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July 1, 1997

Chief, Rules and Directives Branch
Division of Administrative Services
Office of Administration
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Comments on NUREG-1606, Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests or Experiments)

Dear Sir:

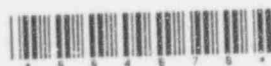
In a Federal Register Notice on May 7, 1997 (62 Fed. Reg. 24997), NRC requested comments by July 7, 1997 on NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests or Experiments)." We are hereby submitting comments on NUREG-1606 on behalf of Commonwealth Edison Company, Houston Lighting & Power Company, IES Utilities, Inc., Illinois Power Company, Pennsylvania Power & Light Company, and Texas Utilities Electric Company.

As background for our comments, we note that there have been more than thirty years of experience in implementing Section 50.59. The NRC itself has stated that Section 50.59 has worked well in practice and has given the nuclear industry a sound foundation to establish a process that will produce effective evaluations of changes in plants and procedures.^{1/} Section 50.59 has provided the industry with reasonable flexibility to make changes, while ensuring that NRC review and approval are required for any changes that adversely impact the basis for NRC's regulatory acceptance of the safety analysis report (SAR) for a plant. Although there have been isolated violations of Section 50.59, these violations have not, in general, reflected any problem

^{1/} See Memorandum dated April 15, 1996 from James M. Taylor to Chairman Jackson, entitled "Action Plan for Improvements to 10 CFR 50.59 Implementation and Oversight," Attachment p. 15.

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with the provisions or interpretation of Section 50.59. As a result, we believe that Section 50.59 as written and interpreted by the industry is adequate, and there is no compelling reason to revise Section 50.59 or to modify its interpretation.

In particular, we do not believe that there is any need for issuing NUREG-1606. The industry has developed detailed 50.59 guidance in NSAC-125, "Guidance for 10 CFR 50.59 Safety Evaluations," and has recently revised and reissued this guidance in draft form as NEI 96-07 to account for NRC staff concerns on NSAC-125. Thus, extensive industry guidance on Section 50.59 already exists, and additional NRC guidance will only serve to confuse both industry and NRC personnel regarding the validity of existing guidance. Rather than issuing new guidance, we recommend that NRC issue a regulatory guide which endorses the guidance in NEI 96-07 being revised by the Nuclear Energy Institute (NEI). If NRC disagrees with one or more provisions in NEI 96-07, the regulatory guide should simply identify exceptions to NRC's acceptance of NEI 96-07, similar to other regulatory guides which accept industry standards subject to certain qualifications.

In general, NUREG-1606 appears to be consistent with NEI 96-07 and general industry practice. However, in several respects, the guidance in NUREG-1606 contains overly legalistic interpretations of Section 50.59 - - interpretations that are not required by Section 50.59, do not serve any safety purpose, and are inconsistent with long-standing industry practice. In other cases, the interpretations in NUREG-1606 are inconsistent with the language in Section 50.59. Because NUREG-1606 is inconsistent with Section 50.59, NUREG-1606 should not be adopted by NRC. In particular:

- NUREG-1606 states that it is not appropriate to use probabilistic risk assessments (PRAs) for performing 50.59 safety evaluations (unless the PRA is discussed in the SAR). However, there is nothing in Section 50.59 which either requires or prohibits use of a PRA. Thus, at the option of a licensee, use of a PRA should be permissible, especially as a supplement for deterministic evaluations.
- NUREG-1606 states that information may not be removed from the SAR unless it corresponds to an actual change in the plant or procedures (i.e., unnecessary detail may not be removed from the SAR). There is nothing in Section 50.59 which prohibits removal of unnecessary detail from the SAR. Furthermore, such a prohibition is inconsistent with the language in Section 50.59, which allows changes in the SAR without prior NRC approval, provided that they do not involve an unreviewed safety question (USQ) or a change in the technical specifications.
- NUREG-1606 states that licensees must either correct as-found conditions that do not conform with the SAR at the next available opportunity or perform 50.59 safety evaluations for the conditions. Such a requirement is not contained in Section 50.59, is

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not consistent with industry practice, and can be counterproductive to safety. Instead, degraded and nonconforming conditions are subject to operability evaluations under Generic Letter 91-18 and corrective actions under Appendix B to 10 CFR Part 50. A degraded or nonconforming condition would constitute a change warranting an evaluation under Section 50.59 only if a licensee decides under Appendix B to accept the condition as-is.

- NUREG-1606 states that if a nonconforming condition involves an unreviewed safety question (USQ), a licensee may not startup without the amendment even if the condition in question does not render any system or component inoperable. Such a prohibition is not required by Section 50.59 (which is silent on this matter), and imposes unnecessary burdens on licensees without any corresponding increase in safety.
- NUREG-1606 states that an USQ exists if there is "any" increase in probability or consequences of an accident or if there is uncertainty whether there has been such an increase. This overly legalistic interpretation of Section 50.59 is unreasonable, inconsistent with industry practice and, as admitted in NUREG-1606, is not necessary to protect safety or preserve the regulatory basis for NRC's acceptance of the SAR.
- NUREG-1606 would require 50.59 safety evaluations for activities that do not involve changes in the SAR, such as removal of equipment for maintenance, nonconforming and degraded conditions, and additions that have no effect on safety. This is inconsistent with Section 50.59, which only requires a safety evaluation for an activity if it involves a change "as described in the safety analysis report."

Instead of using a legalistic approach of interpreting each word in Section 50.59, NRC should apply Section 50.59 in a manner consistent with its intent when first issued. At that time, the focus was on ensuring the safety of operations and requiring prior Commission review and approval of changes that introduced new safety hazards.

In addition to being overly legalistic and inconsistent with industry practice, the new guidance contained in NUREG-1606 would impose substantial new burdens on the industry and the NRC, without increasing safety. In general, the new guidance would greatly expand the types and number of activities requiring 50.59 safety evaluations, and the types and numbers of changes requiring prior NRC review and approval and an opportunity for hearing. This substantial additional burden will not result in an improvement in safety because, as NUREG-1606 recognizes, Section 50.59 only applies to a change after the licensee has determined that the change is safe. More importantly, the guidance in NUREG-1606 may actually result in an adverse impact on safety. In the past, the industry has used Section 50.59 to make many changes that improve safety. However, under NUREG-1606, both licensees and NRC would be required to apply additional management attention and resources to the 50.59 process. This additional

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burden on licensees will have the effect of reducing their flexibility to make changes and will discourage them from making changes, including changes that could be beneficial to safety. Furthermore, resources needed to comply with the staff's new interpretations of Section 50.59 could be better spent on matters affecting safety.

Each of these comments is discussed in more detail in Attachment 1, together with our other detailed comments on the interpretations of Section 50.59 in NUREG-1606. Furthermore, we agree with the comments of NEI on NUREG-1606.

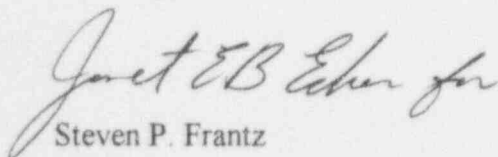
NUREG-1606 also identifies several policy issues, which raise the possibility of a rulemaking to modify Section 50.59. As stated above, more than thirty years of experience have demonstrated the practical effectiveness of Section 50.59. There is no reason to modify a rule which has proven its worth. Furthermore, as discussed in more detail in Appendix 2, the proposed rulemaking changes being considered by NRC are either unnecessary or would impose new burdens on licensees and the NRC with no corresponding improvements in safety. Therefore, we oppose any new rulemaking on Section 50.59.

For the reasons discussed above and in the enclosed attachments, issuance of NUREG-1606 and initiation of a rulemaking on Section 50.59 are not necessary to protect or enhance safety. Given the successful history of implementation of Section 50.59 and the additional burdens that would result from NUREG-1606 or a change in Section 50.59, the NRC should cease any further efforts on both of these initiatives.

If NRC decides to pursue either of these initiatives, it should perform a backfit analysis in accordance with 10 CFR § 50.109. We believe that such an analysis will clearly demonstrate that the change in plant 50.59 procedures required by either of these initiatives would not result in a substantial increase in the overall protection of the public health and safety, and that the costs of the change would outweigh its benefits.

Thank you for the opportunity to submit these comments.

Sincerely,



Steven P. Frantz

ATTACHMENT 1

COMMENTS ON INTERPRETATIONS OF
10 CFR § 50.59 IN NUREG-1606

Section III.A - Definition of Change

A. Rule Language:

The holder of a license authorizing operation of a production or utilization facility may (i) make changes in the facility as described in the safety analysis report, (ii) make changes in the procedures as described in the safety analysis report, and (iii) conduct tests or experiments not described in the safety analysis report, without prior Commission approval, unless the proposed change, test or experiment involves a change in the technical specifications incorporated in the license or an unreviewed safety question.

B. NRC Position:

- 1) A change includes additions (e.g., new systems, structures, procedure steps) as well as modifications and replacements.
- 2) A change includes removal of equipment from service for maintenance, if the equipment is not addressed in the Technical Specifications and removal was not previously considered in the safety analysis report or the safety evaluation report.

C. Comment:

Position 1

The staff's position in NUREG-1606 is too broad. As discussed below, not all additions to hardware or procedures need a 50.59 safety evaluation.

Under 10 CFR § 50.59, a safety analysis report (SAR) is not required to discuss all of the hardware or procedures for a plant; instead, the SAR need only selectively discuss those structures, systems, components, and procedures which affect safety. There are many types of additions that pose no potential impact on safety (e.g., the

addition of administrative procedures imposing additional controls or requirements, the addition of a component that has no safety function and whose failure cannot affect the safety of other components, the addition of a safety component (e.g., a monitor) that satisfies all of the requirements in the SAR for that type of component). Such additions should not be construed as changes requiring a 50.59 safety evaluation. Instead, additions should be subject to a screening process, and a 50.59 safety evaluation should be required for an addition only if it has the potential for affecting safety as described in the SAR, or does not satisfy the existing SAR requirements for the type of component in question.

Position 2

As NUREG-1606 itself recognizes, a 50.59 safety evaluation is not required for removal of equipment from service for maintenance if the equipment is addressed in the Technical Specifications. Similarly, a 50.59 safety evaluation should not be required for removal of equipment from service for equipment that is not addressed in the Technical Specifications. This conclusion is supported by the following reasons:

- 1) Removal of equipment from service for maintenance is not a "change," as that term was intended to be used when Section 50.59 was first issued. Obviously, in development and approval of SARs, it was within the contemplation of both licensees and NRC that equipment described in the SAR would occasionally need to be removed for service for maintenance. There is nothing in the language or history of Section 50.59 which indicates that such removal should be classified as a change requiring a 50.59 safety evaluation.
- 2) The Technical Specifications address the equipment that is most important to protection of the public health and safety. If such equipment may be removed from service for maintenance without a 50.59 safety evaluation, other equipment of lesser importance should also be permitted to be removed from service for reasonable periods of time without a 50.59 safety evaluation.
- 3) Section 50.65(a)(3) of the Maintenance Rule states that licensees should perform an assessment of equipment that is out of service for maintenance to determine its overall effects on safety. Conformance with the Maintenance Rule is sufficient to ensure that removal of equipment from

service for maintenance will not adversely impact safety, and Section 50.59 is not necessary for this purpose.

Section III.C - Definition of Procedures

A. Rule Language:

The holder of a license authorizing operation of a production or utilization facility may . . . make changes in the procedures as described in the safety analysis report, . . . without prior Commission approval, unless the proposed change, test or experiment involves a change in the technical specifications incorporated in the license or an unreviewed safety question.

B. NRC Position:

Changes to the emergency preparedness plan, security plans, and quality assurance plans are controlled by 10 CFR § 50.54 rather than § 50.59, because Section 50.54 has more restrictive requirements.

C. Comment:

This is useful guidance and is consistent with NEI 96-07. In this regard, NRC should explicitly accept the position in NEI 96-07 that, even in those cases where changes are being made in the SAR description of the emergency preparedness plan, security plans, or quality assurance plan, only Section 50.54 should be applied and a 50.59 safety evaluation is not necessary (i.e., the provision in Section 50.54 supersedes Section 50.59 with respect to the descriptions of these plans in the SAR) unless other provisions in the SAR are affected by the change.

Section III.D - Definition of Test or Experiment

A. Rule Language:

The holder of a license authorizing operation of a production or utilization facility may . . . (iii) conduct tests or experiments not described in the safety analysis report, without prior Commission approval, unless the proposed . . . test or experiment involves . . . an unreviewed safety question.

B. NRC Position:

In order to meet the requirements of the rule, any test or experiment not described in the SAR needs to be evaluated to determine if an unreviewed safety question (or Technical Specification change) is involved.

C. Comment:

The NRC's position is unreasonable to the extent that it would require a 50.59 safety evaluation for "any" test or experiment not described in the SAR. There are numerous tests or experiments not described in the SAR, and many could not conceivably affect a safety function described in the SAR. For example, there obviously would be no potential impact if a licensee were to replace a burned-out light bulb to test the circuit and verify that the bulb failed. Similarly, performance of a test on a system that does not interface with or affect a safety system (e.g., sewage water treatment system) should not require a 50.59 safety evaluation, even though the test is not described in the SAR. Additionally, other tests and experiments do not involve any change in system mode of operation or alignment (e.g., use of non-intrusive monitors to gather system data), and such tests and experiments should not require a 50.59 safety evaluation even though they may not be described in the SAR. In summary, we believe that new tests should be subject to a screening process, and that a 50.59 safety evaluation should be required for a test or experiment not described in the SAR, only if the test or experiment could affect a safety function of a structure, system, or component described in the SAR (e.g., it involves a new or different mode of operation or system alignment, or it introduces a new safety hazard)

NUREG-1606 also states that a safety evaluation should be performed for a test done "to verify the adequacy of modifications such that the tests could be

considered a replacement for preoperational or startup tests that formed the basis for NRC's acceptance of the adequacy of the SSC." However, a safety evaluation is needed for such a test, only if the test is different from the preoperational or startup tests (or other tests) described in the SAR and Technical Specifications. Obviously, if a licensee performs a test for a modification using the prescribed methods described in the SAR, the test would not be a "test or experiment not described in the safety analysis report."

Section III.G - Industry Use of a Screening Process

A. Rule Language:

The licensee shall maintain records of changes in the facility and of changes in procedures made pursuant to this section These records must include a written safety evaluation which provides the bases for the determination that the change, test or experiment does not involve an unreviewed safety question.

B. NRC Position:

There are no requirements in 10 CFR § 50.59 to retain records of licensee evaluations performed to determine whether a "change" is within the scope of 10 CFR § 50.59. However, the staff believes that all proposed changes or modifications, wherever in the plant, need to be considered to determine whether a 10 CFR 50.59 safety evaluation is required. Furthermore, while not specifically required by Section 50.59, documentation of screening evaluations might constitute records of activities affecting quality or safety and therefore fall under the documentation requirements established by 10 CFR 50 Appendix B.

C. Comment:

Section 50.59 does not require records of screens, and a licensee cannot be cited for a violation of Section 50.59 for failure to have records of screens on "all proposed changes or modifications."

Additionally, screening is not required by Appendix B, and a screen does not constitute a record of activities affecting quality or safety. As a result, records of screens are not subject to the record retention requirements of 10 CFR Part 50, Appendix B.

Specifically, Appendix B, Criterion XVII, "Quality Assurance Records," requires licensees to maintain records "to furnish evidence of activities affecting quality." However, the purpose of Section 50.59 screenings is to determine whether a proposed change, test or experiment is subject to the rule and whether prior NRC approval is required. As Section II of NUREG-1606 discusses, the need for a 50.59 safety evaluation or screening only arises after a licensee has determined that the change is safe (i.e., after the licensee has conducted the evaluations required by Appendix B).

In some cases, screening records may not be needed; e.g., if a licensee has a 50.59 procedure that identifies specific criteria for types of modifications, procedure revisions, tests, or other activities that do not constitute a change in the SAR, a screening record should not be required for activities that satisfy those criteria.

Nevertheless, we recognize that it is a good practice to prepare and retain records of 50.59 screenings in order to demonstrate that screened changes, test and experiments do not involve a change in the SAR and therefore are not subject to Section 50.59. We support the guidance in NEI 96-07, which states that if screenings are performed within a licensee's process, they should be retained consistent with the retention requirements of the document being screened.

Section III.I - Malfunction of Equipment Important to Safety of a Different Type

A. Rule Language:

A proposed change, test or experiment shall be deemed to involve an unreviewed safety question (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report may be increased; or (ii) if the possibility for an accident or malfunction different than any evaluated previously in the safety analysis report may be created

B. NRC Position:

In performing 50.59 safety evaluations, a licensee must consider not only the results of the malfunction but also the cause and mode of failure.

C. Comment:

As NUREG-1606 acknowledges, for some structures, systems, and components, the evaluation of malfunctions discussed in the SAR may only have been at the train or system level, rather than the component level. In such cases, the cause or failure mode of the component is not important, as long as the overall probability and consequences of the component malfunction are bounded by the train or system malfunction described in the SAR; i.e., the component malfunction would not affect the discussion of the train or system malfunction described in the SAR. In such cases, the component malfunction would not be an unreviewed safety question under Section 50.59.

Section III.J - Definition of Change

A. Rule Language:

The holder of a license . . . who desires . . . to make a change in the facility or the procedures described in the safety analysis report or to conduct tests or experiments not described in the safety analysis report, which involve . . . a change in technical specifications, shall submit an application for amendment of his license . . .

B. NRC Position:

NRC approval of the proposed modification and Technical Specification changes must occur before the modification is implemented.

C. Comment:

In general, the staff's position is valid. However, there may be limited cases when a licensee could implement a modification prior to issuance of the associated Technical Specification amendment. For example, during an outage when a particular system is not required to be operable under the Technical Specifications, a modification involving that system should be permitted provided that the modification does not adversely impact systems that are required to be operable or otherwise affect safety. In such cases, the licensee should be allowed to implement the modification at its own risk pending NRC approval of the amendment. Obviously, the licensee would not be able to rely upon the modification (or to go to a mode of operation in which the system is required to be operable or could adversely impact operable systems) until NRC approval of the amendment is issued.

Section III.L - Licensee Identification of Technical Specifications That Are Not Adequate to Assure Compliance with the Design Basis

A. Rule Language:

10 CFR § 50.36 defines the types of technical specifications that licensees should have, but does not specifically address this issue.

B. NRC Position:

Upon discovery that the Technical Specifications are not adequate to assure compliance with the design bases, the licensee should take the appropriate action to place the plant in a safe condition (such as by imposing more conservative administrative limits), and also take action (such as requesting a license amendment) so that the Technical Specifications represent the minimum requirements. Failure to seek such approval could be considered as a failure of a licensee to take prompt corrective action and would be inconsistent with Criterion XVI (Corrective Action) of Appendix B to 10 CFR Part 50.

C. Comment:

Placement of the plant in a safe condition, such as by imposing more conservative administrative limits, is sufficient to satisfy the requirements in Criterion XVI of Appendix B for prompt corrective action. As discussed below, Appendix B does not require that a licensee also seek an amendment of the Technical Specifications.

Appendix B to Part 50 pertains to the managerial and administrative controls to assure safe operation. Its requirements apply to all activities affecting the safety-related function of structures, systems and components, including "designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying." *See* 10 CFR 50 Appendix B, "Introduction." Appendix B does not discuss the Technical Specifications. Further, Criterion XVI requires that "measures be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected." Since implementation of the necessary

administrative controls will ensure that the affected structures, systems or components will perform satisfactorily, the purpose of Appendix B will have been met whether or not a change in the Technical Specifications is sought.

In this regard, the Technical Specifications are a regulatory document, not a quality-related document. The Technical Specifications identify regulatory limits and controls on a plant. Other documents, such as procedures and design documents, constitute the quality-related documents that are subject to Appendix B. As long as these documents are appropriately corrected, quality and safety are assured and Criterion XVI of Appendix B is satisfied.

Nevertheless, we agree that it is a good practice (and, in some cases, may be necessary under 10 CFR § 50.9(b)) to inform the NRC of inadequacies in the Technical Specifications and to request appropriate changes in the Technical Specifications to remedy such inadequacies. However, this good practice is not required by Appendix B.

Section III.M - Role of Probabilistic Risk Assessment (PRA) in Section 50.59 Evaluations

A. Rule Language:

The rule does not directly refer to or address the use of PRA in 50.59 safety evaluations. It does, however, address probabilities and consequences of accidents.

B. NRC Position:

The PRA is not suitable as a decision-making tool for 50.59 safety evaluations, unless the PRA is included in the SAR.

C. Comment:

Usually, the determination of whether a change involves an increase in probability under Section 50.59 is based upon a qualitative assessment using engineering judgment or evaluations consistent with the original analysis assumptions. However, there is nothing in Section 50.59 which prohibits quantitative analyses, such as PRAs. Thus, under Section 50.59, licensees may utilize reasonable engineering practices, engineering judgment, or PRA techniques, or any combination, as appropriate, in determining whether the probability of occurrence of an event may increase as a result of implementing a proposed change. This position is reflected in NEI 96-07, which allows (but does not require) the use of PRAs.

As discussed in NUREG-1606, PRAs in general are based upon realistic assumptions rather than the conservative assumptions used in the accident analyses in SARs. However, this fact alone should not preclude the use of PRAs for performing 50.59 safety evaluations. For example, a licensee could make appropriate modifications to a PRA to use similar assumptions to those contained in the SAR accident analysis. In such an event, a PRA could provide an accurate estimate of the impact of a change on the probability of the accident analyzed in the SAR. Or, a licensee could perform an evaluation and determine that, even though the PRA uses realistic assumptions, use of the PRA will provide an adequate indication of the *direction* (as distinct from the *magnitude*) of the change in probability. In such a case, the PRA could be used to provide a qualitative determination of whether a proposed change in the plant involves an increase in the

probability of an accident in the SAR. Thus, provided that a licensee appropriately takes into account the differences between the accident analysis in the SAR and the PRA, there should be no prohibition on the use of a PRA in performing 50.59 safety evaluations.

This is not to imply that PRAs are always an appropriate tool for determining whether an unreviewed safety question exists. A licensee must exercise judgment in determining whether a PRA should be used to help evaluate whether an unreviewed safety question exists. In this regard, PRAs are generally used to provide an additional dimension for deterministic 50.59 safety evaluations, rather than to provide the sole basis for an unreviewed safety question determination.

Section III.N - Licensee Practice of Deleting Information from Safety Analysis Reports

A. Rule Language:

There is currently no established policy, regulation, or guidance that governs the removal of information from safety analysis reports when the removal of information is not related to changes to the facility or procedures described in the safety analysis report.

B. NRC Position:

Although there is no established policy or guidance with respect to removal of information from the SAR not associated with changes to the facility or procedures, the staff's position is that licensees may not remove material from safety analysis reports unless the material is changed as a direct result of a change to the facility.

C. Comment:

The NRC staff position is contrary to the provisions of 10 CFR § 50.59, and is not consistent with the Commission's recent Staff Requirements Memorandum, which directed the staff to develop an approach to allow licensees to delete certain information from SARs. Section 50.59 allows a licensee to "make changes in the facility as described in the *safety analysis report*," without prior NRC approval, provided that the changes do not involve an unreviewed safety question or a change in the Technical Specifications. Thus, Section 50.59 expressly allows a licensee to change the descriptions in the SAR, provided the licensee complies with the provisions of the rule. Therefore, the staff's position is inconsistent with Section 50.59.

In this regard, it should be emphasized that Section 50.59 does not require that a system or component be deleted from the plant, merely because the licensee has performed a 50.59 safety evaluation and deleted the description of the system or component from the SAR. There is no requirement that a SAR describe every component in the plant. See 10 CFR § 50.34 (which governs the content of SARs). In practice, every plant contains numerous components that are not mentioned in the SAR. Therefore, if a system or component is not required to be described in the SAR, and if deletion of the description of the system or

component from the SAR does not involve an unreviewed safety question or a change in Technical Specifications, there is no reason to prohibit deletion of the description under Section 50.59.

NUREG-1606 expresses a concern by the staff that, once a description of a system or component is deleted from the SAR, subsequent changes to the system or component might involve an unreviewed safety question, and yet Section 50.59 would not prohibit such changes because the system or component is not described in the SAR. However, the staff's concern is unwarranted. As Section III.E.4 of NUREG-1606 explains, Section 50.59 applies to so-called "indirect" and "secondary" changes; i.e., changes in a system or component not described in the SAR, when such changes affect a system, component, or function that is described in the SAR. As a result, the type of change of concern to the NRC would be addressed by Section 50.59 and should not pose any bar to deletion of the description of the system or component from the SAR.

Section III.O - Application of 10 CFR 50.59 to the Resolution of Degraded and Nonconforming Conditions

A. Rule Language:

There are no provisions within 10 CFR § 50.59 that define how it should be applied to degraded or nonconforming conditions with the SAR. As a general matter, the applicable regulation for dealing with this circumstance is 10 CFR Part 50, Appendix B, Criterion XVI, "Corrective Action," which requires, among other things, that licensees take "prompt" corrective action.

B. NRC Position:

- 1) At the first available opportunity, the degraded or nonconforming condition with the SAR must be corrected or a 50.59 safety evaluation must be prepared for the "de facto" change. The first available opportunity includes the first available outage of reasonable duration and timing to effect the corrective action.
- 2) A plant currently operating with a condition involving an unreviewed safety question (USQ) would not normally be required to shutdown, provided that the licensee has determined that all necessary equipment is operable, and that the licensee expeditiously (i.e., within days) submits its application for license amendment. The staff would not allow plant startup unless the condition is first corrected or staff approval is received.

C. Comment:

Position 1

The staff's position is unnecessary, will create undue burdens on licensees, and could be counterproductive to safety.

Criterion XVI of Appendix B governs corrective action for degraded and nonconforming conditions. Criterion XVI requires that corrective action be "prompt." As long as this requirement in Criterion XVI is satisfied, Section 50.59 is not applicable (i.e., there is no de facto change).

The promptness of corrective action depends upon the particular circumstances. Relevant factors include the safety significance of the degraded and nonconforming condition, the need for preparation for implementation of the corrective action, and the conditions (e.g., outage of suitable duration) required for implementation of the corrective action. In this regard, the "promptness" requirement in Appendix B does not necessarily require that corrective action be implemented at the first available opportunity. For example, if the safety significance of the degraded or nonconforming condition is low or non-existent, corrective action may be deferred beyond the first available opportunity and still be considered prompt. In such cases, Appendix B would be satisfied, and there should be no need to prepare a 50.59 safety evaluation.

This position is consistent with safety. In particular, when a nonconforming or degraded condition is discovered, licensees must determine the operability of the affected equipment under Generic Letter 91-18. If the equipment is operable (or appropriate compensatory action is taken), the safety of the plant is assured. Therefore, neither a 50.59 safety evaluation nor corrective action at the first available opportunity is needed to protect safety.

In contrast, the staff's position may inadvertently have the effect of decreasing safety. By requiring corrective action or a 50.59 safety evaluation at the first available opportunity for degraded or nonconforming conditions that are not safety significant, the staff would, in essence, be prescribing a licensee's priorities. The staff's position could require licensees to divert their attention and resources from matters that are more important to safety, in order to correct conditions that are not safety significant. Such micro-management by the staff is contrary to safety and sound regulatory policy.

In summary, there is no requirement to correct or perform a 50.59 safety evaluation at the first available opportunity for degraded and nonconforming conditions. Instead, there is only a requirement that prompt corrective action be taken for adverse conditions under Criterion XVI of Appendix B. A 50.59 safety evaluation is not needed for the condition, unless the licensee plans on accepting it as a permanent change to the facility.

Position 2

As NUREG-1606 states, a change may be safe and yet still involve an USQ. Provided that the structures, systems, and components in question can perform their safety functions (i.e., structures, systems, and components are operable), there is no regulatory or safety justification for preventing a plant from restarting with an USQ.

- Section 50.59 is silent with respect to this matter. Therefore, startup with a degraded or nonconforming condition is not prohibited by NRC regulations.
- If the affected equipment is operable, adequate protection is provided for the public health and safety. Therefore, there is no safety reason to prohibit startup. In particular with respect to equipment in the Technical Specifications that is degraded or nonconforming, the Technical Specifications contain limiting conditions for operation (LCOs) that were developed in accordance with 10 CFR § 50.36. The LCOs specify the lowest functional capability or performance level of equipment required for safe operation of the facility. Thus, as long as the LCOs are satisfied, plant safety is assured and the plant should be permitted to restart.

Therefore, startup with a degraded or nonconforming condition that constitutes an USQ should be permitted, provided that the affected structures, systems, and components are operable and the plant is safe.

Section III.P - Definition of Increase in Probability

A. Rule Language:

A proposed change, test or experiment shall be deemed to involve an unreviewed safety question (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the SAR may be increased.

B. NRC Position:

The language of 10 CFR § 50.59 (probability may be increased) indicates that any uncertainty or doubt about whether an increase, even a negligible one, has occurred should lead to the conclusion that an unreviewed safety question is involved. Because Section 50.59 uses the term "may be increased," any increase, however slight, triggers an unreviewed safety question and thus requires prior NRC review and approval.

C. Comment:

The staff's position is unduly legalistic and is not a reasonable interpretation of Section 50.59. Additionally, the staff's position would impose an undue administrative burden on both the NRC and licensees by requiring the processing of unnecessary license amendments. As a result, the staff's position is unnecessary and inappropriate and should not be utilized.

As discussed in NEI 96-07, the determination of whether a change involves an increase in probability of an accident or malfunction is generally based upon a qualitative assessment using engineering judgment. When a change in probability is so small as to be negligible, or when the change in probability is within the bounds of uncertainty of the accident analysis in the SAR, such that it cannot be reasonably concluded that the probability has actually changed (i.e., there is no clear trend towards increasing the probability), there is no reason from either a regulatory or safety perspective to classify the change as an increase in probability warranting prior NRC review and approval.

Furthermore, although Section 50.59 uses the term "may be increased," this phrase should be construed in the context in which Section 50.59 was issued. As the staff acknowledges in NUREG-1606, at the time Section 50.59 was promulgated, "the

staff considered accident and transient probabilities in a broad sense, as for instance, frequent (anticipated operational occurrences), or infrequent (postulated accidents)." In this context, it is apparent that negligible increases and uncertain increases would not constitute conditions in which the probability "may be increased," as that term was originally intended by the Commission when it issued Section 50.59.

Finally, the staff's interpretation in NUREG-1606 would impose undue burdens on both the NRC and licensees without any corresponding benefits in safety. As discussed in Section IV.B of NUREG-1606, the staff's interpretation would result in the need for license amendments for changes that "have little true significance for the licensing basis." License amendments are relatively costly, and requiring license amendments for changes involving negligible or uncertain increases in probability would divert management attention from matters that are more important to safety.

In summary, the staff's interpretation in NUREG-1606 is inconsistent with the intent of Section 50.59, would not promote safety, and would be unduly burdensome. For all of these reasons, negligible increases or uncertain increases should not be classified as unreviewed safety questions.

Section III.R - Definition of Increase in Consequences

A. Rule Language:

A proposed change, test or experiment shall be deemed to involve an unreviewed safety question (i) if the probability of occurrence of the consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report may be increased;

B. NRC Position:

Any increase in consequences in the accident doses in the SAR is an unreviewed safety question, even if the dose is less than the acceptance limit specified in the NRC's safety evaluation report.

C. Comment:

Our Comments on Section III.P related to the definition of increase in probability are equally applicable to Section III.R on the definition of increase in consequences.

Furthermore, NUREG-1606 states that the baseline for determining whether an increase in consequences has occurred is the calculated dose reported in the SAR, not the acceptance limit. We believe that it is appropriate to use the acceptance limit. For example, if the SAR itself reports both a calculated dose and an acceptance limit (e.g., a small fraction of the dose in Part 100), a change in the calculated dose that is within the bounds of the acceptance limit in the SAR should not be construed as an increase in consequences or an unreviewed safety question. Similarly, if the NRC's safety evaluation report (SER) reports an acceptance limit (e.g., a small fraction of the dose in Part 100), a change in the calculated dose that is within the bounds of the acceptance limit in the SER should not be construed as an increase in consequences or an unreviewed safety question.

In summary, if the consequences resulting from a change are bounded by the acceptance limits in the SAR or the SER, the change obviously does not involve an *unreviewed* safety question. The staff's interpretation of "increase" is not reasonable and would result in unnecessary burdens on

licensees and the NRC to process license amendments for changes whose consequences are bounded by acceptance limits previously accepted by the NRC. Thus, the staff's interpretation would not contribute to protection of the public health and safety and would be inconsistent with sound regulatory policy.

**Section III.V -Consideration of Compensating Effects When Making an
Evaluation of Whether an Unreviewed Safety Question Exists**

A. Rule Language:

The rule does not use the terms "compensating effects" or "compensatory measures."

B. NRC Position:

In determining whether a change involves an unreviewed safety question, compensating actions may not be credited unless these actions are "linked" to the change. Compensatory actions that are independent of the change may not be credited.

C. Comment:

Initially, it should be noted that NUREG-1606 does not provide a precise definition or a clear example of what it means by the term "linked." Absent guidance on the definition of "linked," licensees may have difficulty in determining whether it is permissible or not to group changes into a single 50.59 safety evaluation.

It appears to be the staff's position that changes are linked only if the initial change "requires a subsequent change in another system or component." Such a definition is much too narrow. We agree that a subsequent change that decreases the probability of an accident should not be used to compensate for an initial change that increases the consequences of an accident, or vice versa. However, if the subsequent change offsets an increase in probability (or consequences) attributable to the first change, credit should be allowed for the subsequent change even if it is not "required" by the first change. For example, the probability of any particular accident scenario is typically the product of the probabilities of several independent events ($P_1 \times P_2 \times P_N$). As long as any increase in P_1 is offset by a decrease in P_2 , there is no increase in probability of the accident and therefore no unreviewed safety question, even if P_1 and P_2 correspond to independent events. Thus, licensees should be allowed to group several changes into a single 50.59 safety evaluation, regardless of whether the

changes are "linked," as that term appears to be understood by the NRC staff.

As noted in NUREG-1606, the NRC staff's position is contrary to established NRC policy (Inspection Manual Chapter 9900 guidance on 10 CFR § 50.59) and industry guidance (NSAC-125, the draft NEI 96-07, and the October 1996 NEI point paper) which allow credit for compensating measures such as administrative controls to offset small increases in probability or consequences or reductions in margin of safety. Furthermore, there is nothing in the language of Section 50.59 which would prevent a licensee from considering a group of changes in performing a safety evaluation.

Additionally, the NRC's new position is not necessary to protect the public health and safety. Because offsetting changes would only be credited in situations involving small changes in the probability, consequences, or margins of safety, such situations would not materially affect plant safety. Thus, prohibiting credit for such offsetting changes would not materially protect the health and safety of the public. Furthermore, when the benefits of the offsetting changes are considered, the NRC's position may actually discourage licensees from implementing groups of changes that would provide an overall safety improvement.

In summary, a licensee should be allowed to account for compensating actions to offset small changes in probability, consequences, or margin of safety. There is no basis in the language of Section 50.59 nor any safety reason to require a licensee to consider separately changes that are part of a single package.

Miscellaneous Comments

Section III.F.4

This section discusses the staff's new interpretation of Section 50.71(e), which represents a departure from the NRC's previous interpretation. The staff's new interpretation of Section 50.71(e) needs to be evaluated under the Commission's backfit criteria in 10 CFR § 50.109. Furthermore, guidance on Section 50.71(e) is not necessary or beneficial to guidance on Section 50.59. Therefore, the NRC should not intermingle guidance on these separate rules.

Various Sections

A number of sections in NUREG-1606 (e.g., III.L.4, III.R.4, III.V.4) state that the NRC may take enforcement action if a licensee does not adhere to the guidance provided in this document. It is inappropriate to take enforcement action for noncompliance with staff guidance. Such statements are not appropriate for staff guidance documents.

ATTACHMENT 2

COMMENTS ON POLICY ISSUES IN NUREG-1606

Comment on Issue IV.A - Scope of Section 50.59

This policy issue raises the prospect of rulemaking to increase the scope of Section 50.59 to include licensing commitments not currently included in safety analysis reports (SARs). We strongly oppose such rulemaking. The Nuclear Energy Institute (NEI) has issued guidance on control of licensing commitments not contained in SARs, and NRC approved this guidance in SECY-95-300. This guidance has worked well in practice, and there is no compelling reason to impose additional regulatory burdens on changes to licensing commitments.

Comment on Issue IV.B - Unreviewed Safety Question Threshold

This policy issue raises the prospect of rulemaking to modify the definition of an USQ, so that negligible increases (or clearly acceptable increases) in probability or consequences of an accident or malfunction would not require prior NRC approval. We approve the goal sought by this policy issue. Changes that involve negligible or acceptable increases should not require prior NRC approval. However, we do not believe that rulemaking is needed to accomplish this goal. As discussed in Attachment 1, a reasonable interpretation of the current language in Section 50.59 would allow achievement of this goal.

This policy issue also raises the prospect of rulemaking to clarify the definition of "margin of safety." However, the clarifications identified in this policy issue are already contained in the guidance in NEI 96-07, and a rulemaking is not necessary to permit implementation of this guidance.

Finally, this policy issue suggests other changes in the definition of USQ, including allowing consideration of risk-significance or small decreases in margin without prior NRC approval. We appreciate and support the goal being sought by these suggested changes. However, we oppose rulemaking to achieve this goal, given the cost and unpredictability of rulemaking and the successful history of implementation of the current provisions in Section 50.59.