

**Comments on Draft NUREG-1606  
“Proposed Regulatory Guidance  
Related to Implementation of  
10 C.F.R. § 50.59  
(Changes, Tests, and Experiments)”**

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**I. Introduction**

The Licensing and Design Bases Clearinghouse and the Nuclear Utility Backfitting and Reform Group have prepared comments on the NRC's proposed guidance in Draft NUREG-1606 and related issues in SECY-97-036. The comments are divided into four sections that discuss (1) regulatory issues raised by SECY-97-036 and NUREG-1606; (2) backfitting implications of positions in Draft NUREG-1606; (3) regulatory philosophy and process; and (4) the NRC's policy question on expanding the scope of Section 50.59.

**II. Comments on Regulatory Issues Raised by SECY-97-036 and Draft NUREG-1606**

In SECY-97-036, "Millstone Lessons Learned Report, Part 2, Policy Issues," dated February 12, 1997, the Staff requested that the Commission approve several actions, both short and long term, associated with NRC oversight processes for assuring licensee "compliance" with a plant's Safety Analysis Report ("SAR"). In the Commission's May 20, 1997, Staff Requirements Memorandum ("SRM") for SECY-97-036, the short-term actions were approved, but the long-term actions were not approved. In the SRM, the Commission directed the Staff to implement Section 50.71(e) in a different manner than in the past. The Commission also directed the Staff to develop guidance on a risk-informed approach to SAR content. The actions associated with SECY-97-036 will affect the final Staff positions on implementation of Section 50.59 and, according to the SRM, the Staff is to provide a paper to the Commission discussing the integration of the guidance on Section 50.59 and the SAR actions. Accordingly, comments on specific issues discussed in SECY-97-036 are provided below because of the interrelationship to the guidance proposed in Draft NUREG-1606.

**A. Use of License Conditions to Enforce Commitments**

The NRC has recently begun issuing license amendments (*e.g.*, new "Appendix D" to the license) with specific license conditions that require certain information to be placed in the SAR.<sup>1/</sup> These license conditions may also incorporate by reference into the license related NRC and licensee correspondence and safety evaluations. This practice could significantly curtail, or even remove, the licensee's ability to use Section 50.59 to make future changes in the area approved by the amendment. As in the days before Section 50.59 was promulgated, the NRC could now be required to review and approve minor and trivial changes that have little or no safety impact.

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<sup>1/</sup> See SECY-97-036.

The NRC should carefully consider the resource demands on the agency that could be created by this approach and whether it is in the best interest of safety. This practice could result in freighting operating licenses with unnecessary detail and substantially increasing the number of license amendment requests. This result could strain the NRC's limited resources and cause delays that place unnecessary economic burdens on licensees (e.g., delays in plant startup or unnecessary plant shutdowns). In addition, when the license condition is imposed for a change that has not already been published in the *Federal Register* under the provisions in 10 C.F.R. § 50.91, an unnecessary delay of NRC approval for a change could ensue.

At a minimum, the NRC should provide guidance on the intent and effect of the license conditions, addressing (1) the extent to which the material covered by the license condition, once incorporated into the SAR, may then be changed according to the provisions of Section 50.59, and (2) what alternative actions licensees may take to avoid the need for such license conditions (e.g., commit to implement the Nuclear Energy Institute ("NEI") guidance document "Guideline for Managing NRC Commitments," endorsed by the NRC in SECY-95-300<sup>2</sup>).

#### **B. Content of SAR**

In the SRM on SECY-97-036, dated May 20, 1997, the Commission directs the Staff to take actions intended to ensure that SARs include "changes to the design bases, and . . . reflect the effects of other analyses performed since original licensing which should have been included under 10 CFR 50.71(e)." This action is significant and changes the manner in which Section 50.71(e) has historically been applied (see discussion below in Section II.C and in Section V). In the same action, the Commission directs the Staff to "formulate an approach" and to "promptly develop regulatory guidance for making . . . risk-informed decisions on information to be contained in the updated" SAR.

Licensees should not be forced to review the SAR for all historical changes to the design bases and effects of other analyses performed since original licensing, and then have an opportunity, once NRC guidance is issued, to refine the SAR and remove much of the material added (if it was not risk significant). A better and more efficient approach would be to combine the efforts so that the SAR review could be risk-informed and focus on the important material that should be included in the SAR. To accomplish this, the NRC should complete the risk-informed guidance and issue it to licensees along with an extension of the two-year period of enforcement discretion given in the NRC's policy and procedure for enforcement actions on departures from the SAR. 61 Fed. Reg. 54,461 (October 18, 1996).

The economic and resource impact of SAR reviews and updating could be in the range of tens to hundreds of millions of dollars for each plant. The resources would likely be greater for the older plants with less-detailed SARs, potentially forcing early shutdown of a plant that is otherwise operating safely and within its operating license and technical specifications. Imposition

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<sup>2</sup> SECY-95-300, "Nuclear Energy Institute's Guidance Document, 'Guideline for Managing NRC Commitments,'" December 20, 1995.

of such an economic burden has not been justified; therefore, the SRM actions cannot proceed until rulemaking has been conducted (see discussion below). We are concerned that the Commissioners may not understand the full impact of the actions directed by the SRM.

*Changes in Enforcement of Section 50.71(e)*

In the May 20, 1997 SRM on SECY-97-036, the Commission requested the Staff to apply Section 50.71(e) so as to include in the periodic SAR updates the effect of all licensee analyses since original licensing. The action appears to direct the Staff to enforce 10 C.F.R. § 50.71(e) in a manner differently than it has been applied since the rule was promulgated approximately 16 years ago. The NRC's position could, in effect, lead to requiring that the SAR be revised to include all current licensing basis ("CLB") information, although the NRC has previously evaluated the need for compilation of the CLB and determined that it was not cost effective.

Though the language of Section 50.71(e) is somewhat ambiguous, the industry has implemented, and the NRC has enforced, the rule in the manner it was intended when initially issued. We base this conclusion on the NRC's own statements at the time the rule initially became effective. For example, when the final rule was issued in 1980, the Statement of Considerations provided that updating the SAR did not change the scope of the SAR, did not constitute a licensing action, would not result in re-reviews of plants, and was only intended to provide information.<sup>3/</sup> The rule says that the updated SAR is to include the effects of:

- changes made to 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's request.

While an expansive interpretation of the rule might suggest that licensees must include essentially all of the information that would form the CLB, the NRC Staff has itself said that this is not the way that the agency has interpreted and enforced Section 50.71(e) since it was promulgated. In SECY-97-036, the Staff states:

As implemented, the agency and nuclear power industry did not interpret the rule to require adding to FSARs new design bases or commitments for new regulations, generic issues, or plant-specific events or enforcement. . . .

The agency recognized that FSARs did not contain the complete CLB when it

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<sup>3/</sup> See 45 Fed. Reg. 30,614, 30,615 (May 9, 1980).

promulgated the license renewal rule, 10 C.F.R. Part 54. In 1992, the staff acknowledged that neither the NRC nor industry have interpreted the FSAR update rule (Section 50.71(e)) to require new commitments or design bases for new rules, generic letters, bulletins, enforcement actions, and event reports be included in the SAR. . . .

10 C.F.R. § 50.71 (e) requires periodic updates to FSARs that contain "all changes necessary to reflect information and analysis submitted to the Commission by the licensee." However, it has not been implemented to consistently add new design bases or commitments for new regulations, generic issues, or plant-specific actions. The variability in the content of FSARs also contributes to the inconsistent content of FSAR updates in two ways: (1) the updates are to be, as a minimum, at the same level of detail as the original FSAR, and (2) the updates are to include the effects of "all changes made in the facility or procedures as described in the FSAR."<sup>4/</sup>

The NRC should not depart from its longstanding interpretation of Section 50.71(e). To implement a new interpretation that would effectively make the SAR into a single compilation of the entire CLB would be a significant undertaking that should only be considered through notice-and-comment rulemaking. We do recognize that the NRC is concerned about the completeness and accuracy of the SAR; however, changes to the historical application of the update rule must be carefully considered and the appropriate administrative processes must be followed. In fact, to change the way a rule has historically been enforced, the NRC must pursue notice-and-comment rulemaking according to the Administrative Procedure Act.<sup>5/</sup> A new interpretation would also be subject to the provisions of Section 50.109 for determining if backfitting is justified.

A more reasoned approach would be for the NRC (1) to continue to encourage licensees to review and update the SAR to correct inaccuracies and to add to, or delete from, the scope so that the focus of the SAR is on the design bases (as was the original intent of the SAR), and (2) to suspend enforcement of Section 50.71(e) for a period of time to allow this to occur, consistent with the two-year enforcement discretion given in the NRC's policy statement of October 18, 1996. 62 Fed. Reg. 54,461. Depending on the results of reviews this period, the NRC could assess whether to proceed with rulemaking to clarify Section 50.71(e).

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<sup>4/</sup> SECY-97-036, *supra*, Attachment 1 at 17, 20, and 29.

<sup>5/</sup> See *National Family Planning and Reproductive Health Ass'n v. Sullivan*, 979 F.2d 227, 231, 234 (D.C. Cir. 1992) (when an agency promulgates a legislative rule through notice and comment, announcing its interpretation to the public, the agency cannot repudiate that announced meaning without further notice-and-comment rulemaking). See also *New England Power Co. (NEP Units 1 and 2), Public Service Co. of New Hampshire*, (Seabrook Station, Units 1 and 2), ALAB-390, 5 NRC 733, 741-42 (1977) (rulemaking needed to change longstanding construction of regulation).

*D. Current Licensing Basis and Section 50.59*

In the SRM for SECY-97-036, the Commission approved short-term Action Item 9 on implementing Section 50.71(e), which, as discussed above, could effectively make the SAR a compilation of the CLB. Also, in Section IV.A of Draft NUREG-1606, the NRC asks for comments on possible options for expanding the scope of Section 50.59, one of which would be to effectively expand the scope of the SAR to that of the CLB.

If the NRC proceeds with actions to expand the scope of the SAR to include a compiled CLB, effectively expanding the scope of Section 50.59 to encompass any changes to that CLB, the action should only be applied prospectively, *i.e.*, to CLB changes made *after* these actions are implemented through notice-and-comment rulemaking. Absent an express statutory grant of authority, an agency does not have the authority to promulgate retroactive regulations. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208-09 (1988). It is impermissible for the NRC to impose "a new law or rule . . . to transactions completed in the past, prior to the new rule, where the rights and obligations of the parties already have been fixed." *The Curators of the University of Missouri*, CLI-95-1, 41 NRC 71 (1995) (quoting NRC analysis of retroactivity challenge to final regulations regarding license fees in 49 Fed. Reg. 21,293, at 21,296).

Many docketed commitments made by licensees over the years can be construed to be within the CLB under the current definitions in 10 C.F.R. Part 54 and Generic Letter ("GL") 91-18.<sup>6</sup> Most of these commitments are well beyond what is necessary for adequate protection of the public health and safety and for compliance with the license and regulations. They were generally made as voluntary commitments to apply conservative criteria (*e.g.*, in response to NRC Generic Letters requesting information that results in licensee actions) and, when made, both the NRC and the licensee understood these commitments were not legally binding because they were beyond applicable requirements. *See, e.g.*, SECY-95-300, "Nuclear Energy Institute's Guidance Document, 'Guideline for Managing NRC Commitments'" (December 20, 1995). Because these commitments were not legally binding, licensees had flexibility to change or eliminate these commitments without subjecting them to Section 50.59 and/or the license amendment process.

The NRC's proposal to expand the scope of Section 50.59 would retroactively alter the prior practice by subjecting such voluntary commitments to Section 50.59. By way of example, the NRC has made clear its current position that a safety margin as defined in Section 50.59 is measured by the difference between the licensee's commitment and underlying regulations or license provisions. Any reduction in this margin, according to the NRC, is an unreviewed safety question that requires a license amendment. Once placed within the scope of Section 50.59, these voluntary commitments, intentionally made more conservative than the underlying requirements, in order to work with the regulator in addressing a concern, would now routinely require a license amendment

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<sup>6</sup> Generic Letter 91-18, "Information to Licensees Regarding Two NRC Inspection Manual Sections on Resolution of Degraded and Nonconforming Conditions and on Operability," November 7, 1991.

to change because there would be a reduction in a safety margin within the scope of Section 50.59. Subjecting these commitments to Section 50.59 alters the well-settled rights and obligations of licensees by retroactively making these once voluntary commitments, for which the NRC may have lacked the regulatory authority to impose (*i.e.*, backfit), legally binding.

Based on the foregoing, the NRC should not retroactively apply Section 50.59 to the entire existing CLB (as defined in 10 C.F.R. Part 54 or GL 91-18). Even if the NRC could do so, licensees have significantly relied on the present state of the law in making conservative commitments, so that any commitment that could be within the CLB should be subject to renegotiation with the NRC before including it in the scope of Section 50.59. The NRC's proposal could have unintended effects in that licensees may no longer want to maintain these conservative commitments, given the NRC's proposed positions regarding Section 50.59, and may choose not to make similar, conservative commitments in the future.

#### *E. Legal Status of the SAR*

The effective result of certain of the NRC's actions, such as adding conditions to the license for managing licensee commitments, is that the legal significance of portions of the SAR is on par with the Technical Specifications ("TS"). For example, by including a condition in a plant's license stating that certain information must be added to the SAR, the NRC may have made that information legally-binding on the licensee, as if it were in the TS.

Historically, the Final SAR ("FSAR") was a licensing document describing the facility and its design bases. Before rulemaking in 1962, the document that was later designated as the SAR was called the "hazards summary report" and was an integral part of the license. In 1962, Sections 50.36 and 50.59 were promulgated. 27 Fed. Reg. 5,491 (June 9, 1962). Together, these two rules allowed licensees to designate part of the hazards summary report as TS. The TS remained *part of the license*, subject to Commission approval of any changes. The hazards summary report (later referred to as the SAR) was no longer an essential element of the license and could be changed by the licensee according to Section 50.59.

In 1968, Section 50.36 was revised to more clearly define the scope of the TS. The Commission intentionally limited TS requirements to those matters that require "rigid conditions or limitations on reactor operation." *Portland General Electric Company, et al.* (Trojan Nuclear Plant), ALAB-531, 9 NRC 263, 271-74 (1979). These legally-binding requirements and controls were derived from analyses related to plant features "that are of controlling importance to safety." *Id.*, citing "Guide to Content of Technical Specifications for Nuclear Reactors," 33 Fed. Reg. 18,610 (November 1968). The SAR did not have the same legal import as when it had been part of the license, and could be changed according to Section 50.59. Until Section 50.71(e) was promulgated in 1980, SARs were not required to be updated.

When Section 50.71(e) was promulgated, the NRC stated in the accompanying Statement of Considerations that the purpose of an updated SAR was "to provide an updated

reference document to be used in recurring safety analyses performed by the licensee, the Commission, and other interested parties." 45 Fed. Reg. 30,614 (May 9, 1980). The NRC further stated that submittal of updated SAR pages did *not* constitute a licensing action, was not intended for the purpose of re-reviewing plants, and was only intended to provide information. In fact, it was stated that the update rule "is only a reporting requirement." *Id.*, at 30,615.

Throughout the subsequent history related to the regulatory requirements for the SAR, the legal status has not been changed. Accordingly, the preparers of the original SAR for a facility and the licensee, in revising the SAR, did not draft it as a legal document. Neither were many of the values, such as nominal setpoints or pump flow rates, in the SAR meant to represent operating parameters or safety limits, like those values included in TS. Many of the values included in the SAR were values that came from vendor data, not from the underlying design analyses. Accordingly, design change programs were established to ensure that a design engineer reviews the underlying design analyses when modifying the plant.

The SAR describes the design features of a plant. The NRC should not enforce the content of the SAR, and thus any discrepancies from the SAR, as if the information were a *legal description* of the plant that has been maintained at that level throughout the life of the plant. To be sure, much of the content of the SAR is enforceable (*e.g.*, if there is a violation of an underlying regulatory requirement, or a violation of Sections 50.59 or 50.71(e)). Discrepancies from the SAR can also be cited as "deviations" under the NRC Enforcement Policy, even if there is no violation of a requirement. But the descriptive information in the SAR was never intended to be a *legal description* of the facility. To the extent that the NRC enforces the regulations in a manner that raises the legal significance of the SAR to that of binding requirements, the action would represent a change in policy or a new Staff position that may not be imposed on licensees until the NRC has followed the proper administrative processes (*e.g.*, rulemaking with a regulatory analysis justifying the imposition of the new requirements).

### III. Backfitting Implications of Positions in Draft NUREG-1606

In various sections of Draft NUREG-1606, the proposed guidance represents a change from a previous NRC position, such as a position in inspection manual chapters on Section 50.59. Section 50.109(a)(1) defines "backfitting" as, in part, modifications of or addition to procedures required to design, construct, or operate a facility, any of which may result from "the imposition of a regulatory staff position interpreting the Commission rules that is either new or different from a previously applicable staff position." The NRC has not previously issued detailed official guidance on Section 50.59 other than that in inspection procedures and technical guidance. The guidance found in the following inspection procedures represents the existing Staff positions that have been applied during inspections at licensee facilities:<sup>2/</sup>

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<sup>2/</sup> The listing is not meant to be all inclusive of past NRC guidance. For example, we note that IE Circular 80-18, "10 C.F.R. § 50.59 Safety Evaluations for Changes to Radioactive Waste Treatment Systems," August 22, 1980, contained guidance that could be applicable to the

- NRC Inspection and Enforcement Manual, Part 9800, "Changes to Facilities, Procedures, and Tests (or Experiments)," January 1, 1984.<sup>8/</sup>
- NRC Inspection Manual 37001, "10 C.F.R. § 50.59 Safety Evaluation Program," December 29, 1992.
- NRC Inspection Manual Part 9900, "Interim Guidance on the Requirements Related to Changes to Facilities, Procedures, and Tests (or Experiments)," April 9, 1996.

Where the proposed guidance is a new interpretation of the current requirements or is a change from past guidance, such as that in the documents listed above, reinterpretation should not be imposed until the NRC has performed the required backfitting analysis in accordance with the provisions of Section 50.109 or completed rulemaking to revise Section 50.59.

#### *A. Changes to the Facility*

In Section III.A of Draft NUREG-1606, the proposed guidance states that components replaced by "substitute (*i.e.*, not identical) components" would not be considered maintenance, but rather a change requiring a Section 50.59 evaluation. The proposed guidance also states that a change is a replacement of a component with "something that is not identical to the original in design requirements." The proposed guidance narrows the definition of "maintenance" from that in Part 9800 which states that "maintenance activities . . . which replace components with replacements procured to the same (or equivalent) purchase specifications, do not require a written safety evaluation to meet 10 C.F.R. § 50.59 requirements." (Part 9800 does note that the use of "substitute" components would not constitute "maintenance.")

We believe the proposed guidance should be revised to be consistent with previous guidance to the effect that the replacement of "equivalent" (rather than "identical") components would not be a change within the meaning of Section 50.59. The proposed guidance in fact conflicts with existing regulations. Section 50.55a, "Codes and Standards," incorporates the American Society of Mechanical Engineers ("ASME") Code into the regulations. Section IWA-7000 of Section XI of the 1983 Edition of the ASME Code gives specific provisions for replacement of ASME Code Class 1, 2, and 3 components. Paragraph IWA-7220 (1983 Edition) provides that a component may be replaced with a different component if a suitability analysis justifies the replacement. A licensee should not be required to reconcile a replacement of an ASME Code Class component allowed

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facility as a whole.

<sup>8/</sup> Part 9800 contains a number of examples that are useful illustrations of the NRC's positions. To the extent practical, Draft NUREG-1606 should be revised to include examples that would be useful to licensees when implementing Section 50.59.

according to the ASME Code and Section 50.55a with a Section 50.59 evaluation. Therefore, the guidance in final NUREG-1606 should define maintenance and replacement of components so that it is consistent with previous Staff positions (*i.e.*, Part 9800) or existing regulations (Section 50.55a).

Inspection Procedure 37001 states the following in discussing "changes to the facility":

Removing equipment from service (making it inoperable) for maintenance for the technical specification (TS) allowed outage time does not require a Section 50.59 safety evaluation. However, if the plant's safety analysis as described in the FSAR depends on the functioning of non-TS equipment, then removing that equipment from service (*i.e.*, disabling its function) for maintenance during plant operation should be evaluated in accordance with Section 50.59 for involvement of an unreviewed safety question.

Draft NUREG-1606, in Section III.A.4, provides similar guidance for removing components not addressed in plant TS from service for maintenance. The practical effect of this guidance is that it would elevate maintenance activities to the level of a facility "change." This is illustrated by an example. A plant has three non-safety related condensate pumps, with the description in the SAR stating that two pumps are normally operating with one in standby. A licensee could, according to the provisions of Section 50.65 (the "maintenance rule"), remove the third condensate pump from service for maintenance by performing "an assessment of the total plant equipment that is out of service . . . to determine the overall effect on performance of safety functions." 10 C.F.R. § 50.65. However, under the proposed guidance, a Section 50.59 evaluation would have to be performed, even though the maintenance activity results in no actual "change." Contrast this with the removal of a standby high-pressure injection pump with a TS Limiting Condition for Operation ("LCO") of 72 hours, which must be removed from service for corrective maintenance. A licensee would be allowed to perform the corrective maintenance within the TS LCO time period without performing a Section 50.59 evaluation.

Moreover, requiring a Section 50.59 evaluation, and a resulting license amendment, for maintenance could have the unintended effect of delaying corrective or preventative maintenance. This result could have an adverse safety impact. The final guidance should at least provide a means for allowing a licensee to use the offsetting improvement in safety through performing maintenance on components not covered by plant TS if a Section 50.59 evaluation is deemed to be required for these activities.

Therefore, the NRC's guidance on Section 50.59 could have (depending on the specific language in a plant's SAR) the effect of raising the level of importance of a non-safety related, non-TS component to above that of a safety-related TS component. The guidance should be revised to provide that a non-safety related component can be removed from service for maintenance when necessary according to the provisions in Section 50.65 without applying Section 50.59, so long as no actual change is made to the facility.

**B. Increase in Probability**

In Section III.P of Draft NUREG-1606, the proposed guidance would interpret "may increase" in Section 50.59 to mean that any proposed change that potentially increases the probability of an accident or malfunction of equipment by any amount would be an unreviewed safety question ("USQ"). This is a change from the past NRC position in its letters to NEI (previously NUMARC). For example, in NRC's letter of May 10, 1989, to NUMARC,<sup>9/</sup> the Staff presented comments for incorporation into NSAC-125<sup>10/</sup> that are consistent with the discussion on an increase in probability that was finally issued in NSAC-125. The NRC has, therefore, previously acknowledged that a negligible increase in probability is within the range of acceptable interpretations of the regulation. Accordingly, the final guidance should be revised to recognize that the industry guidance in NSAC-125 is also acceptable for compliance with the regulations.

**C. Margin of Safety**

In Sections III.S and III.T of Draft NUREG-1606, the proposed guidance on reductions in the margin of safety and establishing the basis for TS appears to be a change from previous guidance. The NRC's past guidance on the margin of safety included in the basis of TS has been that the TS Bases section is the appropriate information to review for determining whether a USQ is created. For example, in GL 80-110,<sup>11/</sup> the NRC's guidance on Section 50.71(e) included a question regarding updating the SAR and whether, in the future, the FSAR would be used as the TS basis. The NRC's response was:

The bases for the technical specifications are included along with the technical specifications. If the technical specifications have referenced the FSAR, they may continue to reference the updated FSAR.

In Part 9900 guidance on Section 50.59, the NRC notes that the "NSAC-125 guidance is broader than the rule regarding where a licensee must look to find a margin of safety in that it recommends looking beyond the TS Bases."<sup>12/</sup> Additionally, the NRC informed NUMARC in a letter

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<sup>9/</sup> Charles E. Rossi (NRC) to Thomas E. Tipton (NUMARC), May 10, 1989.

<sup>10/</sup> NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations," June 1989.

<sup>11/</sup> Generic Letter 80-110, "Periodic Updating of Final Safety Analysis Reports (FSARs)," December 15, 1980.

<sup>12/</sup> NRC Inspection Manual, Part 9900, "Interim Guidance on the Requirements Related to Changes to Facilities, Procedures, and Tests (or Experiments)," April 9, 1996.

dated June 25, 1993,<sup>13/</sup> that it could not endorse the industry guidance because some of the guidelines in NSAC-125 go beyond the requirements of 10 C.F.R. § 50.59. Also of note is that the rulemaking to Section 50.59 that added the criterion on the "margin of safety as defined in the basis for any technical specification" also added the requirement for a "summary statement of the bases or reasons for . . . specifications" to Section 50.56(a) for technical specifications. 33 Fed. Reg. 18,610 (December 17, 1968).

In Section III.S of Draft NUREG-1606, the NRC position is that "[i]dentifying all potentially affected technical specification safety margins involves more than just reviewing the Bases sections of technical specifications initially thought to be applicable," and would require licensees to "identify every safety analysis" that supports the basis of the TS, whether the TS includes the margin or not. To the extent that the proposed guidance suggests that Section 50.59 *requires* licensees to assess margins of safety not specifically included in the TS Bases, the guidance represents a new Staff position and is subject to the backfitting provisions of Section 50.109.

A second concern with the proposed guidance in Draft NUREG-1606 is that, as proposed in Section III.S, a reduction in the margin of safety would be deemed a USQ if there is any potential change in the nonconservative direction of a value in the TS Bases, even if the change is either within assumption uncertainties or inconsequential to the overall margin. As an example, suppose a post-accident containment temperature of 344°F is identified in FSAR Section 3.11 (as referenced in the TS Bases) as the peak calculated value for the design basis Main Steam Line Break ("MSLB"). In recent refinements to the calculation, or as a result of proposed design changes, a revised high energy line break ("HELB") analysis (which includes MSLB) is performed. The new calculated peak temperature is 348°F. An evaluation of all inside containment equipment in the 10 C.F.R. § 50.49 program confirms that prior test data adequately envelops the new HELB profile with adequate margin as defined in applicable equipment qualification ("EQ") criteria documents (*e.g.*, NUREG-0588, Category I). Other design considerations outside the EQ program are also evaluated and are determined to adequately envelope the increased temperatures under applicable design criteria.

For this example, under the proposed NRC guidance the licensee is forced to conclude that the proposed change is a USQ based solely on this small change in EQ margin. The licensee concludes that in accordance with the new guidance any incremental increase in the peak calculated HELB temperature will reduce the available "margin of safety" between the required and tested HELB conditions. Thus, although there has been no more than a *de minimus* reduction in the absolute qualification margin, and licensee evaluations demonstrate that all the equipment continues to meet or exceed the minimum margin requirements established in NRC EQ criteria documents, prior Staff approval of this inconsequential change would be required.

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<sup>13/</sup> Brian K. Grimes (NRC) to Thomas E. Tipton (NUMARC), "NSAC-125, 'Guidelines for 10 C.F.R. § 50.59 Safety Evaluations,' June 1989," June 25, 1993.

Contrast the above example with one where the licensee applies a new EQ qualification test for an existing piece of equipment in order to establish an extended qualified life for the piece of equipment. Appropriately, neither specific tests nor individual pieces of equipment are referenced in the SAR. The new test fully bounds existing post-accident profiles, with adequate margins in accordance with NRC criteria. However, the peak post-accident temperature in the test profile is 4 degrees less than the original test. Thus, the overall "margin of safety" could be interpreted in this case also to have been reduced by the same *de minimus* amount as above, but in this case there is no change requiring prior Staff approval because particular equipment and tests are not described in the SAR.

The NRC should therefore consider revising the proposed guidance to address small incremental, or inconsequential changes, to avoid the conclusion that these create USQs even though safety is not an issue.

#### ***D. New or Different Type of Accident or Malfunction***

In Section III.I of Draft NUREG-1606, the NRC's proposed guidance suggests that a licensee must consider a malfunction at a component level, even when the SAR describes the malfunction in terms of systems or trains. Section 50.59 is structured to evaluate changes to the "facility" as described in the SAR. The proposed guidance for the evaluation of a new or different type of accident or malfunction could require licensees to go beyond the description in the SAR. To the extent that an accident or malfunction is described in the SAR, and the change does not create an accident or malfunction *at that level* that is new or different, then no USQ is created by the change. To the extent that the proposed guidance provides that a licensee must consider a malfunction at a different level than that described in the SAR, the guidance would be a new Staff position.

#### ***E. Degraded and Nonconforming Conditions***

In Section III.O of Draft NUREG-1606, the NRC proposes to take the position that a degraded condition must be restored at the "first available opportunity" or it is a change to the plant that requires a Section 50.59 evaluation. This position would have a significant impact on existing practices. In our view, to implement this proposal, the NRC must pursue notice-and-comment rulemaking in accordance with the Administrative Procedure Act because it amends both 10 C.F.R. § 50.59 and 10 C.F.R. Part 50, Appendix B, Criterion XVI. In addition, Section III.O references previous NRC guidance in GL 91-18 that says that, when a USQ is involved, Staff approval in the form of a license amendment is required prior to operating the plant with the degraded or nonconforming condition; however, the focus for restarting a plant should be on compliance with the plant TS and the operability of components, with the determination based on safety (see discussion in Section IV.C below).

The NRC has for many years taken a position that closely follows the language in Criterion XVI, *i.e.*, when a degraded plant condition is discovered a licensee must correct that

condition in a time period commensurate with safety. See, e.g., NRC GL 91-18, Enclosure 2 at 7. Licensees have established corrective action programs based on this concept which have been explicitly approved by the NRC and found to be in compliance with Appendix B. See 10 C.F.R. § 50.54(a). The NRC's proposal would repudiate the longstanding "commensurate with safety" test in Criterion XVI and replace it with a "first available opportunity" test.

The purpose of Criterion XVI, as reflected in the language of the rule and as expressed in NRC interpretations (e.g., GL 91-18), is to allow a licensee time to correct or restore a degraded plant condition and/or modify the plant licensing and design basis to accommodate that condition, *i.e.*, accept the condition "as is" (either permanently or temporarily). The time allowed is driven by the safety significance of the degraded condition. The NRC's proposal would eliminate this time period by automatically declaring a plant changed or modified, thereby forcing one of the two corrective action options at the time the plant is "changed," *i.e.*, restoration of the condition, or performance of a Section 50.59 evaluation to accept the condition "as is." There is no assessment of "safety" in this approach because the corrective action would be required at the first available opportunity (assuming this can be sufficiently defined) -- not at the time the condition should be restored "commensurate with safety."

The NRC's apparent suggestion that the new test (*i.e.*, "first available opportunity") would not disturb the longstanding corrective action scheme is a semantical distinction that overlooks the fact that whether a condition is degraded is assessed by comparing that condition to the design and/or licensing basis. In many cases, the affected equipment can actually perform its function but cannot meet the conservative criteria in the NRC-approved design and/or licensing basis. Section 50.59 would force the licensee to change that criteria to accommodate the degraded condition such that, from a licensing standpoint, the degraded condition no longer exists. The fact that the NRC may ultimately want the licensee to restore the condition to the conservative criteria in the licensing basis, rather than accept it "as is," does not change the fact that NRC dictated to the licensee a corrective action (whether temporary or permanent) not based on safety. Because the proposal amends the "commensurate with safety" test and corrective action scheme set forth in Appendix B and places Section 50.59 in the position of driving the corrective action, rulemaking is required.

The proposal would also require an amendment to Section 50.59 to incorporate the proposed new definition of change, *i.e.*, the plant is changed if not restored at the first available opportunity. The regulations and existing NRC guidance do not articulate or suggest this proposed definition of when a plant is changed. The proposal does more than merely interpret Section 50.59 in that it supplements Section 50.59 by creating a new test from one word in the regulation (*i.e.*, "change"). This new test is contrary to longstanding NRC practice, contrary to agency positions regarding corrective actions in GL 91-18 (as explained above), and would have a substantial impact

on licensees in terms of correcting degraded plant conditions and operating with those conditions when consistent with the operating license. Accordingly, the proposal constructively amends Section 50.59 and requires notice-and-comment rulemaking.<sup>14/</sup>

The NRC's proposed position on this matter would represent a significant backfit. Three aspects of the proposed position that raise backfitting concerns are -- (1) it changes the longstanding NRC position in GL 91-18, (2) it articulates a new standard for corrective actions that has not heretofore been articulated by the agency as its position, and (3) it grafts into Section 50.59 a new definition of what constitutes a "change" to the plant. These positions will require licensees to modify procedures and programs necessary to operate their facilities in order to incorporate the proposed position. This includes corrective action/Appendix B procedures and programs, design control procedures and programs, and Section 50.59 procedures. These programs and procedures have already been evaluated and approved by the NRC and found to be in compliance with applicable regulations through inspection activities. The NRC also engaged in detailed public discourse with the industry, with docketed correspondence, on these same matters when developing GL 91-18 and in reviewing NSAC-125. During these discussions, the NRC did not object to the current approach used by licensees, nor did the NRC articulate the now-proposed definition of "change" as the agency position. Both the explicit and tacit NRC approvals in this area are sufficient to require a backfitting analysis under Section 50.109.

This proposal also has a practical effect that militates against adopting the proposed position. It will have the effect of elevating the legal/safety status of less significant equipment beyond the significance of technical specification equipment.<sup>15/</sup> The status of non-TS equipment will be elevated because this equipment does not have the grace period for performing corrective actions provided by TS action statements (see the example above on condensate pump maintenance versus high pressure injection pump maintenance). Instead, the first available opportunity to correct such a condition may be less than the time provided in technical specification action statements to correct considerably more safety significant equipment.

Based on the foregoing, the proposed position should be rejected by the NRC as unwise. And if the agency pursues this proposal, it will require rulemaking and appropriate backfitting analysis. In addition, the NRC should be prepared from a resource perspective to handle the significantly more active role of approving licensee corrective actions. The provisions of 10

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<sup>14/</sup> See *National Family*, 979 F.2d at 236-38. Cf. *USV Pharmaceutical Corp. v. Richardson*, 461 F.2d 223, 229 (4th Cir. 1972) (suggesting 30 year construction of Food, Drug, and Cosmetic Act by agency may only be changed by Congress), *aff'd*, 412 U.S. 655 (1973).

<sup>15/</sup> See *Portland General Electric Company, et al. (Trojan Nuclear Plant)*, ALAB-531, 9 NRC 263, 271-74 (1979) (technical specifications are reserved for equipment and processes that require rigid controls for safety reasons).

C.F.R. Part 50, Appendix B, Criterion XVI, "Corrective Action," are the appropriate requirements for addressing degraded and nonconforming conditions. Section 50.59 should not apply unless and until a licensee decides that a condition will remain as-is permanently.

*F. Compensatory Actions*

In Section III.V of Draft NUREG-1606, the Staff appears to change the position in previous guidance on the use of compensatory actions to offset an increase in probability or reduction in the margin of safety. The NRC's April 1996 guidance in Part 9900 states that "[i]n considering the acceptability of a licensee's 10 C.F.R. § 50.59 evaluation, the staff has found compensating effects such as changes in administrative controls acceptable in offsetting uncertainties and increases in the probability of occurrence or consequences of an accident previously evaluated in the SAR or reductions in a margin of safety, provided the potential increases or reductions in margin are negligible." This position is consistent with the industry guidance in NSAC-125.

The NRC's proposed guidance in Draft NUREG-1606 suggests that this previous guidance has "evolved" to something different. The NRC explains that the "effect of any change must be evaluated against each of the USQ criteria separately -- that is, an increase in probability cannot be 'compensated' by additional mitigation capability." To the extent that the NRC essentially endorsed the guidance in NSAC-125 in its April 1996 guidance, the guidance in NSAC-125 should be an acceptable interpretation of the regulation.

*G. Use of New Methodologies for Integrated Changes*

In Section III.U of Draft NUREG-1606, the Staff discusses the use of new methods (e.g., analysis methods or new assumptions) to indicate that no USQ is created by a change. The section does not address those changes that are implemented in accordance with an NRC-approved methodology or NRC-approved Code or standard that may be considered a single, integrated change. (This is a concept that is referred to as "linking" changes in Section III.V.4.)

In Section III.V, "Consideration of Compensating Effects When Making an Evaluation of Whether an Unreviewed Safety Question Exists," the NRC proposes guidance to the effect that "elements of a proposed change that are linked with each other in accomplishing the required functions or in establishing the design bases for systems or structures are considered as a single change." The proposed guidance would preclude allowing "compensation" for "a change made in one component or system to offset changes made in another system or component." However, the proposed guidance does recognize that "[t]here may be instances where linking elements of a change may be appropriate."

We assume that one of those instances where linking elements of a change would be considered appropriate is when a new generic methodology has been developed and approved by the NRC to resolve a generic issue (e.g., actions requested by the NRC in a generic letter) or to accept a generic approach (e.g., topical report). As the NRC recognizes in Draft NUREG-1606, "a new

methodology must be a valid methodology for the type of calculation being performed . . . and the analysis must be done for cases of before and after the change, and both analyses must be performed with the same methodology."

With the use of a new methodology, as opposed to a design change, the elements of the methodology are linked with each other to accomplish the resolution of the generic issue, and therefore should be considered a single, integrated change. Unlike changes made in one component or system to offset changes in other components or systems, the multiple elements of the NRC-approved methodology are, of necessity, interdependently linked together to accomplish the required purpose of resolving the generic issue in an overall conservative manner. If the methodology is appropriately implemented as approved by the NRC, each site would be able to conduct a single 10 C.F.R. § 50.59 evaluation on the overall integrated change, rather than on each element of the proposed change individually. Any other aspects of the proposed change, outside the scope of the NRC-approved methodology, would be subject to 10 C.F.R. § 50.59.

The guidance should be expanded to clarify instances where the changes are implemented in accordance with new or different NRC-approved methodologies and could be considered a single, integrated change, such as reanalyzing piping stresses to an updated edition of the ASME Code approved by the NRC in Section 50.55a, conducting a different type of nondestructive examination according to a later edition of the Code, or revising an entire inservice inspection program to a later Code edition according to the provisions of Section 50.55a. Such a change does not lend itself to a quantitative assessment of a single parameter or functional requirement, and to the extent that Section 50.59 would apply to such a change, the evaluation would necessarily be based on a qualitative assessment of the overall results of the new methodology, not the results of the individual elements of the change. (In addition, the changes may be made to comply with an NRC regulatory requirement.) Whereas individual elements of the change, such as the elimination of a 10-year hydrostatic test as allowed by the later Code edition, with the addition of a periodic system leak test, a licensee should be able to rely on the NRC's overall approval to implement the change without further NRC review as a USQ. We believe that such a clarification is consistent with accepted industry practice.

#### IV. Recommendations on the Regulatory Process

We have identified certain concerns that relate to the proposed guidance and offer comments on these issues below. We recommend (1) a feedback process for inspections of Section 50.59 programs; (2) standards for discrepancies between the SAR and the as-built plant; (3) a better focus on safety; (4) changes to address beyond design bases events; (5) alternatives for rule changes; and (6) no retroactive application of the final guidance.

##### A. *Ensuring Consistent Application of Staff Guidance Through Feedback Process*

NRC management should *actively* control and monitor inspector field positions and NRC staff positions regarding Section 50.59, the SAR, Section 50.71(e), and the legal import of

commitments to ensure that they are consistent, correct, and in accordance with applicable law. This is necessary because this is a complex area of regulation with significant economic and legal consequences and because agency positions in this area frequently turn on subtleties in regulations and guidance. The active control could include well documented training sessions for both NRC and licensee staff with publicly available materials (e.g., summaries, questions and answers) that discuss the information taught in these sessions and a candid, periodic, publicly available NRC report on how positions are being implemented in the field. This report should include discussions of incorrect positions taken by both NRC and licensee staff and practical problems that arise from NRC positions in this area.

### ***B. Standards for Discrepancies Between SAR and As-Built Plant***

The NRC must articulate clear, documented standards of what constitutes a discrepancy between the SAR and the plant or plant procedures before it enforces SAR-related requirements (e.g., Sections 50.71(e) and 50.9). Without clear standards, licensees cannot ascertain to what legal standard they are being held. It is inconsistent with good regulatory practice for the NRC to simply articulate ambiguous standards and apply them on a case-by-case basis in an inconsistent fashion. Using this approach thus far has already led to NRC inspectors labeling accurate information in a SAR a discrepancy simply because the inspector (and NRC management involved in the inspection) believes that there should be more or different detail in the SAR or because the inspector does not acknowledge standard industry practices (e.g., providing nominal setpoint values in the SAR rather than specific values articulated in procedures that are controlled through an approved setpoint control process). It is axiomatic that a licensee must be able to ascertain what the standard is before it can be expected to adhere to that standard, particularly when there are enforcement consequences. Moreover, without clear standards, an area of regulation already fraught with inconsistencies and ambiguities will become even more inconsistent and confusing.

### ***C. Focus on Maintaining Safety***

Overall, the NRC's proposed positions, policies, and action items regarding Sections 50.59 and 50.71(e) and the SAR significantly curtail licensee operational flexibility. However, as discussed in Section II, "Relationship of Review of Changes for Effects on Safety and for 10 C.F.R. § 50.59 Evaluation Purposes," of Draft NUREG-1606, the NRC considers Section 50.59 a determination as to whether NRC approval is necessary, not whether a proposed change is safe.<sup>16/</sup> The NRC has identified problems with Section 50.59 implementation, largely related to a few

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<sup>16/</sup> Note that the NRC's guidance in Inspection Procedure 37001, "10 C.F.R. § 50.59 Safety Evaluation Program," states that "[r]ecognizing failures of the licensee to comply with the administrative control requirements of . . . Section 50.59 is important. However, recognizing failures of the licensee to adequately assess how a change will affect plant operational safety is more important. . . . The focus of the implementation part of the inspection should, therefore, be on safety."

facilities. Review of the implementation of Section 50.59 programs throughout the industry, to determine if there are major safety issues, is incomplete; therefore, any decision on the final resolution of the proposed guidance is premature.

The reviews may indicate that most licensees have been effectively implementing Section 50.59 using the industry guidelines and that NRC need only consider whether the regulatory structure could be modified to provide more flexibility, but with a greater focus on safety and risk-significance. In other words, the Commission should consider revising Section 50.59 to be a safety determination rather than a regulatory threshold determination, allowing licensees to make changes to the facility, and conduct tests and experiments, without prior NRC approval as long as these actions remain within the bounds of the safety parameters to which the facility was licensed. Similarly, the content of the SAR should be structured to focus on safety, much as suggested in the Commission's Staff Requirements Memorandum on the SAR (*i.e.*, a risk-informed approach to the content of the SAR).

Over the course of many years, the agency had developed a regulatory approach that placed safety decision-making at the center of the regulatory structure, using its statutory mandate of safety to direct both NRC and licensee resources. The NRC should be careful not to replace the science of nuclear power plant operation with the science of bureaucratic procedure by enforcing a "strict compliance" standard that focuses on procedure rather than safety. Again, a change to the regulatory structure could ensure that the proper focus of the regulations is on safety. Expending resources on purely procedural matters is not in the best interests of either the regulated or the regulator.

As to restart of a plant with a degraded or nonconforming condition that creates a USQ, the proposed guidance in Section III.O reiterates a position in NRC GL 91-18 that a license amendment is required prior to operating a plant that is shut down. This Staff position effectively diminishes the value of holding an operating license for a nuclear plant in that it drives license amendments for situations that could more appropriately be managed in a corrective action program. We believe that the NRC has authority to allow plant startup and operation with a USQ so long as adequate protection is maintained. Accordingly, those issues that are determined to be USQs but do not adversely impact the safe operation of a plant would not cause a plant to remain shut down in order to obtain a license amendment according to Section 50.59. The guidance in both GL 91-18 and NUREG-1606 should be revised to clarify that a plant restart will not be delayed until a license amendment is processed when the associated USQ does not adversely impact safety. Alternatively, the NRC should, under its statutory authority, develop guidance or a policy for Section 50.59 enforcement discretion, much like the process for enforcement discretion of the plant TS,<sup>17/</sup> so that plant startup is not delayed when there is no associated safety issue.

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<sup>17/</sup> See NRC Administrative Letter 95-05, "Revisions to Staff Guidance for Implementing NRC Policy on Notices of Enforcement Discretion," November 7, 1995.

#### *D. Beyond Design Basis Accidents/Events*

Section IV.A.3 of Draft NUREG-1606, includes a statement, in discussing concerns that some information may not be included in the SAR, that "plant features or procedure changes developed to provide [the] ability to cope with severe accidents (beyond the design basis accidents) may . . . not be part of the SAR, and thus would not be subject to the regulatory control of 10 C.F.R. § 50.59." The statement could be read to imply that severe accident management guidelines ("SAMG") should be subject to Section 50.59. However, in its approval of the NEI guidelines for SAMG, the NRC agreed with the NEI position that Section 50.59 need not be applied to the SAMG.

The guidance should be revised to clearly indicate that changes to Emergency Operating Procedures and the development of SAMG that address conditions beyond design bases are not within the scope of Section 50.59. This would be consistent with NRC's letter of February 16, 1994, to NUMARC (now NEI), which states that "[w]e further believes that plant-specific SAMG implementation can proceed within the context described in your October 29, 1993, letter to NRC regarding applicability of 10 CFR 50.59 and 10 CFR 50.54(x), without prior approval by NRC."<sup>18/</sup>

#### *E. Alternative Approach for Revising Section 50.59*

Section 50.59 was developed in 1962, early in the evolution of nuclear power. At the time it was developed, there was little operating experience. As the nuclear industry developed, many design features were enhanced and refined to make the plants more inherently safe. The types of changes that have occurred over the more than 30 years that Section 50.59 has been in effect have been (1) to correct problems in the design identified by the Nuclear Steam Supply System ("NSSS") vendor; (2) to address concerns identified by the NRC as a generic issue (e.g., post-Three Mile Island modifications imposed on plants through NRC Orders); (3) to make modifications deemed necessary through plant-specific backfits or through generic backfits and/or the advance of technology (e.g., motor-operated valve improvements in accordance with GL 89-10); (4) to make modifications to improve human performance and reduce operator error; (5) to make modifications to correct recurring problems with specific components or systems; and (6) to improve reliability and availability of the plant. The provisions of Section 50.59 have generally worked well throughout its history.

With advances in technology and improvements in the use of probabilistic risk methodologies, the NRC should consider modifying Section 50.59 to be a more risk-informed and performance-based regulation. As part of the NRC's initiatives to reduce regulatory burden and to move toward a risk-informed and performance-based regulatory structure, it is the appropriate time to assess alternatives for revising Section 50.59.

In our view, an alternative approach should include specific provisions for allowing an increase in probability or consequences and a reduction in the margin of safety within certain

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<sup>18/</sup> William T. Russell (NRC) to William H. Rasin (NUMARC), February 16, 1994.

design and safety limits. Section 50.59 was originally intended to allow licensees to make changes without prior NRC approval that did not alter the key safety parameters of the facility or the licensed authority. Allowing changes to be made under Section 50.59 that do not *significantly* change probabilities, consequences, or margins (*i.e.*, stay within the design and safety limits) would be consistent with the original intent of the rule. Furthermore, the Atomic Energy Act does not require that the form of approval for a USQ change be a license amendment (so long as the change does not conflict with Technical Specifications). Thus, the NRC has authority -- and should exercise it -- to establish provisions that would provide an expeditious approval process under Section 50.59, with public notice and comment as appropriate.

***F. Final Guidance Should Not be Applied Retroactively***

We are concerned that when the final guidance is issued, the inspectors will apply the guidance to Section 50.59 evaluations that were completed before the guidance was issued. The NRC should ensure that the guidance is applied prospectively only. Absent an express statutory grant of authority, an agency does not have the authority to promulgate retroactive regulation. *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208-09 (1988). Licensees have implemented Section 50.59 for over 30 years. Many of the positions represent reinterpretations of the rule and it would be a backfit to apply the new positions to past evaluations. In the 30 years of applying the rule, little or no guidance existed until NSAC-125 was issued; however, the NRC conducted inspections and audits of licensees' programs throughout this time period, as discussed in the Executive Director for Operations memorandum to Chairman Jackson in April 1996.<sup>19/</sup> In addition, the rule itself contains a reporting requirement for describing changes, tests, and experiments conducted during the reporting period (annually or with the SAR updates, or at shorter intervals as may be specified in the license).

In consideration of the fact that the NRC has had ample opportunity to review and evaluate the adequacy of the past implementation of the rule, the Section 50.59 evaluations that have been conducted in the past should be considered settled issues. No enforcement actions should be taken for past practices, but only for future implementation. There are too many opportunities to question a licensee's interpretation of the rule that could only be viewed in light of today's thinking, putting the licensee in the position of trying to defend the understanding of the rule at the time an evaluation was completed. This approach would not relieve a licensee from taking corrective actions where actual safety concerns are identified, but it would provide some certainty in the area of enforcement.

At any rate, any Section 50.59 evaluations that were completed more than five years ago would be outside the federal statute of limitations, 28 U.S.C. § 2462. In *3M v. Browner*, the U.S. Court of Appeals for the District of Columbia Circuit held that the federal statute of limitations applied "to the entire federal government in all civil penalty cases." 17 F.3d 1453 (D.C. Cir. 1994). The Court also held that the five-year statute of limitations period runs from the time the facts giving

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<sup>19/</sup> James M. Taylor to Chairman Jackson, "Action Plan for Improvements to 10 C.F.R. § 50.59 Implementation and Oversight," April 15, 1996.

rise to the alleged violation occurred, not from the time of discovery. The reasoning for applying the statute of limitations to civil penalty actions is the same as any other in that over time "evidence has been lost, memories have faded, and witnesses have disappeared." 17 F.3d 1453 at 1457 (D.C. Cir. 1994). The Court noted that:

Statutes of limitations also reflect the judgment that there comes a time when the potential defendant ought to be secure in his reasonable expectation that the slate has been wiped clean of ancient obligations.<sup>20/</sup>

Based on the holding in this case and the reasoning as applied to licensees, there should, at a minimum, be a policy that the old design issues and the old Section 50.59 issues are settled. Many of the decisions made during the licensing of nuclear plants are documented, but many decisions were made based on presentations to the NRC by applicants and the NSSS vendors. To attempt to recreate the basis for these original design decisions is an unrealistic imposition on licensees, yet the NRC seems to be going down that path with the Architect/Engineering ("A/E") inspections that began in the Fall of 1996 and are continuing. For example, in the A/E inspection report for the Joseph M. Farley Nuclear Plant,<sup>21/</sup> inspectors questioned the tornado missile spectra that were considered for the design basis of the plant. The report notes that the FSAR did not distinguish between horizontal and vertical/non-horizontal missiles, but the licensee stated that consideration of only a horizontal missile was the design basis of the plant, though it could not produce any documentation that supported that position. Issues such as these were reviewed and evaluated at the time of licensing by the NRC (or its predecessor, the Atomic Energy Commission). Holding an operating license gives little certainty to a licensee if the NRC can continually "relicense" a plant by inspection and enforcement.

This type of inspection and enforcement is neither legal nor necessary in that plant licenses were issued only after the NRC was satisfied with the design of the plant. Licensees have a right to expect that, after operating for a number of years, after applying a regulation that has existed for over 30 years, and after reporting changes under the provisions of the regulation, that the NRC has had its chance to review those issues. In *3M v. Browner*, the Court said that an agency's failure to detect violations, for whatever reasons, does not avoid the problems of faded memories, lost witnesses, and discarded documents in civil penalty actions brought decades after alleged violations are discovered.

#### V. Comments on Policy Issues -- "Scope of Section 50.59"

The comments provided below were developed by the Licensing and Design Bases Clearinghouse Working Group on Safety Analysis Reports. The effort was initiated to discuss

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<sup>20/</sup> 17 F.3d 1453, at 1457.

<sup>21/</sup> NRC Inspection Report 50-348/97-201 and 50-364/97-201, "Design Inspection of Joseph M. Farley Nuclear Plant, Units 1 and 2," May 13, 1997.

concerns with the possible expansion of the scope of Section 50.59. Several points that are discussed in comments above are discussed in more detail in this section.

Section IV.A of Draft NUREG-1606, entitled "Scope of Section 50.59," requests public comment on whether and how the NRC should expand the scope of the regulation beyond the content of the SAR to essentially apply to all information in a licensee's current licensing basis ("CLB"). The Staff has requested public comment on the following rulemaking options by which it could, either individually or in some combination, expand the scope of Section 50.59:

***Option 1:** Take steps to ensure that commitments which the staff considers fundamental to their regulatory approval are controlled in an appropriate process, either by requiring that such commitments be made part of the SAR (and thus controlled by 10 CFR 50.59), or by specifying other control processes. As part of the Division of Reactor Project's Process Improvement Plan, the staff has initiatives underway to accomplish this for future licensing actions.*

***Option 2:** Revise 10 CFR 50.59 to reference the "licensing basis" instead of "SAR," and develop a definition of licensing basis that includes all the information that the staff wishes to [be] subject to the control of the 10 CFR 50.59 process. Such a change could bring the other information that is not presently contained in the SAR, but that is part of the licensing basis as it would be defined, within the scope of 10 CFR 50.59. If this option were followed, a definition of licensing bases, and other changes to Part 50 would be needed.*

***Option 3:** Take regulatory action to require that SARs be updated to correct past omissions. Under this option, licensees could be required to incorporate changes to the design bases and effects of other analyses performed since original licensing that have not been included in the updated FSAR (but which should have been as specified in 10 CFR 50.71(e)). 10 CFR 50.59 itself would not need to be changed; rather, these actions would improve the completeness and accuracy of the SAR, the document upon which 10 CFR 50.59 governs the change process.*

***Option 4:** Revise 10 CFR 50.71(e) update requirements, or develop guidance to improve future updates to specifically identify which information (to what level of detail) needs to be included and maintained in the SAR. These steps would improve the completeness of the SAR for future changes made pursuant to 10 CFR 50.59.*

Herein, we address the technical/safety and policy issues associated with the proposed expansion of the scope of Section 50.59.

In summary, as a matter of policy, we do not support the NRC's proposed expansion of the scope of Section 50.59 because it would be inconsistent with existing policy determinations and is not necessary to accomplish the underlying intent of the regulation. Furthermore, from a technical perspective, we believe that licensees' programs are properly focused on maintaining safe

plant operation. If the Commission ultimately decides to reject these considerations and expand the scope of Section 50.59 to include all of the licensing basis and/or to change Safety Analysis Report ("SAR") updating requirements (including modifications to the manner in which they have been implemented and enforced in the past), then rulemaking is required. As explained below, however, we reject all four of the options set forth in Draft NUREG-1606 and, instead, offer an alternative recommendation consistent with the recent Commission directive to the Staff set forth in the SECY-97-036 SRM dated May 20, 1997.

#### **A. Background**

##### **1. Policy Considerations**

There are important policy considerations which militate against expanding the scope of Section 50.59 as proposed in Draft NUREG-1606. Expanding the scope would be inconsistent with existing policy determinations that, as explained later in this paper, remain technically valid. Before discussing the latter observation, we first turn to the preexisting NRC policies.

##### *A Regulatory Philosophy Lacking a Nexus to Safety*

The issues regarding the CLB, SAR, and Section 50.59 largely are a product of the removal of safety as the basis for regulatory and policy decision making at the NRC. The Staff is effectively replacing safety with regulatory procedure by suggesting in its proposed position that NRC approval and licensee regulatory processes (e.g., Section 50.59) should drive the timing and scope of licensee technical decisions (e.g., control of equipment, corrective actions, plant start-up). This is an administrative test that will not work in the context of existing licensee processes which have been designed to use safety judgment as the decision driver. Therefore, when a licensee's existing program is measured against this new administrative test, it is predestined to fail. A licensee cannot make sensible and timely technical decisions that affect physical plant operation without using safety as the basis for those decisions because the needs and responses of the physical plant transcend procedural matters. By imposing such an administrative test, licensees may be forced to choose between safety/sensible plant operation and violation of procedural regulations.

Historically, NRC's guidance and decisions in this area have used safety as the ultimate filter to resolve application issues in the regulatory process. Many of the positions in Draft NUREG-1606 seek to change this historic approach. For example, one position in Draft NUREG-1606 makes a strained interpretation of a single word in 10 C.F.R. § 50.59 for administrative expediency: i.e., a change that requires a Section 50.59 evaluation is being redefined for degraded conditions as a condition not resolved at the first available opportunity. On its face, the proposed "first available opportunity" test is an ill-defined standard that has no connection to safety; yet, the NRC effectively proposes to use this test to force a physical action in a plant (e.g., restoration of equipment). The historical standard proven effective over time used by both the NRC and licensees is that the equipment should be restored in a time commensurate with safety. The NRC's proposed guidance

effectively places the administrative regulation (Section 50.59) in the driver's seat of the corrective action process.

The Commission continues to use safety throughout its discussions on Section 50.59, yet at the same time recognizes in Section II of Draft NUREG-1606 that the Section 50.59 decision is not one driven by safety. The NRC needs to return to the only workable standard that has been proven over time -- SAFETY. If the NRC continues with this shift away from its statutory safety mandate in this area, it may apply the same regulatory philosophy to requirements in other areas. The NRC needs to carefully consider and examine, in a forthright and public manner, this fundamental shift in regulatory philosophy that is exemplified by the proposed positions in Draft NUREG-1606. This is a Commission-level policy matter that requires serious and careful thought.

We acknowledge that the Staff has raised concerns about the implementation of Section 50.59 at selected plants. Those concerns should not, however, be viewed as indicative of Section 50.59 implementation throughout the industry. Most plants have implemented Section 50.59 in a comprehensive and conscientious manner using the industry guidelines. The Staff needs only to endorse the existing guidelines in NSAC-125/NEI-96-07 to bring a large measure of consistency to the implementation of Section 50.59. Rulemaking or significant policy shifts are not necessary to achieve the Staff's safety goals.

#### *The Need for Regulatory Stability and Consistency*

If the Staff expands the scope of Section 50.59 to encompass the entire CLB (as yet undefined for Part 50 licensed plants) as proposed in Draft NUREG-1606, then it will essentially be implementing a policy that is contradictory to and inconsistent with previous policy decisions on the same subject. Specifically, effective implementation of the proposed policy would require licensees to compile the CLB for each plant, including all licensee commitments. The NRC, on several occasions, has already determined that compiling the CLB, and thereby incorporating all commitments into the SAR, would not offer safety benefits commensurate with the burden imposed on licensees in doing so and therefore is not necessary.<sup>22/</sup>

In particular, in SECY-92-314,<sup>23/</sup> the Staff recommended that the Commission: (1) end the formal pilot program for compiling the CLB; (2) not require compilation of the CLB for plants operating under Part 50; and (3) not revise the interpretation of 10 C.F.R. § 50.71(e) to encompass the entire CLB. In follow-up actions described in SECY-94-066, the Staff evaluated the

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<sup>22/</sup> See generally, SECY-97-036, "Millstone Lessons Learned Report, Part 2: Policy Issues," February 12, 1997 (referring to SECY-94-066, "Evaluation of Issues Discussed in SECY-92-314, 'Current Licensing Basis for Operating Plants'," March 15, 1994; and SECY-96-024, "Semiannual Status Report on the Implementation of Regulatory Review Group Recommendations," February 2, 1996).

<sup>23/</sup> SECY-92-314, "Current Licensing Basis for Operating Plants," September 10, 1992.

adequacy of licensees' existing processes for tracking commitments outside the scope of the SAR and concluded that:

- licensees had developed programs and processes for managing commitments to NRC and controlling changes to those commitments;
- despite the absence of explicit rules or guidelines on commitment tracking, licensees would nevertheless maintain the underlying safety intent of their commitments and compliance would be further ensured through NRC inspections conducted pursuant to existing regulatory processes;
- there was no need to further clarify the term "design bases" as it is used within the regulatory process; and
- changes to the definition of "CLB" in Part 54 for incorporation into Part 50 were not necessary, although guidance was needed to address what constitutes a commitment and how commitments should be controlled.

In addition, in SECY-95-300,<sup>24/</sup> the Staff informed the Commission of its intent to notify the Nuclear Energy Institute ("NEI") that its guidance document "Guideline for Managing NRC Commitments" is an acceptable guide for licensees to follow in managing and changing their commitments to the NRC. (The continued validity of these conclusions is discussed below.) Rather than contradicting these past determinations on CLB and commitment tracking, the Staff's current focus should be on ensuring that both licensees and the regulator are effectively implementing existing processes and controls which have been repeatedly and recently determined to be adequate.

Thus, if the NRC adopts the proposal in Draft NUREG-1606, it will be taking action that is directly contrary to these previous policy determinations. The end result would be regulatory instability and unpredictability -- neither of which is indicative of reasoned regulatory policy.

#### Imposition of Unnecessary Resource Burdens

Expanding the scope of Section 50.59 would bring new items and components into the scope, resulting in an increase in the number of screenings, evaluations, and USQs. This could result in delays, or even cancellations, to plant improvements if prior NRC approval is required. Such action would impose a significant burden on licensees and the NRC Staff, would require a number of procedure changes for activities that could directly impact the operation of a facility, and would have little safety benefit, as concluded in past NRC assessments related to compiling the CLB. Accordingly, as noted in Section IV.A of Draft NUREG-1606, rule changes would not likely pass

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<sup>24/</sup> SECY-95-300, "Nuclear Energy Institute's Guidance Document - Guideline for Managing NRC Commitments," December 20, 1995.

the backfitting analysis provisions of 10 C.F.R. § 50.109.<sup>25/</sup> Because the changes would impose new requirements or represent new policy, they would not fall within the compliance exception to the backfitting rule. The NRC's proposed change in policy for the enforcement of 10 C.F.R. § 50.71(e) as a more substantive rule, as directed in the SRM for SECY-97-036, represents a new interpretation of the rule that also would not meet the compliance exception to the backfitting rule.<sup>26/</sup> (The NRC's past enforcement of Section 50.71(e) is discussed in SECY-97-036.)

Even if the scope of Section 50.59 remains as currently stated in the rule (*i.e.*, the "safety analysis report"), changes that do not affect the facility as described in the SAR are controlled by other processes (*e.g.*, 10 C.F.R. Part 50, Appendix B; industry standards; licensee-developed programs) monitored by NRC's inspection program reviews. Whether a plant's SAR contains less information about the facility, or whether a plant's SAR contains information beyond that recommended in Regulatory Guide ("RG") 1.70, processes are in place to assure the safe operation of the facility. Requiring licensees to change the processes would be a major burden with no substantial increase in safety.

#### Variability of Regulatory Application to Plants

In Draft NUREG-1606, the NRC Staff notes that SARs vary in level of detail and completeness from one plant to another, depending largely on the vintage of the plant's operating license. From this observation, the Staff draws the conclusion that this variation results in an uneven application of Section 50.59's requirements. This conclusion ignores the reality that those prior licensing determinations were made by the Commission in the context of the knowledge and the regulatory requirements existing at the time. Variations in the level of SAR detail are not an unexpected result in an industry that has evolved technologically over a relatively short period of time. Nor does the Staff's observation about variation in the level of detail constitute a legitimate policy basis for expanding the scope of the regulation across the board. Where the NRC has determined that new generic requirements *must* be imposed on plants, it has taken actions in accordance with the provisions of Section 50.109, and imposed the additional requirements for the reasons specified in the regulation (*e.g.*, to ensure the adequate protection of the public health and safety, to ensure compliance with current regulatory requirements, or when cost-justified). In fact, Section 50.109 was designed for the very purpose of assuring that such variability would not result

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<sup>25/</sup> Section IV.A of Draft NUREG-1606 states that "there are questions as to whether a regulatory analysis could be developed that would justify the resource implications for the industry in light of the safety improvements." Draft NUREG-1606, at 41.

<sup>26/</sup> NUREG-1409, "Backfitting Guidelines," July 1990, notes that, with regard to compliance, the 1985 Statement of Considerations for 10 C.F.R. § 50.109 indicates that "the compliance exception is intended to address situations where the licensee has failed to meet known and established standards of the Commission because of omission or mistake or fact . . . new or modified interpretation of what constitutes compliance would not fall within the exception." NUREG-1409, at 12.

in a safety shortfall. As a matter of policy, the NRC should not impose the level of detail for newer plants to older plants unless the variability affects the *safety* of the plants. If, nevertheless, the NRC needs standardization, then it should develop guidance for the SAR content that allows licensees with greater detail in the SAR to remove material unrelated to safety at the same time that licensees with less detail in the SAR must include additional information.

For example, the draft NUREG concludes that the SAR may not include all accidents previously evaluated for the facility. We would point out that, even if Section 50.71(e) had been implemented and enforced in a manner that ensured the effects of all new analyses were included in the SAR, this would not ensure that all accidents previously evaluated for a plant are described in the SAR. For instance, the design process for many of the operating nuclear power plants included evaluation of a broad spectrum of accidents, as noted in Chapter 15 of NRC Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants," Revision 3, November 1978. Initially, the accidents are qualitatively evaluated. Only a few of the spectra of accidents are considered bounding and are further evaluated on a quantitative basis in the plant's Final SAR ("FSAR"). Chapter 15 of RG 1.70 says that "an analysis should be provided for each limiting event. These analyses should be based on design basis assumptions acceptable to the NRC for purposes of determining adequacy of the plant design to meet 10 CFR Part 100 criteria."<sup>27/</sup> The requirements of Section 50.59 addressing whether a proposed change to the facility could create a new or different type of accident would ensure that a reviewer considers those accidents not specifically evaluated in the SAR. Therefore, the NRC's proposed expansion of Section 50.59 would not necessarily achieve the stated purpose in Draft NUREG-1606 that all accidents evaluated for a plant are described in the SAR (by NRC's own guidance document -- RG 1.70).

## 2. Technical/Safety Considerations

In addition to policy considerations described above, there is no technical/safety justification for expanding the scope of Section 50.59.

### Application of Millstone-Specific Conclusions Across the Industry Is Not Appropriate Based on Recent Architect-Engineering Design Inspection Findings That Have Not Identified Safety Deficiencies Due to SAR Discrepancies

In Section IV.A of Draft NUREG-1606, the Staff justifies its proposed expansion of Section 50.59 on the basis of its design and licensing basis-related findings at Millstone. We do not believe, however, that such plant-specific findings generically undermine the underlying premise for the NRC's previous decision to not require licensees to compile their CLBs, including all licensing commitments.

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<sup>27/</sup> Regulatory Guide 1.70, at 15-7 (November 1978).

The Millstone Lessons Learned review<sup>28/</sup> was initiated as a result of issues that are largely specific to one facility and which have not been demonstrated by the NRC to be representative of the *entire* industry. In SECY-97-036, the NRC Staff concludes that the operational safety of the industry remains good and the NRC's regulatory processes are fundamentally sound. The weaknesses identified by the Staff generally pertained to the management and use of licensing and design bases information at Millstone, rather than safe operation of its facilities.

In further support that major safety concerns do not exist due to discrepancies between the SAR and the as-built condition of a plant, the NRC's conclusions in recent Architect-Engineering ("A/E") design bases inspections indicate that, generally, the descriptions are consistent or do not impact operability of the systems. The following A/E inspection findings exemplify this observation:

- "Overall, based on the above findings, the team found the design of the two selected systems to be good, with adequate design margins. FP&L's understanding of the design basis was good, as was their inspection preparation and their ability to resolve team identified concerns. The implementation of the design was found to be adequate with some issues noted." St. Lucie Nuclear Plants Units 1 and 2 Design Inspection (NRC Inspection Report Nos. 50-335/96-201 and 50-368/96-201), March 25, 1997.
- "The team concluded that there was evidence that the reviewed systems generally adhered to the design and licensing bases and the as-built configuration was consistent with the FSAR." Three Mile Island - Unit 1, Design Inspection (NRC Inspection Report No. 50-289/96-201), April 15, 1997.
- Though the inspection team identified discrepancies in the FSAR, "overall, the inspection team determined that the selected systems are capable of performing their safety functions." Washington Nuclear Project No. 2 (WNP-2) Design Inspection (NRC Inspection Report No. 50-397/96-201), April 15, 1997.
- Though the inspection team identified discrepancies in the FSAR, "overall, the inspection team determined that the selected systems are capable of performing their safety functions and have adequate design margins." Design Inspection of Joseph M. Farley Nuclear Plant, Units 1 and 2 (NRC Inspection Report No. 50-348/97-201 and 50-364/97-201), May 13, 1997.

*The Results of Intensive Section 50.54(f) Reviews of Design Bases Further Confirm Plant Safety and Individual Plant Examination Reviews*

In letters to all licensees dated October 8, 1996, the NRC requested, pursuant to 10 C.F.R. § 50.54(f), that licensees describe their processes for maintaining design bases information.

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<sup>28/</sup> SECY-97-036, *supra*, referring to Memorandum, "Lessons Learned From Millstone Unit 1," Shirley Ann Jackson, Chairman, to James M. Taylor and Karen Cyr, November 30, 1995.

With the exception of a very few plants that are currently not operating, licensees confirmed that they have reasonable assurance that their plants are operated consistent with the underlying design bases. A request for information pursuant to Section 50.54(f) must be justified against the highest standards for the NRC to make a decision whether to revoke, modify, or suspend a license; thus, unless the NRC informs licensees otherwise, licensees should assume the processes described in their responses adequately address the NRC's concerns that originally prompted issuance of the information requests.

The NRC has begun conducting follow-up inspections and reviews of the information provided by all licensees in response to the Section 50.54(f) requests. As explained above, the NRC Staff has selected plants for A/E inspections of their design bases in cases where the licensees' Section 50.54(f) responses indicated possible weaknesses. To date, these inspections have confirmed that licensees are, in general, adequately maintaining licensing and design bases information in a manner that ensures safe plant operation.

Further, in response to the Commission's policy on severe accidents and Generic Letter 88-20, "Individual Plant Examination for Severe Accident Vulnerabilities -- 10 C.F.R. § 50.54(f)," licensees confirmed the SAR Chapter 15 accident analysis. Each licensee developed probabilistic risk assessments ("PRA") for the plants that identified plant-specific vulnerabilities. These vulnerabilities are being addressed in a programmatic fashion. These efforts further verify the safety of the plants.

#### Most Licensees Will Implement Revised Standard Technical Specifications

The NRC's discussion in the draft NUREG further states that (referring to SECY-97-036, "Millstone Lessons Learned, Part 2, Policy Issues," dated February 12, 1997) Section 50.71(e) requirements for updating the SAR were neither implemented nor enforced in a manner to ensure that the effects of all new analyses were included in SARs. However, the implementation of revised Standard Technical Specifications ("RSTS" -- also referred to as "Improved Technical Specifications") accomplishes essentially the same purpose as expanding the scope of the SAR or Section 50.59 because the "BASES" section of the RSTS and information relocated from the TS to the SAR greatly expands the information subject to Section 50.59 as part of the voluntary upgrade of the majority of plants to RSTS. Therefore, changes in the NRC's enforcement of Section 50.71(e) are not necessary to accomplish the expansion of the scope of Section 50.59 because (1) the NRC has approved the RSTS for each type of reactor through the issuance of NUREGs which provide guidance to licensees for developing the RSTS, and (2) the NRC reviews and approves the final RSTS, which would include any plant-specific changes to the RSTS.

#### Potential Detriment to Safety

Because the controls for the Section 50.59 reviews are not structured to determine whether or not a proposed change to the facility is "safe," as discussed in Section II of Draft NUREG-1606, but only to determine if NRC review is required prior to implementing the proposed change, the expansion of the scope of Section 50.59 would not enhance the safety of the facility. In

fact, the safety of a facility could potentially be degraded by an increase in the scope of Section 50.59. For example, at one facility where the licensee had voluntarily implemented portions of the NRC's proposed guidance on Section 50.59, three separate safety enhancements were delayed, awaiting NRC approval, and potentially will be canceled. The proposed changes added or modified equipment not currently described in the SAR. As the licensee reviewed the proposed changes in a conservative manner, applying Section 50.59 not only to the effects of the proposed change on equipment described in the SAR but also to the entire modification, it concluded that the modification increased the probability of a malfunction of equipment and that the three changes created USQs.

The conclusion that these examples created USQs did not reflect a perceived degradation in safety, or represent an important policy matter warranting Staff review for this plant. The conclusion, however, represents an example of the administrative restrictions that would result from the proposed Staff positions. These administratively-based decisions could result in worthwhile actions not being implemented or in a diversion of attention from actual safety issues because of the focus on administrative issues.

## ***B. Discussion***

### **1. There is no Policy or Technical Basis for Expanding the Scope of Section 50.59 at the Present Time**

Based on important policy and technical/safety considerations, rulemaking to expand the scope of Section 50.59 is not necessary at the present time to ensure that licensees properly maintain safe plant operation and control changes to their facilities. As a broad policy matter, the primary focus of the NRC's regulatory processes should be on safety. From a policy perspective, the NRC should maintain a reasonable level of regulatory stability and consistency, rather than continually reassessing past decisions in reaction to events that are not representative of broad, generic safety issues throughout the industry. Unnecessary resource burdens should not, as a matter of policy, be imposed on licensees when there is no justification from a safety perspective. (It should be pointed out that the NRC has the responsibility to justify the imposition of new positions.) As a further policy consideration, the NRC should not attempt to require all licensees to meet current standards for all regulatory applications (e.g., level of detail in SAR) where little safety benefit would result.

At the same time, from a safety perspective, licensees have programs and processes in place to maintain the licensing and design bases of the plants, which ensure safe plant operation. Recent NRC inspections have confirmed the adequacy of these programs and processes. Moreover, they were reviewed and reconfirmed by licensees in response to the NRC's October 8, 1996, Section 50.54(f) information requests. On an ongoing basis, the NRC Staff can rely on its inspection and enforcement authority to identify and address weak programs at specific facilities rather than impose new generic requirements on all licensees.

**2. Alternative Recommendation if Policy and Technical Considerations are Rejected and the Commission Pursues Rulemaking to Expand the Scope of Section 50.59**

If the Commission rejects the policy and technical considerations discussed above and, nevertheless, pursues rulemaking to expand the scope of Section 50.59, we recommend against implementation of the four proffered options in Draft NUREG-1606 for the following reasons:

***Option 1:** Take steps to ensure that commitments which the staff considers fundamental to their regulatory approval are controlled in an appropriate process, either by requiring that such commitments be made part of the SAR (and thus controlled by 10 CFR 50.59), or by specifying other control processes. As part of the Division of Reactor Project's Process Improvement Plan, the staff has initiatives underway to accomplish this for future licensing actions.*

The NRC has already implemented Option 1 as short-term Action 1 in SECY-97-036 without providing for a public notice and comment period on the new policy. For example, several licensees have received license amendments that have imposed license conditions requiring licensees to include information in the plant's SAR. NRC Safety Evaluations for licensing actions have been conditioned by requiring licensees to include information in the plant's SAR, or the NRC's approval is voided. The NRC implemented these actions without informing all licensees of the new policy. Though the actions resulted from a "plan" already being reviewed when Draft NUREG-1606 was issued, the NRC should have issued information explaining the concept and the expectations for the new treatment of commitments. The NRC has not explained the full implications of the license conditions, and whether the information required to be placed in the SAR can later be changed pursuant to Section 50.59 or whether a license amendment must be processed before changing the specific information. If licensees cannot make changes to the information under the provisions of Section 50.59, once the information has been added to the SAR, the NRC has effectively raised the level of legal significance of that information to the same level as information contained in the plant Technical Specifications.

We believe that, at a minimum, licensees should be informed of the new policy and its effects in a generic communication. We believe that licensees should have (and already should have had) an opportunity, through public notice, to comment on the actions prior to NRC's implementation of the new policy, consistent with statutory and regulatory requirements as well as the ideals articulated in the NRC Strategic Assessment Initiative on communications.<sup>29/</sup> In the Commission's SRM for SECY-97-036, dated May 20, 1997, the Commission approved certain short-term actions related to commitment tracking (Actions 1, 2, 3, and 4); however, the Commission did not approve the long-term actions related to commitment management discussed in Actions 5, 6, and 7. The need to continue the short-term actions, such as imposing a license condition for updating the SAR, should be reassessed at the time the long-term actions associated with Section 50.59 and

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<sup>29/</sup> NRC Strategic Assessment Issue: 14. "Public Communication Initiatives," September 16, 1996.

licensee commitments are developed. We believe that the intent of this action (*i.e.*, identify which licensee commitments should be included in the SARs) is best achieved through licensees' commitment tracking programs rather than through a license condition which appears to raise the legal significance of the information beyond that which can be justified by its safety significance.

***Option 2:*** *Revise 10 CFR 50.59 to reference the "licensing basis" instead of "SAR," and develop a definition of licensing basis that includes all the information that the staff wishes to [be] subject to the control of the 10 CFR 50.59 process. Such a change could bring the other information that is not presently contained in the SAR, but that is part of the licensing basis as it would be defined, within the scope of 10 CFR 50.59. If this option were followed, a definition of licensing bases, and other changes to Part 50 would be needed.*

This option is not justified under the backfitting provisions as a "substantial increase in . . . safety" where the "costs of implementation for that facility are justified in view of this increased protection." 10 C.F.R. § 50.109(a)(3). Licensees may elect to compile the licensing basis of the plant, or to apply Section 50.59 to information other than that contained in the SAR. However, we do not believe that imposition of these requirements on licensees on a generic basis is justified or is necessary to ensure safety. As noted above, there generally have been no significant impacts on the safe operation of facilities where discrepancies between the SAR and the as-built conditions have been found. (This is not inclusive of any design issues that are identified as the result of extensive reviews by licensees or vendors such as the issues addressed in Generic Letter 96-06, "Assurance of Equipment Operability and Containment Integrity During Design-Basis Accident Conditions" which involve a different level of design information than that typically contained in the SAR.) In addition, the NRC may review the information in licensees' responses to the October 8, 1996, Section 50.54(f) information request on maintaining the design bases to assess the adequacy of specific programs to identify weaknesses, or lack of detailed information, and these reviews are incomplete. Therefore, any action at this time would be premature. We note that the Commission did not approve the Staff's recommended long-term actions associated with developing a rulemaking plan on the need for licensees to compile the CLB, developing a definition for "CLB" for Part 50, and establishing required controls for licensing-basis commitments not covered by current requirements.<sup>30/</sup>

The NRC seems to imply that the SAR should represent the entire CLB due to its predominate importance to safety. It is appropriate here to reiterate the hierarchy that has been developed in the licensing process. The operating license is the primary controlling document to assure that a facility is controlled safely for protection of the public health. Within the operating license exist license conditions and technical specifications ("TS"). The TS are primary in assuring the safe operation of the plant based on strict, controlling safety parameters that must be maintained. These cannot be changed without NRC approval under 10 C.F.R. § 50.92. Included in the context of the TS is the BASES which provide the primary basis for the margins and conclusions reached for imposing the TS limits. Even though these can be changed pursuant to Section 50.59, the NRC

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<sup>30/</sup> "Staff Requirements - SECY-97-036, Millstone Lessons Learned Report, Part 2: Policy Issues," May 20, 1997.

directly controls and generally approves these changes during the license amendment process. The NRC also issues orders which cannot be overturned without NRC approval. Below these documents are documents that represent the remainder of the licensing basis, including the SAR. The SAR contains various design bases information and plant descriptions, but does not contain the most safety significant operating parameters. Accordingly, adding information to the SAR should not be necessary to improve safety of the plant.

***Option 3:** Take regulatory action to require that SARs be updated to correct past omissions. Under this option, licensees could be required to incorporate changes to the design bases and effects of other analyses performed since original licensing that have not been included in the updated FSAR (but which should have been as specified in 10 CFR 50.71(e)). 10 CFR 50.59 itself would not need to be changed; rather, these actions would improve the completeness and accuracy of the SAR, the document upon which 10 CFR 50.59 governs the change process.*

It appears that the Commission's directions to the Staff to take certain actions related to the SAR effectively direct the Staff to implement Option 3 of the NRC's proposed guidance in Section IV.A of Draft NUREG-1606.<sup>31/</sup> Nevertheless, the Commission's actions do not meet the necessary regulatory process identified in the Administrative Procedures Act for a major change in policy, and rulemaking is required to change the enforcement of Section 50.71(e) for SAR updating. We do not endorse this option because the intent of SAR was not to capture and incorporate all licensing and design basis information and commitments, as defined in 10 C.F.R. § 50.2. Rather, the SAR was intended to be a general description of the facility, providing a broad overview of the underlying design bases of the plant. The SAR was not developed as a legal document -- SARs were generally prepared by engineers and analysts attempting to put very technical concepts into plain, descriptive language.

In the SRM for SECY-97-036, the Commission directed the Staff to implement Section 50.71(e) to ensure that all updated information on changes to the design bases and the effects of other analyses since original licensing are added to the SAR. The Commission noted that enforcement discretion has already been provided in SECY-96-154 for a two-year period ending October 18, 1998. This is a major regulatory action and has significant impacts on the programs and procedures directly related to operation and maintenance of a facility. As noted in Commissioner Rogers' comments on his vote for the SECY-97-036 SRM, there clearly was some disagreement as to the interpretation of the final rule, and that there has been more than one NRC interpretation.<sup>32/</sup>

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<sup>31/</sup> "Staff Requirements - SECY-07-036, Millstone Lessons Learned Report, Part 2: Policy Issues," May 20, 1997.

<sup>32/</sup> "Commissioner Rogers' Comments on SECY-97-036, Thoughts on the FSAR Updating Rule," "Commission Voting Record - SECY-97-036," May 20, 1997.

Commissioner Rogers also said that interpreting the requirements in a manner different from previous practice should not be carried out without public notice and comment.<sup>33/</sup>

We agree that taking regulatory actions to change the way the rule has been understood and enforced in the past necessitates rulemaking, subject to the provisions of Section 50.109, the Administrative Procedures Act, and the Small Business Regulatory Enforcement Fairness Act. The SAR has not previously been considered a document of legally-binding requirements, such as the license and technical specifications. For the NRC to now impose license conditions on the content of the SAR, and raise the legal status of the SAR to that of the operating license, creates a standard that is unduly onerous and unnecessary from a safety perspective.

***Option 4:** Revise 10 CFR 50.71(e) update requirements, or develop guidance to improve future updates to specifically identify which information (to what level of detail) needs to be included and maintained in the SAR. These steps would improve the completeness of the SAR for future changes made pursuant to 10 CFR 50.59.*

Here again, licensees have various processes and controls for maintaining and operating the plant in a safe manner and maintaining the licensing and design bases of the plant and, thus, adoption of this option is not warranted. Because of the variations in the plants, one single approach may not be the best option for managing all of the information processed for a facility. Requiring more information to be contained in the SAR would likely make it so cumbersome, its value could actually be degraded due to the fact that there would be more information of varying degrees of value to the safety of the plant. Information currently controlled by well-defined programs and procedures would be folded into a "super SAR" controlled by a single process (*i.e.*, Section 50.59). The Commission has recognized that "less meaningful information and commitments" should be removed from the SAR based on risk-informed decisions.<sup>34/</sup> RSTS and other ongoing actions provide a better approach for the NRC to achieve its objectives than changes to the SAR updating requirements.

Thus, we recommend that the Staff not expand the scope of Section 50.59, as suggested in any of the four options set forth in Section IV.A of Draft NUREG-1606, but rather endorse the Commission's mandate in the SRM in response to SECY-97-036. The latter directs the Staff to develop regulatory guidance for making risk-informed decisions on information to be contained in the updated SAR.<sup>35/</sup> Implementation of this directive would, in turn, focus the scope of Section 50.59 on the most risk-significant issues associated with plant operation.

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<sup>33/</sup> *Id.*

<sup>34/</sup> "Staff Requirements - SECY-97-036, Millstone Lessons Learned Report, Part 2: Policy Issues," May 20, 1997.

<sup>35/</sup> "Staff Requirements - SECY-97-036, Millstone Lessons Learned Report, Part 2: Policy Issues," May 20, 1997.

In essence, the NRC's proposed options are focused on modifying existing regulations and Staff positions, making so-called "Band-Aid improvements" to the processes. We propose that the NRC first determine its goals for the proposed actions. For example, rather than expanding the scope of the SAR, there may be advantages in making the SAR more concise and narrowly focused on the design of the facility -- *i.e.*, a design bases description as it was originally intended rather than a licensing basis description. The scope of Section 50.59 would also be more narrowly focused on the design bases of the plant. Such an approach would be consistent with the aforementioned Commission's directions to the Staff on developing guidance for a more risk-informed SAR.

The draft NUREG does not clearly identify the NRC's goals in all of the various action plans and lessons learned reviews. Because there has not been any comprehensive comparison of goals and objectives to the current regulatory processes to determine if these processes already achieve these goals and objectives, the NRC's efforts are incomplete. Accordingly, the efforts could be misdirected and result in confusion. The goals and objectives should be clearly related to safe operation of the plants and not result in the unnecessary use of resources to correct a non-problem.