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

CHAIRMAN

February 13, 1997

Mr. Joe F. Colvin
President and Chief Executive Officer
Nuclear Energy Institute
Suite 400
1776 I Street, N.W.
Washington, D.C. 20006-3708

Dear Mr. Colvin:

In a meeting on October 10, 1996, you presented a list of principles for conducting licensing basis reviews that you believe would clarify licensee and Nuclear Regulatory Commission (NRC) responsibilities associated with final safety analysis reports (FSARs) and 10 CFR 50.59 implementation. The NRC staff has carefully reviewed your list, and I am enclosing its views on the individual points. To the extent that the comments are identified as preliminary views, they will not be applied in practice pending further evaluation and decision.

From the Commission's perspective, the essential question of licensee and NRC responsibilities is already clear. As discussed in my letter to NEI dated August 14, 1996, we take the position that individual licensees are responsible for knowing their licensing basis, for having appropriate documentation that defines their design basis, and for having procedures to perform necessary assessments of plant or procedure changes. The NRC is responsible for maintaining cognizance of the licensees' programs for maintaining the design basis and for assuring that those programs are effective and conform with NRC regulations. The NRC, in order to ensure adequate protection of public health and safety, will enforce the regulatory requirements that address the licensee's obligation to maintain the licensing bases for their plants.

Nevertheless, the Commission is reexamining a number of regulatory positions relating to the FSAR and 10 CFR 50.59 implementation as part of the NRC lessons-learned activities related to the Millstone Station. We will consider improvements in, or changes to, our policies, practices and regulations in light of our evaluation and comments from the industry and the public.

Sincerely,

Shirley Ann Jackson

Shirley Ann Jackson

Enclosure: As stated

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Responses to Nuclear Energy Institute's
"Principles For Conducting Licensing Basis Reviews"

1. Legally binding requirements are those established by statute, regulation, license condition, technical specification, or order.

The staff agrees, as a general proposition, that binding requirements are contained in statutes, regulations, license conditions, technical specifications (TS), and orders. The plant-specific implementation of the requirements of regulations or license conditions are often found in other licensing documents, such as the final safety analysis report (FSAR) or other correspondence submitted as part of license applications or amendments to operating licenses. Certain documents, such as the FSAR, the emergency plan, quality assurance plan, and safeguards contingency plan, also contain binding requirements, in the sense that the Commission has limited by regulation a licensee's ability to change the information contained in them. For example, General Design Criterion 2 requires that nuclear power plant systems, structures and components be designed to withstand the effects of natural phenomena, such as earthquakes, tornadoes, hurricanes, floods, and tsunami without the loss of capability to perform their safety function. Part 100 of Title 10 of the Code of Federal Regulations defines a set of conditions that must be satisfied in calculating the type of earthquake against which the plant must be capable of operating. The FSAR describes the type of earthquake against which the plant is designed and the nature of the ground motion response used to evaluate the plant's toughness to withstand earthquakes. The staff considers the information described above in the FSAR to constitute binding requirements for the plant in that a licensee's ability to change such information is limited.

A licensee can change the design bases or operating characteristics over the life of the license, using 10 CFR 50.59 to determine when NRC approval is required for changes to plant design bases or operating conditions. Changes to the license (including TS) must follow the process described in 10 CFR 50.90. Relief from requirements specified in a regulation in Part 50 can be sought, by exemption, under the special circumstances specified in 10 CFR 50.12.

2. The central element in ensuring adequate protection of public health and safety is the design basis [sic] as defined in 10 CFR 50.2 for the portions of the plant design important to safety, together with the regulatory requirements contained in 10 CFR 50.48, 50.49, 50.61, 50.62, and 50.63. This should be the focus of ongoing initiatives with respect to the role and use of the FSAR, including licensee FSAR verification efforts, NRC inspection efforts, and NRC enforcement actions. The industry's "Design Basis Program Guidelines" (NUMARC 90-12), provide a useful framework for maintaining the design basis.

The NRC disagrees that regulatory requirements that are "central" to assuring the protection of public health and safety are limited to the set of regulations described in the NEI position. In accordance with 10 CFR 50.34, licensees are required to include information in the FSAR that describes the facility, presents its design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and "of the facility as a whole." This language recognizes the interrelation of all

systems in the plant and the effect that one system can have on another, and on the overall safety of the plant.

It is the NRC's view that each system or structure should be subject to evaluation to assure that the established design and licensing requirements are being met. Further, the NRC implements its inspection and enforcement activities to verify compliance with the terms and conditions of licenses and NRC regulations, including whether the updated final safety analysis report and facility are consistent.

The NRC's position on the use of NUMARC 90-12 was documented in a letter to NUMARC dated November 9, 1990. In that letter, the NRC stated that the NUMARC approach could provide a useful framework and worthwhile insights to utilities considering a range of options for undertaking design basis reconstitution programs. The NRC also stated that the goal of any design reconstitution program should be to establish confidence that the existing facility is in accordance with current design documents and that any deviations are reconciled. Finally, the NRC provided additional comments on several areas in which the guideline did not address specific issues. Specifically, the staff provided additional insight in the areas of design document technical review, essential design documents, prioritization of missing or inadequate documents, and the need for licensees to establish essential design bases documents. In its comments, the NRC stated that the reestablishment of the design bases without reconstitution of the supporting essential design documents may not provide a sufficient amount of information to support future plant modifications or current plant operation.

It is the responsibility of each licensee to know their licensing basis, to have appropriate documentation that defines their design bases, and to have procedures for performing the necessary assessments of plant or procedure changes required by NRC regulations. As stated in a letter to NEI from Chairman Jackson dated August 14, 1996, an in-depth, vertical slice review of design bases documentation and comparison of "as built" and "as operated" safety systems is a more appropriate method of assessment. For example, reviews similar to safety system functional inspections (Inspection Procedure 93801, "Safety System Functional Inspections"), may be used to evaluate the licensee's program effectiveness to adequately maintain the licensing and design bases.

3. The FSAR serves as a reference document that describes the relevant safety design basis of the plant and its conformance to legally binding requirements (i.e., statutes, regulations, license conditions, technical specifications and NRC orders). SERs document the basis of the NRC's evaluation and acceptance, sometimes with conditions, or rejection of a licensee's submittal with the basis for the rejection. However, neither FSARs nor NRC SERs by themselves establish stand-alone legally binding requirements.

The staff agrees that the FSAR describes the design bases of the plant and its conformance to the Commission's regulations. The FSAR is the portion of an application for an operating license that sets forth technical information specified in 10 CFR 50.34. The principal purpose of an FSAR is to inform the

Commission of the nature of the facility, the plans for its use, and the analyses that have been performed to evaluate whether the facility has been constructed and will operate without undue risk to public health and safety. The specific information that must be included in an FSAR is listed in 10 CFR 50.34(b).

The FSAR is the primary radiological health and safety document upon which the Commission bases a decision to issue an Operating License (OL) and is, as such, part of the licensing basis of a facility. The FSAR also is a basic document used by NRC inspectors to determine whether the facility has been constructed and is operating within the plant design bases and other licensed conditions.

Although the FSAR is not incorporated into the OL, information contained in an FSAR is, nonetheless, subject to varying degrees of regulatory control. For the purpose of assessing the regulatory significance of the FSAR, information contained in an FSAR can be placed into three categories. The first category comprises information that has been designated as technical specifications and has been incorporated into the license, pursuant to 10 CFR 50.36. This information may not be changed without prior Commission approval by means of an application to amend the OL in accordance with the provisions of 10 CFR 50.90. Section 50.91 requires that notice and an opportunity for a hearing on an amendment to an OL be provided.

The second category comprises information concerning the description of the facility, the description of procedures, the conduct of tests and experiments, and the description of the quality assurance and emergency preparedness programs. This category of information also includes information that is incorporated by reference into the FSAR, such as fire protection plans, radiation protection (as low as is reasonably achievable [ALARA]) programs, or industry codes and standards. Under 10 CFR 50.59, changes to the facility or its procedures as described in the FSAR and performance of tests and experiments not described in the FSAR that involve a change to the technical specifications or an unreviewed safety question may not be performed without the Commission's approval. If a change or a conduct of test and experiments involves an unreviewed safety question or a change to technical specifications, the licensee must submit an application to amend the OL under 10 CFR 50.90. Failure by the licensee to perform the analyses required by 10 CFR 50.59 may be the basis for enforcement action. Changes to the licensee's quality assurance program and emergency preparedness program, which must be described in the FSAR, are controlled by the requirements of 10 CFR 50.54(a) and 50.54(q), respectively. Changes to the licensee's security and safeguards program are controlled by the requirements of 10 CFR 50.54(p).

The remainder of the information contained in an FSAR, the changes to which are not addressed under 10 CFR 50.59 or are not controlled specifically under 10 CFR 50.54, falls into a third category. For example, an FSAR contains such information as a description of the population surrounding the facility.

The SER is the staff's document setting forth the results of its review of an FSAR at the time of initial licensing. In general, the SER discusses (1) the scope of the staff's review; (2) which review areas were emphasized; (3) which

matters were modified by the applicant, require additional information, or will be resolved in the future; (4) where the plant departs from the standard review plan criteria and the bases for such departures; and (5) exemptions from the Commission's regulations. The SER may contain a restatement of the Commission's regulations and it contains the staff's findings and conclusions regarding compliance with regulatory requirements. In addition, the SER reflects commitments made by the applicant that the staff determined to be a necessary element to support an acceptable finding. In order to be binding, these commitments must be reflected in supplements or amendments to the FSAR, technical specifications, or license conditions.

Subsequent to the issuance of an operating license, the staff prepares and issues safety evaluations in response to requests for amendments to the operating license, exemptions, reliefs, and the resolution of newly identified regulatory issues or other changes to the licensing basis. These safety evaluations contain the same type of information previously described and document the conditions and assumptions used by the staff in reaching its conclusions pertaining to the safe operation of the facility. As such, the staff uses the safety evaluations to document the licensee's revisions to the plant-specific design bases (as defined in 10 CFR 50.2), as well as to document the staff's acceptance of licensee's programs and processes for meeting license requirements.

4. It is important to ensure that the FSAR be updated, as specified in §50.71(e), to include essential safety information, consistent with the collection of documents that provided the legal basis for the NRC issuing or amending the plant's operating license.

Section 50.71(e) states, in part, that "the updated FSAR shall be revised to include the effects of: all changes made in the facility or procedures as described in the FSAR; all safety evaluations performed by the licensee either in support of requested license amendments or in support of conclusions that changes did not involve an unreviewed safety question; and all analyses of new safety issues performed by or on behalf of the licensee at Commission request." In the statements of consideration for the update rule, the NRC stated that all analyses submitted to the NRC since the original application for an operating license were to be incorporated into the updated FSAR, either in the associated sections or in an appendix to the FSAR. Neither the rule nor the statements of consideration for the rule limits the information required to be placed in the updated FSAR to "essential safety information" as the NEI statement seems to imply.

Existing guidance and licensee implementation of the rule have, however, resulted in variability in the content of FSARs. Based on the information provided in Generic Letter 80-110, dated December 15, 1980, and the statements of consideration for the update rule, it was the staff's expectation that, if the NRC requested an analysis that resulted in a change in the facility or procedures as described in the FSAR, the analysis would be incorporated into the FSAR. The FSAR updates should include "all analyses of new safety issues performed by or on behalf of the licensees at Commission request." The staff is reassessing the regulatory guidance and the regulations as they relate to the need for the FSAR to accurately describe the facility and to provide the

bases against which to perform sound 10 CFR 50.59 evaluations. The staff will make recommendations on the need for any regulatory improvements to the Commission.

5. To ensure that the FSAR can effectively serve as a reference document of the safety significant portions of the design, licensees may remove non-safety relevant information from the FSAR through a disciplined program that documents the rationale for the change and the evaluations are retained by the licensee.

The staff recognizes that there is no established policy or guidance with respect to removal of information from the FSAR not associated with changes to the facility or procedures. For this reason, the staff is currently developing its guidance in this area. In the interim, however, it is the staff's view that licensees may not remove material from FSARs unless the material is changed as a direct result of a change to the facility.

According to 10 CFR 50.34, an FSAR must include the following information: (1) all current information that has been developed since issuance of the construction permit relating to site evaluation factors; (2) a description and analysis of the structures, systems, and components of the facility; (3) the kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in 10 CFR Part 20; (4) a final analysis and evaluation of the design and performance of structures, systems, and components; (5) a description and evaluation of the results of the applicant's programs to demonstrate that any safety questions identified at the construction permit stage have been resolved; (6) information concerning facility operation, including the applicant's organizational structure, allocations, or responsibilities and authorities, and personnel qualifications requirements; managerial and administrative controls to be used to assure safe operation; plans for preoperational testing and initial operations; plans for conduct of normal operations, including maintenance, surveillance, and periodic testing of structures, systems, and components; plans for coping with emergencies; and proposed technical specifications; (7) the technical qualifications of the applicant to engage in the proposed activities; (8) a description and plans for implementation of an operator requalification program; and (9) a description of protection provided against pressurized thermal shock events.

Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants, LWR Edition," and the Standard Review Plan (NUREG-0800) provide additional clarification of the information necessary to support a licensing review; however, applications for at least half of the plants were submitted before these documents were issued. Some plants were licensed with FSARs consisting of just a few volumes; other FSARs are many times larger, with much more detail. The NRC is currently evaluating the need for changes in the guidance or requirements related to the content and use of the FSAR.

6. To determine under § 50.59 whether the probability or consequences of an analyzed accident described in the FSAR would be affected by a proposed change, test or experiment, small or uncertain increases would not constitute an unreviewed safety question if compensatory measures are implemented that would offset the increase and an administrative tracking process established to assure that the compensatory measures remain in place. "Compensatory measures" are not intended to include actions taken to compensate for a degraded or nonconforming condition over an extended period of time, but rather are those measures initiated in an integrated manner with the proposed change so that the result is risk neutral.

NRC policy on the issue raised by this "principle" is currently under review; however, the staff's preliminary views are as follows.

Under 10 CFR 50.59, a licensee is required to determine, prior to implementation, whether a proposed change, test, or experiment would result in a change in the TS incorporated in the license or in an unreviewed safety question. An unreviewed safety question is involved (1) 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, (2) if a possibility for an accident or malfunction of a different type than any previously evaluated in the FSAR may be created, or (3) if the margin of safety as defined in the basis for any TS is reduced.

Section 50.59 establishes a process which assures that changes to a facility or procedures would preserve the design bases, functions, and margins of safety established during the licensing process. A licensee must evaluate each change on its own merits to determine if the change may result in (1) an accident of a new or different kind, (2) any increase in probability, (3) any increase in consequence or (4) a reduction in margin of safety. Therefore, proposed changes, tests, or experiments involving any increase in probability or consequences of an analyzed accident, regardless of whether considered small or essentially negligible, would involve an unreviewed safety question and would require a license amendment to implement. The NRC recognizes that when 50.59 was written, the use of probabilistic risk assessment was not considered when referring to an "increase in probability" of an accident, and notes that the above interpretation does not address the overall risk significance of any changes. These are policy issues regarding the use of probabilistic risk assessment in the context of Section 50.59 reviews and related information that the NRC is currently reviewing.

Compensatory measures have typically been utilized in short-term situations where a licensee undertakes actions to deal with a degraded or nonconforming condition. These measures provide a licensee a basis for continued operation until such time as a licensee achieves the final resolution of the degraded or nonconforming condition. However, these actions redefine the way the plant will be operated from that previously described in the plant safety analysis. Thus, such compensatory actions are viewed by the staff as a licensee "making changes to the facility or procedures," and thus require a 10 CFR 50.59 evaluation against the FSAR-described condition before they are implemented.

NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations," issued by the Nuclear Management and Resources Council and the Nuclear Safety Analysis Center in 1989, states that a small increase in the probability or consequences of an accident or malfunction previously evaluated in the safety analysis report does not involve a USQ. As stated in recently issued inspection guidance (NRC Inspection Manual, Part 9900; April 1996), this guidance conflicts with the rule which says that a USQ exists if the probability of occurrence or consequences of such an accident "may be increased." The staff has accepted the use of compensatory effects or measures to offset negligible increases in probability of consequences, as discussed in the April 1996 inspection guidance. However, the discussion in the previous paragraph clarifies the staff position relative to implementation of the rule in this area.

As described in GL 91-18, a licensee may continue to operate the plant in accordance with the regulations, license conditions and the Technical Specifications, if a system, structure or component is degraded or nonconforming but operable. However, a licensee must promptly identify and correct the condition in accordance with 10 CFR 50 Appendix B, Criterion XVI. When a licensee changes its facility or procedures as described in the FSAR to resolve a degraded or nonconforming condition, and the change involves a USQ, the licensee must obtain a license amendment prior to resuming operation of the plant with the degraded or nonconforming condition.

7. For purposes of conducting a § 50.59 evaluation, the margin of safety is the difference between the acceptance limit, which was established in the licensee's FSAR (as may have been modified by an SER), and the regulatory limit (i.e., the limit specified by the regulations or technical specifications). Changes that do not implicate a technical specification do not result in any change to the margin of safety. Draft NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations," (formerly NSAC 125), provides useful guidance in conducting evaluations of proposed changes in accordance with the requirements of § 50.59.

NRC policy on the issue raised by this "principle" is currently under review; however, the staff's preliminary views are as follows.

Pursuant to 10 CFR 50.59, a licensee may make changes to its facility or procedures as described in its Final Safety Analysis Report (FSAR) without NRC approval if it determines that such changes do not involve an unreviewed safety question or a change in a technical specification. As provided in 10 CFR 50.59, an unreviewed safety question is considered to exist if, among other matters, the margin of safety as defined in the basis for any technical specification is reduced. If a licensee proposes to modify its facility or procedures as described in the FSAR in a way that would involve a reduction in the level of margin, as established by the licensee and considered in NRC licensing reviews, then a USQ is involved and NRC review and approval of the proposed change is required.

In determining what changes represent a reduction of the margin of safety, it should be recognized that the technical specifications and the accident analyses on which they are based, provide assurance that the response of the

plant to various design basis accidents and transients is acceptable. A reduction of the margin of safety has occurred when an acceptance limit is no longer met as a result of a proposed change, test, or experiment. Acceptance limits are specific values within which the licensee has proposed to operate the facility and which the NRC has accepted during its review of a license application. These values are derived from the plant-specific design bases analyses reviewed by the NRC, and are found in the plant-specific FSAR (unless a different value is explicitly established in the NRC safety evaluation as the acceptance limit) and may, in some cases, be found in the "Bases" section for individual technical specifications.

Broad acceptance criteria such as those contained in the Standard Review Plan (NUREG-0800) are not acceptance limits as described above and, therefore, are generally not appropriate for evaluating whether an unreviewed safety question would exist.

The NRC staff has previously indicated that NSAC-125 provides useful guidance for conducting evaluations in accordance with the requirements of 10 CFR 50.59. However, the staff was unable to fully endorse this document because of inconsistencies with the rule. For instance, the staff disagrees with the NSAC-125 guidance that not every change resulting in an increase in radiological consequences is an unreviewed safety question.

By letter dated August 13, 1996, the Nuclear Energy Institute submitted NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations" for staff review. These guidelines seek to revise the NSAC-125 document in the areas of concern previously identified by the staff. The staff currently has the guidelines under review and will be working with NEI to resolve our concerns.

Principles For Conducting Licensing Basis Reviews

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- The central element in ensuring adequate protection of public health and safety is the design basis as defined in § 50.2 for the portions of the plant design important to safety, together with the regulatory requirements contained in §§ 50.48, 50.49, 50.61, 50.62, and 50.63. This should be the focus of ongoing initiatives with respect to the role and use of the FSAR, including licensee FSAR verification efforts, NRC inspection efforts, and NRC enforcement actions. The industry's *Design Basis Program Guidelines* (NUMARC 90-12) provide a useful framework for maintaining the design basis.

- The FSAR serves as a reference document that describes the relevant safety design basis of the plant and its conformance to legally binding requirements (*i.e.*, statutes, regulations, license conditions, technical specifications and NRC orders). SERs document the basis of the NRC's evaluation and acceptance, sometimes with conditions, or rejection of a licensee's submittal with the basis for the rejection. However, neither FSARs nor NRC SERs by themselves establish stand-alone legally binding requirements.

- It is important to ensure that the FSAR be updated, as specified in § 50.71(e), to include essential safety information, consistent with the collection of documents that provided the legal basis for the NRC issuing or amending the plant's operating license.

- To ensure that the FSAR can effectively serve as a reference document of the safety significant portions of the design, licensees may remove non-safety relevant information from the FSAR through a disciplined program that documents the rationale for the change and the evaluations are retained by the licensee.

- To determine under § 50.59 whether the probability or consequences of an analyzed accident described in the FSAR would be affected by a proposed change, test or experiment, small or uncertain increases would not constitute an unreviewed safety question if compensatory measures are implemented that would offset the increase and an administrative tracking process established to assure that the compensatory measures remain in place. "Compensatory measures" are not intended to include actions taken to compensate for a

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degraded or non conforming condition over an extended period of time, but rather are those measures initiated in an integrated manner with the proposed change so that the result is risk neutral.

- For purposes of conducting a § 50.59 evaluation, the margin of safety is the difference between the acceptance limit, which was established in the licensee's FSAR (as may have been modified by an SER), and the regulatory limit (*i.e.*, the limit specified by the regulations or technical specifications). Changes that do not implicate a technical specification do not result in any change to the margin of safety. Draft NEI 96-07, *Guidelines for 10 CFR 50.59 Safety Evaluations* (formerly NSAC 125), provides useful guidance in conducting evaluations of proposed changes in accordance with the requirements of § 50.59.