NEI estimates that the costs associated with processing a change that involves NRC review and approval prior to implementation, would be at least equivalent to the costs associated with the existing change process. As such, the potential economic burden and degree of uncertainty with pursuing such changes that require NRC approval prior to implementation is a significant and additional disincentive to proposing changes that involve an unreviewed safety question or Technical Specification change.

As a result, a licensee would only pursue a change involving an unreviewed safety question if there were substantial and quantifiable benefits. A review of Section 50.59 changes indicate that only under exceptional circumstances, and only where there are significant and quantifiable benefits, do licensees pursue changes that require NRC review and approval prior to implementation, i.e., pursue changes that involve an unreviewed safety question.

If the industry's petition is granted, it will result in a more consistent, effective and efficient change process for a licensee's quality assurance program description. The change will encourage and promote a better focus of licensee and NRC resources on matters of safety significance instead of utilizing regulatory resources on matters that have minimal or no safety implications. The cost effectiveness of the regulatory regime from a safety perspective will be improved.

DRAFT

Attachment 1 to Enclosure 1 of NEI Comment Letter on 10 CFR 50.54(a) Petition

NEI - XX-YY

GUIDELINE FOR QUALITY ASSURANCE PROGRAM DESCRIPTION CHANGES PER 10 CFR 50.54(a)

GUIDANCE FOR IMPLEMENTING CHANGES TO QUALITY ASSURANCE PROGRAM DESCRIPTIONS PER 10 CFR 50.54(a)

TABLE OF CONTENTS

1.0 INTRODUCTION

This document is designed to provide additional guidance to a licensee effecting a change to its quality assurance program description included or referenced in its Safety Analysis Report (SAR) per the requirements of 10 CFR 50.54(a).

This guidance should be read in conjunction with NSAC-125, *Guidelines for 10 CFR 50.59 Safety Evaluations,* because of the similarity between the requirements of the two change processes: evaluating whether a proposed change involves an unreviewed safety question or a change to the Technical Specifications. This document provides additional clarification to assist licensees in making the correct interpretation for changes that are of a programmatic nature associated with quality assurance. Examples to assist in interpretation and implementation are provided in Appendix A.

In the past some licensees have experienced difficulties in using the Section 50.59 criteria to evaluate non-hardware related changes to procedures and programs that are described in the SAR. This guidance is designed to provide some additional insights to assist licensees in making similar programmatic changes associated with quality assurance. Some licensees may determine that their current Section 50.59 implementation regime for procedural and programmatic changes to matters described in the SAR is satisfactory. In such cases, those licensees might make the determination not to adopt this guideline.

2.0 BACKGROUND

In 1983, the NRC issued a new regulation, 10 CFR 50.54(a), governing changes to a licensee's quality program description included or referenced in its SAR. The regulation was introduced as a result of a concern that licensees were not informing the NRC of changes to their quality assurance program descriptions that presented a potential to impact safety. The rule permitted a licensee to make changes to its quality assurance program description included or referenced in its SAR, providing the change did not reduce the commitments in the program description previously accepted by the NRC.

In 1993, the NRC performed a regulatory review of power reactor regulations and related programs, processes and practices with special attention focused on the feasibility of substituting performance-based regulatory requirements and guidance for the prescriptive requirements and guidance of that time. The NRC Regulatory Review Group Report, dated August 1993, concluded that the regulatory burden on licensees could be reduced if each licensee were held to a consistent set of requirements provided by the NRC's regulations. The NRC report identified specific examples of inconsistency and incoherence in the regulations and in

associated administrative requirements. The regulatory change process for a licensee's quality assurance program description, 10 CFR 50.54(a), was given as an example.

The Nuclear Energy Institute's Appendix B Working Group recommended the submittal of a petition to amend Section 50.54(a) in 1994, to provide for a consistent change process for matters described or referenced in the SAR. Specifically, the working group recommended a process, similar to the proven change process for 10 CFR 50.59, for establishing a threshold for seeking prior NRC approval for changes to a licensee's quality program description. The working group advised that such a change would improve regulatory consistency, efficiency and predictability, emphasizing that a single change process for changes to the facility, its procedures, tests or experiments, or other matters described in the SAR would reduce the burden on licensees and the NRC staff. The working group maintained that the threshold for seeking prior NRC approval should be one of safety significance, not reduction in commitment.

In June 1995, NEI submitted a petition to amend Section 50.54(a). The petition proposed changing the regulation to:

(a) Require a licensee to implement a quality assurance program pursuant to 10 CFR 50.34(b)(6)(ii);

(b) Provide a licensee the flexibility to make changes to its quality assurance program description, providing the change does not result in a change to its Technical Specifications or involve an unreviewed safety question; and

(c) Inform the NRC staff of the change as part of a licensee's standard SAR reporting and revision update requirements.

3.0 GUIDANCE

This guidance on changes to a licensee's quality program description, included or referenced in its SAR, supplements the guidance given in established industry guidance documents (NSAC-125) for changes to the facility and procedures that are described in the SAR, or to tests and experiments that are not described in the SAR.

The revised change process focuses licensee and regulatory attention and resources on matters of safety significance affected by a proposed change to a licensee's quality assurance program description. Further, it requires the NRC to be informed of a change as part of the routine SAR reporting and update requirements, unless the change involves an unreviewed safety question or a change to the Technical Specifications.

Change Process for Implementing 10 CFR 50.54(a)

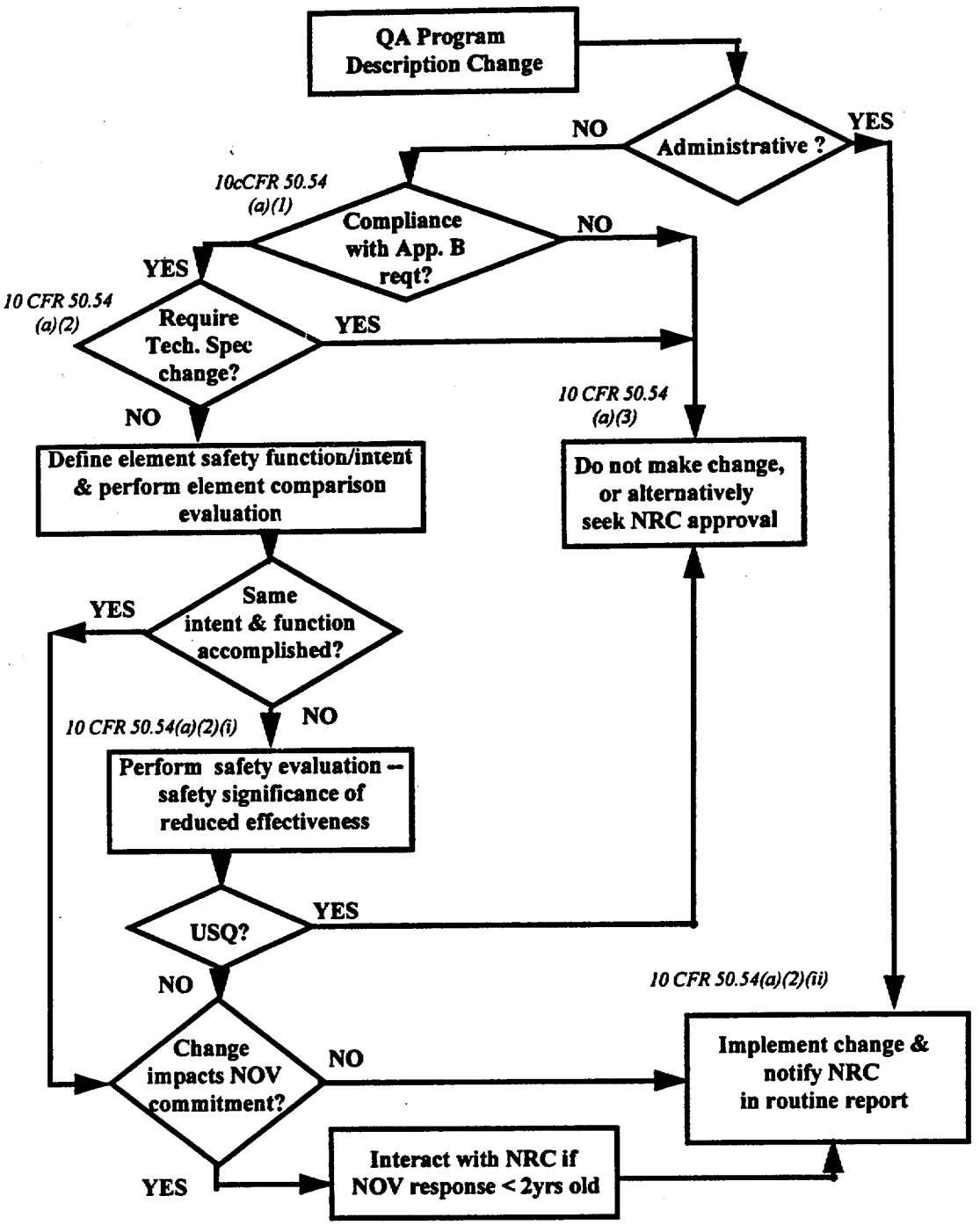

Figure 1

The revised 10 CFR 50.54(a) permits a licensee to make a change to its quality assurance program description without prior NRC approval providing the change does not involve a change to the Technical Specifications or an unreviewed safety question. Fundamentally, through Section 50.54(a) [as amended], a licensee has the flexibility to make a change to its quality assurance program description without prior NRC approval, providing that a determination can be made that the revised quality measures, e.g., inspections, tests, corrective action, etc., described in the revised quality program description, still provide reasonable assurance that the safety function(s) will be performed. A licensee needs to provide the rationale for assuring the analyzed safety considerations prior to implementing the change are not being reduced, or that the change does not create a new safety concern. Naturally, a licensee's quality program description must still meet the requirements of 10 CFR 50, Appendix B.

In addition to the evaluation described in this document, a licensee needs to be aware of the safety considerations and purpose of the quality program description approved in the original licensing proceedings, or in the regulatory interactions in response to the NRC's 1983 Section 50.54(a) requirements. It is important to ensure that the original intent of the quality assurance program description is not inadvertently degraded to an extent beyond that analyzed in the SAR through incremental changes.

The overall change process is depicted in figure 1.

3.1 Screening Criteria

Before evaluating the change to determine if an unreviewed safety question (USQ) exists, there are several questions to be answered. These are:

(a) Is a change being made to the quality program description, described or referenced in the SAR?

(b) Is the change of an administrative nature?

An administrative change is one that meets the following criteria:

(i) Editorial corrections (e.g., textual ambiguities, typographical errors, grammatical errors, formatting errors);
(ii) Changes in organizational position titles, descriptions, and/or reporting relationships;
(iii) Organizational realignment, wherein the overall scope of activities is unchanged;
(iv) Relocation of requirements from one licensing basis document to another, (e.g., specific reporting requirements may require NRC notification); and

(v) Renewal, updating or clarification of regulatory approved documents reproduced or referenced in the quality assurance program description (e.g., updates to later approved ASME Code editions) that have been generically approved by the NRC staff.

If the change is administrative, the change may be made and implemented without further evaluation, with a report being forwarded to the NRC as part of the normal SAR or annual update, or at shorter intervals as prescribed by each licensee.

(c) Does the revised quality program description continue to comply with 10 CFR 50, Appendix B?

(d) Does the change result in a revision to the Technical Specifications?

If the change results in a change to the Technical Specifications, a licensee would either withdraw the change or seek prior NRC approval through the process prescribed by 10 CFR 50.90.

3.2 Quality Program Element Comparison

Does the revised program description perform the same activities and achieve the same purpose (function) as the existing program description?

A comparison of the proposed program against the current program is performed. To accomplish this activity a licensee performs the following three step process:

(a) Defines the safety function or intent of the program description or activity that is being changed.

(b) Defines the safety function or intent of the program or activity in the new quality program element program description.

(c) Compares the differences between the two program descriptions to determine if the same safety function is being performed, or the same safety objective accomplished.

In performing the three step process described above, the following guidance should assist licensees:

The intent (purpose or objective), the desired output (result, conclusion or product), and task (activity) from a safety perspective for the existing and proposed elements should be described. If the element is not specifically described in the revised program because another element envelopes and

accomplishes the original function; the activity, intent, desired output and task of the pertinent element from a safety perspective should be noted.

Once the safety functions of the existing and revised quality program elements have been established, they can be compared, and any differences with respect to safety can be identified. In performing the comparison, the following questions may be of assistance:

- Is the same task, from a safety perspective being accomplished?
- Is the same intent with respect to safety being achieved as that described in the existing quality program description?
- Is the same result or output, with respect to safety, being achieved as described in the existing quality assurance program description?
- Is the program less complex (fewer steps) than the existing?
- Are software programs or databases involved? If so is the same database or program (revision) being used?

Example: Transfer of the quality assurance department's responsibilities to the line organizations with the introduction of a line assessment coordinator/director whose responsibilities include, the coordination of multi-disciplined reviews of identified areas of weaknesses, and resolving professional differences of opinion between the line assessment and work sections.

Current function: The purpose and activities (the safety function) of the quality assurance department is to conduct independent reviews to confirm that the defined and established quality controls and measures are being implemented correctly, to identify defects and deficiencies, and to ascertain that identified defects and deficiencies are addressed through the licensee's corrective action program.

New function: A departmental (line) assessment coordinator ensures the same activities are performed by line personnel, as currently performed by the QA department personnel, providing the personnel are not performing the work. Each department is responsible for providing personnel, as necessary, to support detailed group reviews of identified areas of weakness, or concern. As appropriate and necessary, differences in professional opinion are resolved by the department assessment section leader/coordinator, the site assessment director/coordinator, or the senior executive responsible for safety. The personnel qualifications for implementing the tasks would continue as for the exiting element consistent with the safety significance and complexity of the task.

Conclusion: From a safety perspective, the current activities, or work functions continued to be performed, and the original intent and purpose of the quality program description continue to be fulfilled: hence, a safety evaluation is not required. The change can be made following the assessment of the notice of violation step.

Defining the safety significance of the program description or its associated activities that are being changed focuses attention on the safety considerations related to the proposed change. In addition, the comparison will assist a licensee in making the correct safety determination (see Section 3.3), when addressing the standard questions associated with safety evaluations.

If the initial comparison review, described above, determines that the safety function of the existing program is not changed, then the licensee proceeds to the final step described in Section 3.4. The basis for the conclusions of this evaluation should be documented and held in the licensee's files for a period of five years.

If the safety functions (intent, output, and task) are not the same as that of the existing quality assurance program description, a safety evaluation, as described in Section 3.3, is performed.

3.3 Safety Evaluation

The objective of the safety evaluation is to determine whether the change would result in any reduction in program adequacy that has safety significance. The evaluation determines whether the proposed revised program description challenges or changes the safety function of the existing quality assurance program description to an extent that is significant, and that might be detrimental to the protection of public health and safety. The safety evaluation determines the impact on safety, in terms of plant (equipment and personnel) performance and overall risk.

The program comparison performed in Section 3.2 is used in answering the seven safety evaluation questions. Primarily, a licensee uses the output from Section 3.2 to determine whether the differences in the quality assurance program description established in Section 3.2 potentially impact a safety function or activity described in the SAR? If the answer is yes, a determination is made as to whether the impact is beyond that analyzed in the SAR?

The discussion section on the seven questions (the same as the questions described in NSAC-125, Section 3) is intended to provide further amplification and guidance for addressing programmatic changes to the SAR. In regard to quality assurance program description changes, it is important to note that such changes have the potential to impact more than one activity, system or component. The following aspects relating to quality assurance activities should be taken into consideration:

Q.1. May the proposed activity increase the probability of occurrence of an accident previously evaluated in the SAR?

If the answer is yes, an evaluation on whether the change would increase the probability of an accident needs to be considered. Licensees have established methods for determining whether the probability of an accident is increased to an extent that is beyond the accidents analyzed in the SAR. If the probability of an accident has been increased to an extent that impacts the safety analyses described in the SAR then an unreviewed safety question is involved.

Q.2. May the proposed activity increase the consequences of an accident previously evaluated in the SAR?

In this question, the licensee makes the same determination as for normal 50.59 evaluations; a determination on whether the dose consequences of any analyzed accident are affected to an extent beyond that analyzed in the SAR, for changes to the quality assurance program description that could impact a mitigative safety function.

Q.3. May the proposed activity increase the probability of occurrence of a malfunction of equipment important to safety previously evaluated in the SAR?

Using the results from the program comparison in Section 3.2, a determination is made on whether the performance of a structure, system or component (SSC) is degraded to an extent that it impacts the safety function of those SSCs? If the answer is yes, the licensee determines whether the impact on the safety functions are significant to affect the safety analyses beyond those described in the SAR. The important aspect is associated with the probability of a malfunction being increased to an extent that could impact the events previously analyzed in the SAR

Q.4. May the proposed activity increase the consequences of a malfunction of equipment important to safety previously evaluated in the SAR?

Could the revised program result in an impact on plant SSCs that degrades safety beyond that analyzed in the SAR? If the answer is yes, a

determination of the dose consequences of the malfunction must be performed. If the dose consequences exceed the limits described in the SAR, or other licensing documents, the change is considered as presenting an unreviewed safety question.

Q.5. May the proposed activity create the possibility of an accident of a different type than any previously evaluated in the SAR?

The issues in this question are similar to those being addressed in question (1) from a quality assurance program description change consideration and no additional guidance beyond that already discussed in this supplement or in NSAC-125 is necessary.

Q.6. May the proposed activity create the possibility of a different type of malfunction of equipment important to safety than previously evaluated in the SAR?

If the evaluation indicates that a different type of malfunction will occur, are the consequences of the malfunction bounded by the SAR analyses? The probability of the accident or event being assessed should be similar to the probability of the accidents and events described in the SAR, i.e., considered to be as credible as the accidents described in the SAR (see NSAC-125 for additional information).

Q.7. Does the proposed activity reduce the margin of safety as defined in the basis for Technical Specifications?

No additional clarification is required beyond the guidance given in the NSAC-125.

3.4 Commitment Change Determination

The final step is to assess whether the proposed revision changes any licensing commitments made as a result of a notice of violation within the last two years. If the answer is yes, the change can still be processed. However, the NRC staff should be notified as soon as possible and the rationale for changing the commitment made in response to the report or violation should be prepared.

This final step is to assure a degree of consistency between the process for managing NRC commitments and the change process for making changes to a licensee's quality assurance program description.

4.0 CONCLUSION

On completion of the change process, a licensee should have confidence that its quality assurance program description retains the appropriate quality controls and measures that provide reasonable assurance that the applicable (safety related) structures, systems and components will satisfactorily perform their intended safety functions. If this assurance would be degraded through a quality assurance program description change to an extent that impacted public health and safety beyond that analyzed in the SAR, the change should be withdrawn, or NRC approval should be requested prior to implementation.

APPENDIX A
Guideline for Quality Assurance Program Description Changes per 10 CFR 50.54(a)

EXAMPLES

Introduction

The differences in levels of regulatory commitments as a result of licensing and enforcement activities can result in varying interpretations, and can influence a licensee's decision on whether a change to the quality assurance program description is needed, whether NRC approval should occur prior to implementation, or whether the change can be implemented prior to NRC notification.

Currently, some licensees may have the regulatory flexibility to implement a change described in this Appendix without performing the evaluations described in this guidance document. Other licensees may decide not to implement a change because of specific regulatory interactions, licensee specific nuances in design or operational philosophy, or unique licensing conditions.

The following examples are designed to assist licensees in understanding the process described in the main document by providing additional clarification by way of example.

1. Examples of changes that would result in a licensee seeking NRC approval prior to implementation.

The changes in this section assume that a licensee has not graded its quality programs into high and low safety significance categories, or does not distinguish between high and low safety significance for design considerations. These changes are associated with changes to quality programs for safety-related structures, systems and components.

A. Elimination of design authority reviews of safety-related equipment modifications

Basis: In the current regulatory environment, a safety evaluation using the Section 50.59 criteria would conclude that the change involves an unreviewed safety question. Having defined the purpose and intent of the design authority reviews of modification packages, and how the change would impact the safety functions of one or more systems, the responses to the questions described in the main document, Q.1 through Q.5 would be yes.

In the current organizational structure, design engineering (design authority) is the organization that has the technically qualified personnel and possesses the design

basis information to evaluate the safety impact of modifications. Such evaluations ensure that the specific, and sometimes design unique, conditions associated with design basis operational, transient, or accident conditions are addressed. Through such a process there is reasonable assurance that the plant (structures, systems and components) remains capable of satisfactorily performing its intended safety functions. To eliminate such a review could significantly increase the probability of occurrence of the matters that would present an unreviewed safety question: an increase in probability of the consequences or occurrence of an accident or malfunction, or an increase the possibility of a different type malfunction or accident, or a reduction in the margin of safety defined in the basis for the technical specifications.

B. Deletion of design engineering/authority review of completed modification packages prior to final acceptance into operation. (Maintenance/craft (contractor) group responsible for final engineering approval of completed modification package (field changes implemented) prior to acceptance for service).

Basis: Having defined the purpose and intent of the design authority review of completed modification packages, the safety evaluations from Q.1, Q.3, Q.6 or Q.7 would be evaluated as presenting an unreviewed safety question for such a programmatic change.

The design authority may place specific work (craft) requirements, inspection and acceptance criteria, or tolerances in modification packages and procedures because of concerns over a potential design weakness, or reductions in operational safety margins. These design requirements may be more restrictive and severe than the requirements of the construction codes, guidance given in the industry consensus standards, or in the standard licensee's craft procedures and work instructions. These additional installation requirements are imposed to assure that the design basis is not degraded.

If in the course of installation, such additional instructions are changed, or deleted because they are in excess of code, or standard work instructions the designer assumptions may be impacted and the margin of safety impacted through such activities. Without a design authority review of changes, the safety analyses described in the licensee's SAR may be impacted, or the safety margins reduced to an extent that is unacceptable and beyond the conditions and criteria described in the SAR.

Example: The piping configuration requirements for a pump suction line may be critical from NPSH considerations. A change in bend radius, or reduction in pipe length prior to the impeller suction inlet resulting from a construction interference may invalidate the design basis performance characteristics of the pump during a plant transient or event.

C. Deletion of component and vendor documentation verification for structures, systems and components of high reliability.

Basis: Even if a determination was made that the change continued to comply with the requirements of Appendix B, this change would result in an unreviewed safety question during performance of a safety evaluation using the Section 50.59 criteria. Also, having defined the purpose of the vendor/component receipt inspection process, the safety evaluation described in the main document would result in an unreviewed safety question from answering questions Q.1 through Q.6.

The purpose of inspection/verification on receipt is to identify deficiencies that indicate a component has not met the requirements of the procurement order, and may not meet the requirements for its intended safety application. In the majority of instances, high reliability components from manufacturers do not have deficiencies, and when they occur they are often associated with documentation, rather than hardware deficiencies. However, some instances have occurred where components are rejected or require some work before being utilized. In addition, test deficiencies sometimes go undetected during manufacture, and deficiencies do occur in high reliable components. Such deficiencies could impact the safety analysis assumptions that form the basis for the scenarios, resulting in an adverse impact on SAR assumptions and supporting analyses.

D. Appointment of line managers (engineering, maintenance, health physics, and design) as the final authority for the resolution of safety concerns within their area of responsibility.

Basis: Having defined the purpose and intent of the company, site, or plant senior nuclear officer having the final authority for the resolution of safety issues, the safety evaluation described in the main body of the guideline would, as a minimum result in Q.3, Q.4, Q.6 or Q.7 being assessed as an unreviewed safety question.

In addition, for some licensees, such a change may require a change to their Technical Specifications incorporated in their licenses, and as such, NRC approval would be required.

A licensee's Technical Specifications or quality assurance program description sometimes state that the final authority for the resolution of safety issues resides with the company, plant, or site senior nuclear officer (executive). Operational, design, health physics and maintenance safety issues often require input from one or more of the other line organizations, e.g., operations sometimes need input from design, and health physics; design often needs input from maintenance and operations.

In general, line managers reach a consensus on the correct course of action. However, instances do occur where there are differences in professional opinion or advice on the correct course of action. These differences of opinion are sometimes a result of differences in experience, knowledge, or qualifications, and occasionally are exacerbated by operational pressures. When such differences in professional opinion occur and cannot be reconciled, the company senior nuclear officer is tasked with resolving safety issues to ensure the appropriate and correct action is taken.

E. Elimination of the audit function based on plant reliability and licensee self assessment activities.

Basis: This would be inconsistent with the requirements of 10 CFR 50, Appendix B, Criterion XVIII. In addition, some licensees may be required to address the issue through a change to their Technical Specifications incorporated in their license. In both instances, NRC approval would be required prior to implementation.

F. A programmatic change in software validation and instrument calibration of Regulatory Guide 1.97 instrumentation and indication in the control room based on modifications to other instrumentation.

Basis: A general programmatic reduction in instrument calibration or software validation requirements that are primarily based on the presence of other, more resilient, commercial equipment, instruments or indication in the control room that is not qualified or categorized as Regulatory Guide 1.97 equipment, the evaluations of Q.1, Q.3, Q.4, Q.6, or Q.7 would result in an unreviewed safety question.

Note: For a specific change, based on a partial, or full system upgrade, the evaluations may indicate that the change does not present an unreviewed safety question.

The purpose and intent of the calibration is to ensure that the instrumentation is accurately providing the correct information, and does not result in an unsafe condition during normal, transient conditions, or cause inappropriate operator or automatic initiation based on control room indication. Likewise, software validation ensures that there are no errors in the software program that would impact safety through in inaccurate information, false alarm annunciation, or result in the initiation of incorrect automatic or manual sequences.

Operators react to indications and alarms as directed by operating procedures. Reg. Guide 1.97 instrumentation and software programs are designed, developed, installed, tested, calibrated and maintained in a manner that provides reasonable assurance and indication that the plant is being operated within its design basis. The operator actions (manual or automatic) are initiated at the correct time and in the correct sequence based on indication or annunciation from this set of instrumentation and indication. Incorrect operator response, even during normal

operations can rapidly lead to operations that are inconsistent with the plant's design basis, or the safety analyses described in the SAR.

2. **Examples of changes that would be implemented by a licensee with NRC notification through the standard SAR update process.**

The changes in this section assume that a licensees has not graded its quality program into high and low safety significance categories, or does not distinguish between high and low safety significance for design considerations. These changes are related to the quality program practices for safety related structures, systems and components.

A. Change specific qualification standards (experience and education) for line or section supervisors to one based on licensee management's assessment of the candidates abilities to perform the duties, responsibilities and tasks.

Basis: The qualifications for line or section supervisors should be based on licensee management's assessment of the candidate's competency in fulfilling the duties and responsibilities required by the position. The selection process should be based on the candidate's education, experience, and performance, and assessed abilities to undertake the tasks demanded by the position.

The activity, (the supervision of activities, personnel, and safety) is still being performed. Plant performance or safety is not degraded. The change is not administrative, does not result in a Technical Specification change, and the requirements of Appendix B are still satisfied. The activity, the selection and performance of the duties of the line supervisor are still being performed, and will be assessed on a continuous basis through the personnel appraisal process.

B. Transfer of receipt inspection activity and oversight from the QA department to the line organization.

Basis: The change is considered administrative (organizational realignment) and the prescribed activity, duties and functions are still being performed.

The activity is still being performed, and the verification of the equipment is independent of the supplier. In addition, it may be more appropriate for the line organization to perform the receipt inspection activity, and track and monitor any identified deficiencies. A licensee's nonconformance and corrective action programs assure that deficiencies are corrected and that defective material and equipment are not installed.

The interface with the supplier's organization is maintained through the appropriate department tasked with the supplier interface. Such interactions may be through the project, line, or assessment/QA departments.

C. Change offsite review committee reporting relationship for Site #1 from Executive Vice-President - Power Supply to Senior Site Manager - Site #2.

Basis: This is an administrative change. The offsite review committee is described in the quality assurance program description and its activities continue to be performed. The activity (function) is still being performed and there is no impact on safety or plant operations.

D. Utilize associate company personnel and programs to perform support services (design, quality assessment, training, maintenance, etc.,) for nuclear operations.

Basis: . The associate companies have quality programs sufficient to meet the requirements of 10 CFR 50, Appendix B. The change is administrative. The licensee remains responsible for operations and activities that are performed in accordance with the requirements of the NRC regulations, including 10 CFR 50, Appendix B, and the conditions of the license. There is no impact on safety, beyond that described in the licensee's SAR

E. Create a new department on-site to perform plant modifications.

Basis: Change is administrative. Design control, installation, testing, and maintenance activities are still performed in accordance with the licensee's quality assurance program description consistent with safety significance. Design basis information is still available to the personnel performing design modifications and the senior site/plant manager remains responsible for safety.

F. Create a matrix-type organization that allows for maintenance personnel to perform QC inspections of work performed by other maintenance personnel.

Basis: Personnel performing inspections are qualified per industry, company, or licensee standards. Compliance with the prescribed standards in regard to independence of inspectors and organizations is ensured by a matrix reporting relationship to the assessment/inspection coordinator or assessment section supervisor within that department (maintenance department). Plant maintenance and inspection activities continue to be performed in accordance with plant procedures. There is no detrimental impact on plant safety significant activities, or on the safety analyses described in the SAR.

NUCLEAR ENERGY INSTITUTE

Joe F. Colvin
EXECUTIVE VICE PRESIDENT

December 4, 1995

Mr. James M. Taylor
Executive Director for Operations
U. S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

SUBJECT: NEI 10 CFR 50.54(a) Petition for Rulemaking – Response to NRC Request for Additional Information and Comment (60 Fed. Reg. 47716 – September 14, 1995)

Dear Mr. Taylor:

The subject *Federal Register* notice of our petition on 10 CFR 50.54(a) included a request for public comment and information on eight issues. While the enclosure provides our detailed response, I thought it might be helpful to summarize our view for you.

The Commission issued the current version of 10 CFR 50.54(a) in 1983 because of concerns that licensees were not informing the NRC of QA program changes that potentially could degrade public health and safety. The QA program is the only program designed to improve the reliability of safety-related equipment described in the SAR that has a change process separate from the rest of the SAR. The NEI petition provides for a more effective, efficient, and flexible process to address the Commission's original concern. The petition requires a licensee to utilize the well proven and accepted change process for changing other safety-significant information in the SAR. When implemented, the petition will improve the consistency and coherency of the NRC's regulations and their implementation. It will ultimately improve the protection of public health and safety by improving the focus of licensee and NRC attention and resources on matters that have safety significance.

The industry has significant reservations on three alternative considerations described in the *Federal Register* notice: (i) the use of a "departure from commitment" standard as the threshold for requesting NRC approval prior to implementation; (ii) a separate change process and mechanism for review and audit functions, as suggested in Issue 3 of the *Federal Register* notice; and (iii) the development of additional guidance for implementing the current regulation.

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We believe that the adoption of these alternatives would further decrease the coherency and consistency of the NRC regulations and their implementation, and would be a regressive step in regard to the protection of public health and safety. Licensee and NRC management would be required to address all matters described in a licensee's quality assurance program description, whether or not there is a nexus to safety. Such measures would increase the potential for not identifying a safety concern as licensee and NRC attention and resources are distracted and diverted from safety significant matters.

In regard to a "decrease in effectiveness" standard, the industry believes that such a standard would not engender the same degree of improvement in the regulatory regime and public health and safety as the process described in the petition. Rather, such a threshold would increase regulatory incoherence and inconsistency by having three different change processes and interpretations for the same term, contained in a single NRC regulation, viz., 10 CFR 50.54. This would increase the potential for miscommunication, misinterpretation and misunderstanding.

The petition comports with the recent Administration and Congressional initiatives for improving the federal regulatory process. Additionally, it fulfills, and is consistent with, a number of recommendations of the NRC's 1993 Regulatory Review Group by:

- Improving the coherency and consistency of the NRC's regulations, specifically 10 CFR 50.54(a);

- Providing for a more consistent, effective, efficient and flexible process for changing a licensee's quality assurance program description included or referenced in its Safety Analysis Report (SAR); and

- Utilizing a Section 50.59 type process for changing a licensee's commitments to the NRC (the industry believes there should be a consistent change process for changing a licensee's FSAR commitments regardless of topic).

I hope this summary is helpful. If you have any questions on this letter or its enclosure, please feel free to contact me or Bill Rasin.

Sincerely,

Joe F. Colvin

Enclosure