September 10, 1997 SECY-97-205

FOR: The Commissioners

FROM: L. Joseph Callan /s/
Executive Director for Operations

SUBJECT: INTEGRATION AND EVALUATION OF RESULTS FROM RECENT LESSONS-LEARNED REVIEWS

PURPOSE:

This paper has four main purposes: (1) discuss the experience gained by the staff with implementation of the Millstone Lessons Learned short-term actions (described in SECY-97-036); (2) discuss staff activities related to the implementation of 10 CFR 50.59, including the feedback received during the comment period on proposed regulatory guidance; (3) present options for integrating a number of proposals for regulatory improvements for the 10 CFR Part 50 framework to derive an effective and integrated approach for modifying existing regulatory processes; and (4) provide recommendations for a course of action based on these reviews.

SUMMARY:

This paper discusses the staff experience with implementation of the Millstone Lessons Learned short-term actions. It also discusses staff activities related to implementation of 10 CFR 50.59, including the information obtained during the comment period on proposed regulatory guidance. This paper presents five options to improve the regulatory process by integrating a number of proposals. Specifically, the options include proposed actions to improve the regulatory process in the areas of implementation of 10 CFR 50.59, the use and content of the plant safety analysis report (SAR), design bases, and NRC oversight of licensee commitments and other related internal process improvements.

This paper also describes how the staff has developed a conceptual framework that it considers the best means of meeting the pertinent staff requirements memoranda (SRMs) which have directed the staff to develop an approach that will revise existing regulatory processes to make them more fully risk-informed. The framework will discuss the scope of systems, structures, components (SSCs); programs and procedures, including requirements for corrective action processes and timeliness of closure; processes for changing the licensing basis; and enforcement issues. Specifically, the staff approach would (1) define a

CONTACT: Frank Akstulewicz, NRR
301-415-1136, Email: fma

common scope for the application of 10 CFR Part 50, (2) employ the use of risk-informed decisionmaking to rank the regulatory importance of SSCs, (3) include a process for identifying high-risk degraded or nonconforming plant conditions, and (4) revise existing corrective action processes, such as 10 CFR Part 50, Appendix B (Criterion XVI), to focus on the risk significance of identified deviations from established requirements. In order to address issues that are currently impacting the industry, the staff also proposes some concurrent steps to improve existing regulatory processes, including guidance on selected aspects of 10 CFR 50.59 implementation, guidance on updating of SARs, and 10 CFR 50.59 rulemaking.

BACKGROUND:

On February 12, 1997, the staff forwarded two Commission papers summarizing the staff's examination of the regulatory process in the areas of design and licensing bases, the use and content of the plant SAR, and issues related to 10 CFR 50.59. The first paper, SECY-97-036, "Millstone Lessons Learned Report, Part 2: Policy Issues," presented the staff's findings and conclusions regarding the regulatory process issues discussed in Part 1 of the Millstone Lessons-Learned report. The second paper, SECY-97-035, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, or Experiments)," presented regulatory guidance that reaffirmed existing regulatory practice in many areas, clarified the staff's expectations and positions in areas in which the industry practice or position differs from the staff's expectations for implementation of Section 50.59, and proposed guidance in areas where previous guidance did not exist.

In a memorandum also dated February 12, 1997, the staff informed the Commission that SECY-97-035 and SECY-97-036 represented substantive evaluations of regulatory issues and policy questions affecting both the maintenance of the current licensing basis for operating nuclear power plants, and their operation in a manner consistent with their design bases. The staff further stated that careful evaluation would be required before a cohesive regulatory policy could be developed by integrating the recommendations stemming from each paper. This is because small changes in regulatory policy and the timing of implementation could have a significant impact on the nuclear industry, the staff, or both. In addition, the staff noted that it would be necessary to examine the safety significance of proposed policy changes, as well as the related backfit considerations. At that time, the staff had not yet completed its overall integration of the recommendations contained in the two Commission papers, and so had not yet compiled a proposed regulatory strategy responsive to all the issues. The staff informed the Commission that it intended to propose such an integrated strategy, including resource estimates, after receiving the Commission's comments and guidance regarding the approaches discussed in the two Commission papers. The Commission responded with two SRMs dated April 25, 1997 (SECY-97-035), and May 20, 1997 (SECY-97-036). This paper responds to the actions required by these memoranda.

DISCUSSION:

In the sections below, the staff discusses the experience gained from implementation of short-term Millstone Lessons-Learned actions (Section A), and activities concerning 10 CFR 50.59, including public comments on the staff's proposed guidance (Section B). The staff evaluated these ongoing activities as a foundation to develop options for more comprehensive regulatory

process improvements and to include risk-informed approaches as requested by the Commission. These options and resource and schedule estimates, are presented below (Sections C and D, respectively).

A. Implementation of Millstone Lessons Learned Short-Term Actions

In response to events at Millstone Station and at Maine Yankee, the NRC has conducted special inspections and lessons-learned reviews. These activities have formed the basis for a number of specific corrective actions. Attachment 1 to this paper summarizes the staff activities completed or under way to implement the short-term actions identified from these reviews (detailed in SECY-97-036). In most cases, the staff is still evaluating the effectiveness of the short-term actions in resolving the identified regulatory issue or in identifying any new licensing- or design-bases issues.

B. Staff Activities and Public Comments on Regulatory Guidance Related to 10 CFR 50.59

Attachment 2 summarizes staff activities regarding 10 CFR 50.59, including the development of guidance and overseeing licensee implementation through NRC inspections and enforcement.

In the area of developing guidance, a notice was published in the *Federal Register* on May 7, 1997 (62 FR 24947) announcing the availability for public comment of draft NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, or Experiments)." The draft NUREG outlined staff positions in 22 topic areas related to 10 CFR 50.59 implementation. In response to the notice, interested licensees, vendors, industry groups, and individuals filed 46 comment letters. The commenters included the Nuclear Energy Institute (NEI) and three law firms filing on behalf of various nuclear utilities. In addition, the NRC received individual letters from 33 utilities; many of these letters expressed support for the more detailed comments filed by NEI or the law firms. Attachment 2A identifies the commenters.

In general, the commenters concluded that the staff's proposed guidance would cause confusion within the industry and the NRC, and would create instability in the regulatory process. Six topic areas generated most of the comments: (1) the definition of a change, (2) what constitutes a malfunction of a different type, (3) what constitutes an increase in probability, (4) what constitutes an increase in consequences, (5) what constitutes a bases for a technical specification and how safety margins are established, and (6) how 10 CFR 50.59 should apply to degraded or nonconforming conditions at operating plants. Further, the commenters concluded that the guidance would result in a significant burden for both the industry and the staff because of the number of changes that will require NRC approval. The commenters asserted that the guidance would lower the threshold for unreviewed safety questions (USQs) so much that almost any change could be deemed to involve a USQ. Lastly, the commenters stated that the guidance would adversely affect safety because it would divert resources to insignificant issues, impede the use of compensatory actions to add margin, or hinder licensee plans for design improvements.

Attachment 2B specifically discusses the topic areas of the public comments. The staff has not yet completed its analysis of the comments nor the proposed resolutions; therefore, an item-by-

item response is not available at this time. For the issue about how 10 CFR 50.59 should apply to degraded or nonconforming conditions at operating plants, the staff has developed a proposed course of action, namely issuance of a revision to NRC inspection guidance, which is discussed in Attachment 2C and in a later section of this paper.

C. Integration of Recommendations for Regulatory Process Improvements

1. Integration Process

Since early May 1997, the staff has been working to define various approaches for implementing changes, including a range of possible actions and timing, that would result in effective regulatory changes that could be instituted in a timely manner. To date, the staff has identified the need to pursue various activities in four categories related to the reactor licensing and oversight programs: (1) implementation of 10 CFR 50.59, (2) use and content of the plant SAR, (3) design bases, and (4) NRC oversight of licensee commitments and other related internal process improvements.

The staff has developed five options and has organized the five options in a hierarchy of activities that generally increase in complexity, schedule duration, and resource impact from one option to the next. The proposals for minor rulemakings under Options 1 and 2 incorporate elements of risk-informed decisionmaking, although to a lesser degree than Options 3, 4, and 5. Options 3 and 4 examine changes to the existing processes that promote greater use of risk-informed decisionmaking and regulatory oversight. The staff has selected several elements of Options 1 through 4 to create Option 5 as the best means of meeting the pertinent SRMs which have directed the staff to develop an approach that will revise existing regulatory processes to make them more fully risk-informed. Option 5 is an incremental and progressive transition toward increased use of risk-informed decisionmaking. This option includes both small, risk-informed enhancements to existing regulatory processes in selected areas in the near term and, in the longer term, development of much broader implementation of risk-informed decisionmaking and oversight for many regulations.

Attachment 3 provides a detailed presentation and discussion of Options 1 through 4 and additional information on the techniques and tools that the staff used in developing the options. While Options 1 through 4 are presently packaged with distinct boundaries (as summarized below), the staff considers that the best option requires a blend of activities from the first four options to create the most comprehensive solution (Option 5).

The legal implications of these options are presently being examined by the Office of the General Counsel (OGC) which will provide views to the Commission by separate correspondence.

2. Summary of the Options

Option 1 continues ongoing staff actions designed to provide near-term improvement in regulatory oversight of licensees' design-bases programs and of facility changes made under 10 CFR 50.59. This option includes a 10 CFR 50.59 rule change to allow some increase in the

probability and consequences of a change before it requires prior NRC approval, as well as a clarification or modification of the statement in the rule, "margin of safety as defined in the basis for any technical specification," so that the meaning is clear. This option also notifies the industry of NRC expectations with respect to implementation of 10 CFR 50.71(e) but does not provide for deletion of SAR information. In addition, Option 1 uses information available to the staff to evaluate the implementation of 10 CFR 50.59 and 10 CFR 50.71(e), and the availability, accessibility, and control of design bases information. This option is responsive to the SRM requirements on 10 CFR 50.59, but does not fully implement the direction on the SAR and design bases.

Option 2 includes the 10 CFR 50.59 and SAR activities as in Option 1, but adds an opportunity for licensees to remove unnecessary information from the SAR and to update the SAR with the more risk-significant information first, while bringing the SAR content into conformance with the requirements of 10 CFR 50.71(e). Risk information will be used only in evaluating the priority with which the information should be incorporated into the existing SAR. Option 2 also includes some development of guidance on design bases. This option is more responsive to the SRM requirements on SAR updating, but does not implement the direction on risk-informed SAR contents.

Option 3 includes actions that more fully embrace risk-informed approaches to existing regulatory processes. Specifically, this option includes development of more extensive rule changes on 10 CFR 50.59 and development of regulatory guidance, as well as rule changes to Sections 50.34 and 50.71(e), as needed, to prescribe requirements for the content of the SAR and to update the SAR in a risk-informed manner. This would be a departure from traditional licensing practices by bringing consideration of severe accidents more fully within the regulatory processes. These actions are directed at revamping the 10 CFR 50.59 process and improving understanding of what information needs to be maintained in the SAR. If this option is pursued, NRC may also wish to perform some of the actions from Option 1 or Option 2 to achieve some improvements while the staff is developing the necessary rulemaking and guidance for a risk-informed process. Further, in order to avoid significant backfit issues with imposition of risk-informed approaches, this option may require parallel regulatory processes that would permit licensees to choose which process they wish to use. This option would involve a substantial departure from the framework under which operating plants were licensed and, thus, would involve significant resource, schedular, and legal considerations. This option would implement the Commission direction for risk-informed approaches to SAR contents and for 10 CFR 50.59.

Option 4 includes an approach by which the staff would specify what essential elements of the licensing basis cannot be changed without prior NRC approval rather than defining criteria for a change control process. Like Option 3, this option has substantial schedular, resource, and legal considerations. Further, there are implementation issues associated with defining the essential elements for which no changes are permissible without prior NRC approval, and that large changes might occur without review for other elements. This option satisfies the underlying purpose of the SRM requirements in a different way from the specific actions requested by the Commission.

Option 5 is an incremental and progressive transition toward increased use of risk-informed decisionmaking. This option includes both risk-informed enhancements to existing regulatory processes in selected areas in the near term, and development of much broader implementation of risk-informed decisionmaking and oversight for many regulations in the longer term. The staff believes that Option 5 is responsive to the Commission direction on risk-informed approaches and the broader consideration of the relationship of 10 CFR 50.59 to other Part 50 requirements. Option 5 is discussed below.

Conceptual Framework for Risk-Informed Regulatory Processes

The staff proposes to develop a cohesive set of revisions to established regulatory processes to take into account advances in risk assessment and present such a regulatory approach to the Commission. These efforts would build upon the approaches to establish and modify individual license requirements that explicitly consider risk, such as those discussed in Draft Regulatory Guide DG-1061, "An Approach for Using Risk Assessments in Risk-Informed Decisions on Plant-Specific Changes to the Current Licensing Basis." The proposal would include a general concept of what the regulatory scope should be and how to grade requirements based upon risk significance. The staff will start at the heart of the issue — "what should be regulated and to what degree." This is a difficult subject because it involves fundamental regulatory concepts and affects numerous individual regulations. The staff believes that a realistic plan can be developed and progress can be made on interim steps as long as a clear and agreed-upon framework is put in place. The framework would allow the staff and Commission to evaluate the implications of individual changes to the regulations or to the regulatory guidance documents. Attachment 4 provides an outline of the steps that the staff has planned; the first milestone is for transmittal of the framework, in the form of an Advanced Notice of Proposed Rulemaking, for Commission review by February 27, 1998.

A significant step towards consistent and coherent regulation can be made by assuring that the scope of each "operationally oriented rule" is the same. These rules and requirements include quality assurance (QA), design controls, maintenance, and operations, as well as the identification and correction in a timely manner of degraded or nonconforming conditions. The staff approach would (1) define a common scope for the application of 10 CFR Part 50, (2) employ the use of risk-informed decisionmaking to rank the regulatory importance of SSCs, (3) include a process for identifying high-risk degraded or nonconforming plant conditions, and (4) revise existing corrective action processes, such as 10 CFR Part 50, Appendix B (Criterion XVI), to focus on the risk significance of identified deviations from established requirements. A common scope for all operational regulations should be determined using the risk-informed approach as presented in the Commission Policy Statement on probabilistic risk assessment (PRA), as reflected in the recent draft regulatory guides and standard review plans; that is, the NRC should regulate traditional engineering activities related to design-basis accidents (i.e., "safety related" SSCs and activities for design-basis accident prevention and mitigation) plus risk-significant SSCs and activities (as discussed in DG-1061). Note the NRC Defense-in-Depth philosophy is an integral part of these concepts. The adoption of any single scope definition for requirements would mean that some requirements are likely to be increased and others reduced. For instance, the scope of 10 CFR Part 50, Appendix B (Quality

Assurance) would expand to add "risk significant" SSCs and the scope of the Maintenance Rule (10 CFR 50.65) would likely be reduced.

In a risk-informed approach, the traditional design-basis approach is not replaced, it is complemented. This risk-informed approach could range from that which was utilized in the development of the maintenance rule to the more substantive risk-based methodologies discussed in Attachment 3. The design-basis accident analysis (e.g., SAR Chapter 15) is retained (although it could be modified to remove risk-insignificant postulated events). These analyses would continue to be used to demonstrate that relevant postulated accidents could be mitigated (with margin) under conservative initial conditions, with a single failure. In fact, these analyses serve to show robust system capability when establishing PRA "success criteria."

A risk-informed approach would also retain other SAR sections as they relate to engineering margins in the design or to defense-in-depth features. A risk-informed approach only allows the elimination of existing requirements if they are explicitly shown to be unnecessary for controlling core damage frequency, large early release fraction, defense-in-depth, or engineering safety margins; and if the staff agrees to the change.

In addition to the issue of scope, this framework of regulatory requirements would need to address the depth (level) of requirements. The staff's recent experience in the graded QA area indicate that the risk-grading of requirements (within a defined regulatory scope) is both feasible and appropriate. The grading of requirements would apply to such processes as change control, timeliness of corrective action (closure), and requirements for corrective action processes.

With respect to the safety analysis report, under the above approach, changes to what information is documented in the SAR would result from revising the regulations which establish the requirements which are reflected in the SAR, rather than making decisions about which requirements should form the content of SAR directly on a risk basis. The staff anticipates that a risk-informed SAR would look very much like a typical SAR with some additions (e.g., risk-significant but non-safety-related components) and some reductions. Along with the other rule changes, there may be a need to revise 10 CFR 50.34 concerning the content of the SAR. As part of its efforts, the staff would also evaluate rulemaking for 10 CFR 50.59 to revise the existing change control process into one that is also risk-informed. A 10 CFR 50.59 change process could be built upon risk-informed DG-1061 by defining a risk threshold for allowable changes without NRC review and by defining PRA quality expectations.

There will, of course, be difficult decisions in implementing this suggested approach. One obvious example is how to treat certain non-design-basis SSCs and activities with this risk-informed approach (e.g., training, fire protection, seismic "two-over-one" issues). In addition, the staff will need to consider what should be done in areas where risk analysis techniques are not fully developed.

Immediate Risk-Informed Improvements to the Existing Regulatory Framework

Option 5 includes four actions that are designed to stabilize NRC oversight of licensee activities and to improve the existing regulatory processes during the transition period to a regulatory

framework that is more risk-informed. These actions do not affect the scope of existing requirements such as for 10 CFR 50.59 or for corrective action. Two of these actions arise from ongoing activities and review of the public comments on NUREG-1606. The third action is the SAR updating element of Option 2, and the fourth action is the 10 CFR 50.59 rulemaking element of Option 1. These actions are discussed below.

1. Revision to Generic Letter 91-18

As a result of the staff's heightened focus on licensee implementation of 10 CFR 50.59, several issues emerged regarding the role of 10 CFR 50.59 in the resolution of degraded and nonconforming conditions. Specifically, the staff determined that immediate guidance is necessary to clarify (1) when 10 CFR 50.59 should be applied to situations in which licensees identify degraded or nonconforming conditions; (2) how 10 CFR 50.59 should be applied to evaluate compensatory measures used by licensees to provide added assurance that important equipment will remain operable while actions are taken to correct degraded or nonconforming conditions; and (3) a change in staff practice which would not require, provided certain conditions are met, that licensees resolve any identified USQs before plant startup after a normal or unanticipated shutdown.

The staff determined that these issues could be addressed by a revision to NRC Generic Letter (GL) 91-18, "Information to Licensees Regarding NRC Inspection Manual Section on Resolution of Degraded and Nonconforming Conditions." This generic letter proposes guidance that differs from that forwarded to the Commission in SECY-97-035 based on staff experience and the public comments on NUREG-1606. Attachment 2C provides the proposed generic letter, which explains the staff positions and their basis. The staff proposes to publish the revised GL 91-18 to transmit to all licensees the revised NRC inspection guidance related to the applicability of 10 CFR 50.59 to degraded and nonconforming conditions and to explain the staff's expectation for prompt correction of the degraded or nonconforming condition. As noted in Attachment 4, all appropriate NRC staff will be informed of the change in agency practice concurrent with the issuance of the revised generic letter.

The staff has concluded that issuance of this revision to GL 91-18 would ease immediate problems with the guidance and would not foreclose any options for regulatory improvements that are under consideration. Therefore, unless Commission direction is provided to the contrary, the staff plans to issue the revised generic letter within 14 days from the date of this paper.

2. Enforcement Policy

The second area relates to the enforcement policy for implementation of 10 CFR 50.59 and 10 CFR 50.71(e). On October 18, 1996, the NRC published a revision to the NRC Enforcement Policy to provide additional examples illustrating the severity levels for violations involving 10 CFR 50.59 and 10 CFR 50.71(e) (see SECY-96-154). In accordance with the revision, a number of enforcement cases have involved USQs which resulted in escalated enforcement action notwithstanding that there was little impact on safety. The staff recognizes that the Commission, in the Statement of Considerations for the October policy change, emphasized the importance of maintaining the regulatory envelope. The Commission stated:

> Not every unreviewed safety question is a significant safety issue. However, until the question is reviewed and understood, there is an uncertainty in the basis for the Commission's safety decision in licensing the plant. Therefore, the failure to follow the regulatory process established by 10 CFR 50.59, regardless of the actual safety significance of the change, when there is an unreviewed safety question or a conflict with a technical specification, is a significant regulatory concern. Licensees must ensure that they are in conformance with the FSAR as it was a key element for the basis for the Commission's decision in licensing the plant and continues to be an important consideration in current licensing actions. The enforcement process is a tool that the Commission intends to use to emphasize the importance of achieving this conformance and deter violations from continuing in this area.

Based upon experience with the Enforcement Policy and the potential changes to 10 CFR 50.59 as to what should constitute a USQ, the staff believes that the Enforcement Policy treatment of USQs should be reconsidered. While the staff appreciates the importance of maintaining the regulatory envelope, the staff is of the view that every USQ is not a significant regulatory concern warranting escalated action. The staff intends to submit to the Commission a revision to the Enforcement Policy to accompany the draft changes to 10 CFR 50.59.

In addition, pending changes to the Enforcement Policy, the staff intends to exercise enforcement discretion on a case-by-case basis pursuant to Section VII(B)(6) of the Enforcement Policy to lower the severity level of violations involving USQs where the staff does not consider them to be significant. To provide greater assurance that the staff will be consistent in exercising this discretion and that enforcement actions reflect an agency-wide perspective with a consistent approach to 10 CFR 50.59 issues, the Office of Enforcement (OE) is developing a 10 CFR 50.59 Enforcement Panel, similar to the currently standing Maintenance Rule Enforcement Panel, to review all 10 CFR 50.59 issues identified through the inspection process. The staff intends to keep this panel in place until it is satisfied that there is sufficient consistency with the treatment of these violations. The staff expects the panel to last for about six months after the proposed rulemaking is published. This panel would be composed of senior members of OE and NRR with assistance from the involved regions as necessary.

3. Guidance on Updating Safety Analysis Reports

Third, the staff will publish regulatory guidance to achieve the Commission's intent related to implementation of 10 CFR 50.71(e) to ensure that plant-specific SARs are appropriately

updated to reflect changes to the design bases and to reflect the effects of other analyses performed since initial licensing. This guidance will establish a time frame within which licensees must incorporate the updated information into the plant SARs.

During that time, licensees could use a phased approach to update their SARs to reflect the more safety- or risk-significant information first. The staff would further propose to use enforcement discretion during this time, provided that a licensee had an established program under way to improve the content of the plant SAR. The staff is investigating methods through which a licensee could establish a process to eliminate obsolete information, less meaningful information, or less meaningful commitments from the SARs within certain constraints; although OGC has advised the staff that rulemaking may be necessary to permit such removal. The risk information would be used only in evaluating priorities for incorporation of information into the SAR. The staff will also revise existing inspection guidance such that inspectors review the licensee's processes to ensure that a licensee is complying with the regulations and established guidance. The staff will provide its implementation approach, including specific proposals on enforcement discretion and for removal of information, to the Commission by December 30, 1997, consistent with the May 20, 1997, SRM.

4. Rulemaking on 10 CFR 50.59

The staff will initiate rulemaking on 10 CFR 50.59 to modify the language of the rule to (1) clarify the scope of the rule, (2) clarify Commission requirements related to increases in probability and consequences, (3) clarify where the bases of technical specifications are located, and (4) define how margins are to be evaluated under the regulation. As part of the rulemaking activity, the staff intends to respond to public comments received on NUREG-1606 and to publish regulatory guidance either similar to that contained in the NUREG or that would endorse, possibly with certain exceptions, industry-developed guidance. (Attachment 3 to this paper presents some of the rulemaking options that the staff has been considering.)

D. Resources and Schedules

The staff's proposed schedules and resource estimates for Option 5 are shown in Attachment 4. These estimates were based upon a review of staff resource data for issuing generic communications and for issuing new regulations (such as license renewal). Completion dates were estimated based upon the complexity of the issues and are subject to change as the framework concept is more fully developed. The staff can complete the actions planned for fiscal year (FY) 1998 within the resources currently budgeted. Significant NRC resources will be necessary, however, to fully implement the transition to the more risk-informed regulatory framework. The staff will reexamine its budget estimates and resource impacts for FY 1999 and beyond and provide that information with an advanced notice of proposed rulemaking (ANPR) on the conceptual framework for risk-informed regulatory processes.

COORDINATION:

The Office of the General Counsel has reviewed this paper and will provide views on legal implications by separate correspondence to the Commission.

The Office of the Chief Financial Officer has reviewed this paper for resource implications and has no objections.

The Chief Information Officer has no objection to this paper.

On September 9, 1997, the staff briefed the Committee to Review Generic Requirements on draft GL 91-18, Revision 1. The Committee supports issuance of this revised generic letter and the attached inspection guidance without public comments (beyond those already obtained on NUREG-1606). Because of the clarification of the staff position represented in this document, the Committee recommended that the staff develop plans to clearly communicate the inspection guidance to the regions to ensure consistent implementation.

A copy of draft GL 91-18, Revision 1 was also provided to the Advisory Committee on Reactor Safeguards (ACRS) for their information on August 25, 1997. The staff plans to brief the ACRS on the overall efforts discussed in this paper later this year.

RECOMMENDATION:

The staff recommends that the Commission:

(1) Direct the staff to develop the framework for risk-informed regulatory processes as described in Option 5 and submit the framework, ANPR, and budget estimates and resource impacts for FY 1999 and beyond for Commission review by February 27, 1998.

(2) Direct the staff to submit a proposed rulemaking package for 10 CFR 50.59 for Commission approval in December 1997.

(3) Direct the staff to submit its proposal concerning enforcement policy revisions for 10 CFR 50.59 along with the proposed 10 CFR 50.59 rulemaking package in December 1997.

(4) Approve by negative consent the staff proposal on GL 91-18, Revision 1, within 14 days from the date of this paper.

(5) Note that the staff will provide its approach on SAR updating to the Commission by December 30, 1997, in accordance with the Commission SRM dated May 20, 1997.

L. Joseph Callan
Executive Director for Operations

Attachments:
1. Staff Actions Completed or Under Way to Implement Millstone Lessons-Learned Review Short-term Actions
2. Activities Concerning 10 CFR 50.59
   A. List of Commenters on NUREG-1606
   B. Public Comments on NUREG-1606
   C. Draft NRC Generic Letter No. 91-18, Revision 1: Information to Licensees Regarding NRC Inspection Manual Section on Resolution of Degraded and Nonconforming Conditions
3. Options and Alternatives for Regulatory Changes
4. Resource and Schedule Estimates for the Staff's Proposed Course of Action

ATTACHMENT 1

STAFF ACTIVITIES COMPLETED OR UNDER WAY TO IMPLEMENT MILLSTONE LESSONS-LEARNED REVIEW SHORT-TERM ACTIONS

STAFF ACTIVITIES COMPLETED OR UNDER WAY TO IMPLEMENT MILLSTONE LESSONS-LEARNED REVIEW SHORT-TERM ACTIONS

In a staff requirements memorandum (SRM) dated May 20, 1997, the Commission required the (NRC) staff to prepare a paper discussing the experience gained by implementing of the short-term action items described in SECY-97-036, "Millstone Lessons Learned Report, Part 2: Policy Issues" (February 12, 1997). This attachment discusses the activities taken in response to the short-term action items and presents the results of these activities when available. Only those actions from SECY-97-036 that were supported by the Commission SRM are discussed below.

SHORT-TERM ACTION 1 - Have licensees explicitly identify their licensing-basis commitments in future written communications with the agency.

SHORT-TERM ACTION 4 - Develop a process to identify and track licensing commitments made to the NRC by individual licensees.

As previously noted in a number of Commission papers including SECY-97-036, the Associate Director for Projects (ADPR) of the NRC's Office of Nuclear Reactor Regulation (NRR) established a Process Improvement Plan (PIP) to address concerns regarding the NRC's licensing process that were raised at Millstone, Haddam Neck, and Maine Yankee. As part of ongoing activities under the PIP, the staff continues to modify its processes to clearly identify those licensee commitments on which the staff relied to make regulatory decisions.

On February 21, 1997, the staff issued an interim guidance memorandum for conversion to Improved Standard Technical Specifications. In that memorandum, the licensee commitments to relocate technical specifications requirements to licensee-controlled documents, such as the final safety analysis report (FSAR), are to be made license conditions. Additionally, the staff has developed interim guidance for the NRR staff to use in identifying, tracking, enforcing, and verifying licensee commitments that the staff relies upon for resolving licensing actions. This guidance requires that reviews of licensing actions conducted by the staff must include identification, tracking, and determination of how the commitments will be verified. The guidance is in concurrence at this time.

In parallel with this effort, NRR initiated a pilot program for licensing actions. This program identified commitments upon which the staff is making its regulatory decisions and established these commitments as license conditions. This pilot program is complete, and the staff has incorporated its results into the guidance.

The staff also reviewed existing tracking systems to assess their acceptability for tracking implementation and verification of regulatory commitments. As a result, the staff developed additional screens for the existing NRR Workload Information and Scheduling Program (WISP) computer database system to allow NRR to track certain licensee commitments. As part of the PIP, the staff will also develop guidance to verify and document the licensees' implementation of these commitments. To assess the adequacy of the licensees' implementation of past commitments made to the NRC, the NRR staff will examine various options to ascertain what type of review of past licensing tasks would be most appropriate. Also, the staff will review and strengthen existing processes, as necessary, giving appropriate consideration to resource

implications. In addition, the staff is considering meeting with the Nuclear Energy Institute (NEI) to discuss the staff's actions and intentions in this area.

Finally, the staff is developing a generic communication to inform licensees of how the NRC intends to handle the commitments submitted by licensees and relied upon by the NRC staff in its safety evaluations. This communication will include a provision for licensees to clearly identify their licensing-basis commitments in future written communications with the agency.

SHORT-TERM ACTION 2 - Encourage licensees to use NEI guideline for managing commitments made to the NRC.

In SECY-95-300, "Nuclear Energy Institute's Guidance Document, 'Guideline for Managing NRC Commitments'," dated December 20, 1995, the staff documented its conclusions that the NEI has prepared acceptable guidance for controlling changes to commitments. In a letter to the NEI dated January 24, 1996, the staff informed the industry that the NEI guidance was acceptable and that the NRC would monitor licensees' implementation of the NEI guideline (or alternate commitment control processes) in order to assess the need to promulgate staff guidance or rulemaking. The staff is currently preparing to inspect a series of licensee programs for managing commitments made to the NRC. On the basis of the results of the audits, the staff will determine what additional actions are warranted. Future activities may include expanding the scope of the audits to include additional reactor licensees, conducting workshops on the audit findings, and reviewing commitment management programs as part of routine NRC inspection activities.

SHORT-TERM ACTION 3 - Continue to implement the ADPR PIP. Actions include one to better communicate licensing commitments, clarify guidance on documents to be reviewed, and develop procedures for documenting verbal commitments.

Following the establishment of the PIP by the ADPR, the staff expanded the plan to address many other issues within the NRR Projects organization. As additional staff action items are identified, they are added to the PIP for tracking, and individuals and due dates are assigned to develop guidance, training, or other appropriate actions. The staff continues to complete action items, updating the revised Project Manager (PM) Handbook as needed. As a result, the PIP currently identifies a total of 136 action items, of which more than 96 action items have been completed and a number of others are in final concurrence. The regions and other NRC offices are consulted and their comments incorporated as part of the development of various guidance or generic communications.

Guidance has been clarified or developed, and disseminated to the staff on the coordination and noticing of licensee drop-in visits, control of NRC draft material, management expectations related to handling of unsolicited information, oversight of the FSAR updates, and the process defined by Title 10, Section 50.59 of the *Code of Federal Regulations* (10 CFR 50.59). The staff also developed guidance regarding the need for PMs to consider ongoing agency actions and stakeholders' concerns that could be impacted by the issuance of a licensing action or by staff position and guidance on the handling of sensitive documents.

Most significantly, guidance was developed and disseminated to the staff on the importance of interactions between the PMs and the regional offices. The PMs were reminded on a number of occasions (through written guidance in the PM Handbook, electronic mail messages, PM workshops, and division-level meetings) of the need for close coordination with the resident

inspector for the operating plant. Specific guidance was provided on the need for and what types of information the PM should keep the residents informed of and guidance on the frequency of these conversations.

SHORT-TERM ACTION 8 - Encourage licensees to explicitly identify design bases in future written communications with the NRC.

No staff actions are under way. The staff is considering the need for additional guidance as it relates to definition or identification of the design bases as part of the integration activities. Any recommendations for action in this topic area will emerge as part of these activities.

SHORT-TERM ACTION 9 - Provide guidance to licensees to implement 10 CFR 50.71(e) as explained in the rule's statement of consideration and to include in FSARs new design bases developed at the Commission's request.

The "Discussion" section of this Commission paper and Attachment 3 detail staff plans for developing revised guidance to licensees regarding the implementation of 10 CFR 50.71(e). Attachment 4 provides a schedule (refer to item C).

SHORT-TERM ACTION 10 - Use the information submitted by licensees on their programs in response to the 10 CFR 50.54(f) letters to assign priorities to and better focus design-related inspections and to help ensure that FSARs properly describe the associated facility.

The results of the staff's review of the plant-specific responses to the 10 CFR 50.54(f) letter and how the staff will use the information submitted by licensees on their programs in response to the 10 CFR 50.54(f) letters is discussed in greater detail in SECY-97-160, "Staff Review of Licensee Responses to the 10 CFR 50.54(f) Request Regarding the Adequacy and Availability of Designs-Basis Information" (July 24, 1997). The results of staff's review are being used to prioritize architect/engineer (A/E) design inspections and provide inputs to the detailed plans for the design inspections. Approximately one-third of the sites were initially recommended at varying priority levels for a design team inspection. Regional and NRR senior management then prioritized these sites, considering other ongoing NRC inspection activities. Management then recommended 11 high-priority sites for a design team inspection. The staff inspections of these sites have been completed, are under way, or are planned for fiscal year (FY) 1998.

(Also see the discussion of Short-term Action 11 regarding the guidance issued to PMs on July 22, 1997, relative to maintaining cognizance over issues expected to be addressed by licensees in their FSAR updates, as required by 10 CFR 50.71(e).)

SHORT-TERM ACTION 11 - Pay increased attention to inspection and enforcement of licensee compliance with 10 CFR 50.71(e).

10 CFR 50.71(e) requires licensees to periodically update the FSAR originally submitted as part of the application for the operating license. The intent of this requirement is to ensure that the FSAR contains the latest material developed. Inspections led by the NRR Special Inspection Branch (PSIB) have paid special attention to this area since early 1996. Since November 1996, nine A/E design inspections have been completed, and each has identified significant numbers of FSAR discrepancies. For each, PSIB has recommended that the regions take appropriate enforcement action. In addition, the audit of FSAR accuracy through inspections, as described

in the discussion of Short-term Action 16, is expected to identify additional FSAR discrepancies.

The need for PMs to be familiar with the content of the FSAR and to apply knowledge of the current licensing basis in determining the scope of the reviews has been reiterated to the staff in a number of forums, including PM workshops (four have been held so far), meetings between the ADPR staff and Projects Division Directors, and meetings at the Senior Executive Service level between the ADPR and the Project Directors. Additionally, clarifying guidance was developed, disseminated to the staff, and included in the PM Handbook (on January 14, 1997) regarding the need for PMs to review the applicable portions of the FSARs, technical specifications, and other available current licensing-basis information relevant to staff review. NRR Office Letter 803, "Technical Specifications Review Procedures," includes increased emphasis on this point as well as other policy changes. This revision is being tracked on the ADPR PIP.

Additionally, guidance was issued to the NRR Projects staff on July 22, 1997, directing the PMs to maintain a list of issues that licensees are expected to address in their FSAR update under 10 CFR 50.71(e). The PMs should use this list to ensure that the FSAR updates identify appropriate issues on the basis of the PM's knowledge of licensee changes, license submittals, and so forth. The PMs gain such knowledge during reviews and discussions with the resident inspectors and the licensee, and through situations where NRC approval was contingent upon the licensee updating the FSAR to reflect commitments identified in the staff's safety evaluation.

For those FSAR updates with which the PM is familiar, including the effects of all changes and results of analyses in support of new safety analyses, the guidance also directs that the PM's review should assure that the related FSAR changes are appropriately addressed by licensing actions, 10 CFR 50.59 submittals, or regional inspection activities. The PM should also ensure that there no other licensing actions or related regional inspection activities that have been completed since the last update for which FSAR updates should have been submitted. Questions or concerns identified during the reviews should be discussed with the region and addressed through telephone communications, onsite followup, or docketed correspondence with the licensee, as appropriate. PMs should document the completion of the review and discuss any significant findings in their input to the related inspection report.

In October 1996, the NRC Enforcement Policy[1] was revised to address departures from the FSAR. The revision included changes to address enforceability of the FSAR and provided severity levels for violations of 10 CFR 50.59 and 10 CFR 50.71(e). To encourage licensees to identify and correct violations that are not normally identified through current surveillance and quality assurance activities, the revised policy provides for a 2-year period during which the Commission will not take enforcement action if the licensee identifies violations (up to and including Severity Level II) associated with the FSAR through a voluntary initiative. Appropriate changes were also made to the NRC Enforcement Manual (NUREG/BR-0195).

On April 9, 1997, NRC Inspection Manual Chapter 2515, "Light-Water Reactor Inspection Program — Operations Phase," was revised, providing guidance to the inspectors to review the

[1]NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions."

applicable portion(s) of the FSAR that relate to inspection activities, and verifying that FSAR commitments have been properly implemented in plant practices.

SHORT-TERM ACTION 12 - Reemphasize design inspections.

From the review results and the design team inspections conducted to date, the staff has identified a need to continue its increased emphasis on inspection of licensee conformance with the plant-specific design bases. Consequently, the staff has modified the normal (core) reactor inspection program to provide an inspection procedure that can be used to evaluate licensee design control programs and processes. Known as Inspection Procedure 93809, "Safety System Engineering Inspection," this new procedure provides an alternative method to assess a licensee's engineering effectiveness through an in-depth review of engineering calculations, as well as other engineering activities and analyses. The change to the core inspection program will require performance of a design-basis inspection at least once per systematic assessment of licensee performance (SALP) period.

Regional reviews of licensee responses to the October 9, 1996, 10 CFR 50.54(f) letter on the accuracy and availability of design-basis information have identified the need for design inspections at specific plants. In some cases, the regions have elected to perform safety system functional inspections (SSFIs) or other design inspections. In other cases, the regions have requested PSIB-led A/E design inspections. Twelve inspections will be completed in FY 1997 and ten are planned for FY 1998. PSIB maintains a database of A/E inspection findings, and provides a quarterly assessment of the resulting trends in order to identify the need for generic communications to licensees and inspection program revisions.

SHORT-TERM ACTION 13 - Publish guidance for the staff on design bases (10 CFR 50.2) and supporting information beyond the design bases and their relationship to licensing and inspection.

No staff actions are under way. The staff is considering the need for additional guidance as it relates to definition or identification of the design bases as part of the integration activities. Any recommendations for action in this topic area will emerge as part of these activities.

SHORT-TERM ACTION 16 - Continue to audit FSAR accuracy through inspections.

The inspection program was modified to require continued review of FSAR descriptions and commitments as part of all NRC inspections, including the design-related inspections discussed under Short-term Action 12. For each inspection, the inspectors will review the applicable portions of the FSAR that relate to the assigned inspection activities and verify that the licensees have properly implemented selected FSAR commitments in plant practices. This review is intended to focus on identifying differences between the FSAR description and the plant practices without changing the scope of any planned inspection.

The staff has worked with the NRC's Technical Training Center and the regions to ensure that initial and refresher courses regarding the "fundamentals of inspection" continue the emphasis that senior NRR management has placed on the staff's use of the FSAR during licensing and inspection activities. Recent courses held in April and May 1997 discussed lessons learned from Millstone and emphasized the importance of consulting the FSAR during licensing and inspection activities.

Additionally, during regional counterpart meetings in the regions and at several PM workshops, senior NRR management emphasized the importance of consulting and verifying licensee compliance with the FSAR during inspections and licensing activities. Guidance was developed, disseminated to the NRR Projects staff, and placed in the PM Handbook instructing the PMs to review applicable portions of the FSAR when reviewing licensing tasks. On April 9, 1997, NRC Inspection Manual Chapter 2515, "Light-Water Reactor Inspection Program — Operations Phase," was revised, providing guidance to the inspectors to review the applicable portion(s) of the FSAR that relate to inspection activities and verify that FSAR commitments have been properly implemented into plant practices.

ATTACHMENT 2

ACTIVITIES CONCERNING 10 CFR 50.59

ACTIVITIES CONCERNING 10 CFR 50.59

Staff Activities

The activities conducted by the staff of the U.S. Nuclear Regulatory Commission (NRC) with regard to 10 CFR 50.59 include developing staff-issued guidance, or endorsing industry guidance, and overseeing licensee implementation through inspections and enforcement.

As directed in the staff requirements memorandum (SRM) issued by the Commission on April 25, 1997, the staff published its proposed guidance (as presented in SECY-97-035) for public comment. A *Federal Register* notice (62 FR 24947), published on May 7, 1997, announced the availability for comment of draft NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, or Experiments)." Attachment 2A to this Commission paper discusses the nature of the comments received, while Attachment 2B identifies the originators of the comment letters.

As discussed in Attachment 1 to this Commission paper, NRC has focused considerable attention on assessing the conformance of plants with their safety analysis reports (SARs) and implementation of 10 CFR 50.59. Oversight activities related to 10 CFR 50.59 have been heightened by (1) issuance of guidance to NRR project managers (PMs) concerning management expectations for PM inspection of licensees' 10 CFR 50.59 programs, and (2) addition of hours specifically for inspection of 10 CFR 50.59 programs (NRC Inspection Manual, Inspection Procedure 37001, "10 CFR 50.59 Safety Evaluation Program") to the core inspection program. Typically, such inspections are accomplished during the Engineering/Technical Support inspection performed by the Regions, with the PM as part of the team. Further, on October 18, 1996, the NRC published a revision to the NRC Enforcement Policy (NUREG-1606) which provided additional examples illustrating the severity levels associated with violations of 10 CFR 50.59 and 10 CFR 50.71(e).

Over the last several months, licensee reviews and NRC inspections at operating plants have identified a number of degraded or nonconforming conditions. The existing guidance in NRC Inspection Manual Part 9900, "Resolution of Degraded and Nonconforming Conditions," on the relationship of 10 CFR 50.59 to the resolution of degraded and nonconforming conditions, specifically the guidance stating that situations involving unreviewed safety questions (USQs) require NRC approval before the plant may restart operations, has not achieved the expected results from a safety perspective. Recent efforts to identify and correct discrepancies between the SAR and the as-built plant have led to circumstances where both the NRC and licensees have overly directed attention toward responding to problems that may not warrant such high priority. The staff plans to correct this situation by modifying the position that every nonconforming condition that may involve a USQ must be resolved by NRC license amendment before a plant can restart from any shutdown, including unplanned trips.

Specifically, the staff is proposing to revise its practice by not objecting to plant startup and continued operation, provided the following criteria are met, even when NRC review and

approval is required for changes planned as the prompt corrective action to resolve degraded and nonconforming conditions:

- The plant technical specifications are not violated.

- All necessary equipment is operable for all possible modes of plant operation.

Note that NRC review and approval are needed if there is a need to change a plant technical specification or if a USQ is involved.

This approach acknowledges that the existence of a USQ is not always a safety concern, and decisions about continued operation should focus on operability and prompt corrective action. The staff believes that this step will enable the NRC to focus its attention on ensuring that licensees implement corrective action in a time frame appropriate to the significance of the non-conformance. Because this guidance relates only to applicability of existing regulations in situations where degraded and nonconforming conditions have been identified, the staff believes that its issuance does not foreclose any options for regulatory improvements that are under consideration.

Attachment 2C presents the proposed revision to Generic Letter (GL) 91-18, which would forward revised NRC Inspection Manual Part 9900 guidance clarifying the role of 10 CFR 50.59 for the resolution of degraded and nonconforming conditions to all licensees for their information. Further, the staff recommends that issuance of the revised GL 91-18 proceed *now* (in advance of decisions concerning possible rule changes or other guidance changes on 10 CFR 50.59 or SARs), to ease immediate problems with the existing guidance and practice. As previously indicated, this guidance relates only to applicability of existing regulations in situations where degraded and nonconforming conditions have been identified. Consequently, the staff concludes that its issuance would not foreclose any options for regulatory improvements that are under consideration. The staff, therefore, recommends that the Commission, by negative consent, agree to this action.

Interactions With Industry

In a letter dated July 21, 1997, the Nuclear Energy Institute (NEI) submitted the final draft of a guidance document on performing 10 CFR 50.59 evaluations. Known as NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations," this document was based on a standard (of the same name), issued by the Nuclear Safety Analysis Center (NSAC-125), as modified on the basis of interactions with the NRC. Along with this document, the NEI submitted an analysis which, in its view, demonstrates that NEI 96-07 meets the rule. Therefore, the NEI recommended that the NRC endorse NEI 96-07 as an acceptable method of compliance with 10 CFR 50.59. The staff notes that the revisions primarily address the topic areas discussed in Attachment 2B. However, the staff also notes that the NEI's positions related to USQ determinations (probability, consequences, margin of safety) have changed little from those in NSAC-125 (which the staff was not prepared to endorse).

The NRC staff met with the NEI on July 24, 1997, to give the NEI an opportunity to discuss the revisions to their report. Additional discussions with the NEI are anticipated.

ATTACHMENT 2A

LIST OF COMMENTERS ON NUREG-1606

LIST OF COMMENTERS ON NUREG-1606

This attachment identifies the originators of the comment letters received in response to the draft of NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, or Experiments)," which the U.S. Nuclear Regulatory Commission (NRC) made available for public comment on May 7, 1997.

The numbers associated with the comment letters were assigned by NRC Rules and Directives Branch, Office of Administration. Where the transmittal date is enclosed in parentheses, the NRC received the letter before issuing the *Federal Register* notice (62 FR 24947) soliciting comments. In a few instances, duplicate copies of letters were separately assigned numbers, as noted below.

No.	Commenter	Date	No. of Pages
1.	Dean Baker	(March 12, 1997)	2
2.	Arizona Public Service	June 26, 1997	24
3.	Combustion Engineering Owners Group	June 30, 1997	25
4.	Southern California Edison	July 2, 1997	3
5.	Duke Power	July 3, 1997	2
6.	Carolina Power and Light	July 7, 1997	8
7.	Nuclear Energy Institute	July 7, 1997	45
8.	Niagara Mohawk	July 7, 1997	2 (see #41)
9.	Southern Company	July 7, 1997	2
10.	Houston Light and Power	July 1, 1997	13
11.	Morgan, Lewis and Bockius	July 1, 1997	30
12.	Commonwealth Edison	July 3, 1997	2
13.	IES Utilities	July 3, 1997	6
14.	Indiana Michigan	July 3, 1997	5
15.	Shaw Pittman	July 7, 1997	45
16.	Westinghouse	July 7, 1997	2
17.	Florida Power and Light	July 7, 1997	3

LIST OF COMMENTERS ON NUREG-1606, continued

No.	Commenter	Date	No. of Pages
18.	Entergy	July 3, 1997	25
19.	L. Grime and Associates	July 3, 1997	8
20.	Winston and Strawn	July 7, 1997	35
21.	Nuclear Utility Group on Equipment Qualification	July 7, 1997	5
22.	Florida Power	July 7, 1997	10
23.	North Atlantic	July 3, 1997	4
24.	Northern States Power	July 7, 1997	16
25.	Duplicate of letter #9		
26.	Daniel Williams	July 7, 1997	29
27.	GPU Nuclear	July 7, 1997	2
28.	Pacific Gas and Electric	July 7, 1997	2
29.	Public Service Electric and Gas	July 7, 1997	5
30.	Virginia Power	July 7, 1997	2
31.	Wolf Creek	July 7, 1997	8
32.	TU Electric	July 7, 1997	17
33.	Consumers Energy	July 7, 1997	14
34.	Washington Public Power Supply	July 7, 1997	3
35.	Detroit Edison	July 7, 1997	3
36.	Pennsylvania Electric Company	July 7, 1997	1
37.	Tennessee Valley Authority	July 7, 1997	10
38.	Union Electric	July 7, 1997	2
39.	New York Power Authority	July 7, 1997	2

LIST OF COMMENTERS ON NUREG-1606, continued

No.	Commenter	Date	No. of Pages
40.	South Carolina Electric and Gas	July 7, 1997	4
41.	Niagara Mohawk (Note: Attachments same as letters #20 and #7)	July 7, 1997	60 (see #8)
42.	Duquesne Light	July 8, 1997	1
43.	Arizona Public Service	July 10, 1997	4 (see #1)
44.	Consolidated Edison	July 7, 1997	1
45.	General Electric	July 8, 1997	2
46.	Nebraska Public Power District	July 24, 1997	4
*	JT Beard, Inc.	July 7, 1997	8
*	Union of Concerned Scientists (D. Lochbaum) (Note: Not received in response to notice, but considered because letter contains comments on certain positions in NUREG-1606.)	(April 4, 1997)	2
*	Florida Power Corporation (Same as letter #22, but under cover letter to Chairman Jackson)	July 7, 1997	12

*Not numbered.

ATTACHMENT 2B

PUBLIC COMMENTS ON NUREG-1606

PUBLIC COMMENTS ON NUREG-1606

A *Federal Register* notice (62 FR 24947) published on May 7, 1997, announced that the draft of NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, or Experiments)," was available for public comment. The text of that draft is identical to the attachment sent to the Commission in SECY-97-035 on February 12, 1997.

Specifically, NUREG-1606 outlined staff positions regarding 22 topic areas related to implementation of Title 10, Section 50.59, of the *Code of Federal Regulations* (10 CFR 50.59). In response to the notice, interested licensees, vendors, law firms, and individuals filed a total of 46 comment letters.[1] The commenters included the Nuclear Energy Institute (NEI) and three law firms filing on behalf of various nuclear utilities. Individual letters were received from 33 utilities; many of these letters expressed support for the more detailed comments filed by NEI or the law firms. Three other letters were from nuclear vendors or owners groups.

For purposes of discussion, the feedback can be divided into general comments about the overall effect of the staff's proposed guidance, and specific comments on individual positions. The general comments can be characterized as follows:

- The staff's proposed guidance would cause confusion within the industry and the NRC, and would create instability in the regulatory process.

- The guidance would result in a significant burden for both the industry and the staff because of the number of changes that will require NRC approval. This is because the threshold for unreviewed safety questions (USQs) was considered so low that almost any change could be deemed to involve a USQ.

- The guidance would adversely affect safety because it could divert resources to less safety-significant issues, impede the use of compensatory actions to add margin, or hinder licensees" planned design improvements.

Another theme presented by the majority of commenters was that it would be preferable for NRC to devote its attention toward reviewing and endorsing industry guidance rather than issuing separate guidance. In addition, many commenters thought that some of the staff's positions were new requirements that should be subjected to a backfit analysis. Thus, a number of commenters proposed that the guidance not be used retroactively. While few commenters supported rulemaking, some did indicate that they would favor rulemaking if certain staff positions derived from the existing rule are sustained, or in the longer term, to make the process more risk-informed.

With respect to specific comments, six of the 22 topic areas generated most of the comments. The more prevalent or significant differences are discussed below. (The staff has not yet completed its analysis of the comments or the proposed resolutions; therefore, an item-by-item response is not available at this time.)

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[1]Two of the 46 letters recorded by the NRC Rules and Directives Branch were duplicates. Two other letters were not filed in direct response to the notice although they commented on the staff's position; these are also being considered as comments, bringing the total number of letters back to 46. One of these letters was from the Union of Concerned Scientists.

(1) Definition of Change (III.A)[2]

Commenters thought that the staff's guidance was too restrictive in that the definition of "changes" included replacement equipment that is not identical. Many proposed that if the replacement were functionally identical or procured to the same specifications, it should not require a 10 CFR 50.59 evaluation. (The staff was concerned, however, that such functional equivalence might not account for equipment differences that introduce malfunctions of a different type or have unanticipated effects on the plant.)

Another issue regarding the staff's guidance was that NRC review is required for changes involving removal of equipment from service for maintenance (not already addressed by technical specifications or the safety analysis report). Many commenters stated that these actions should be governed by the requirements of the Maintenance Rule (10 CFR 50.65).

(2) Malfunction of a Different Type (III.I)

Many commenters raised concerns about the staff's position that the cause of a malfunction must be considered in determining whether it is of a different type. Their view was that causes may be a factor in the probability of malfunction, but that the effect on the plant or system should be what determines whether a change introduces a malfunction of a different type.

(3) Increase in the Probability of Occurrence (III.P)

Commenters asserted that the staff's position that "probability may be increased" is too restrictive, and does not take into account how plants were originally reviewed and licensed. Thus, they contend that an increase must be discernable in order to involve a USQ, and that the guidance in NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations," is an acceptable interpretation of the regulations. A number of commenters also stated that to involve a USQ, the increase in probability resulting from the change would have to cause a shift in the event frequency categorization.

(4) Increase in Consequences (III.R)

Regarding the degree of the increase in consequence necessary to result in a USQ, commenters held views similar to those discussed under topic (3), "Increase in Probability of Occurrence." Many commenters also stated that the NRC acceptance limits were the actual licensing basis for the plant and, consequently, those limits should be the basis for determining whether a USQ results from the increase in consequences (rather than the value previously calculated in the SAR). They stated that tying review to the SAR value is counterproductive in that plants with detailed SARs would be at a disadvantage relative to plants with SARs that merely report that an accident consequence was less than the release limits specified in 10 CFR Part 100. Some commenters also stated that licensees should be able to use improved technology, data, or methods that have been approved by NRC for other plants, without specific NRC approval, provided that the results continue to meet acceptance limits.

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[2]These designations refer to sections from NUREG-1606 (and the attachment to SECY-97-035).

(5) Margin of Safety As Defined in the Basis for Any Technical Specification (III.S and III.T)

With respect to the basis for any technical specification, most commenters stated that the legal requirement is only for the "Bases" section, as defined by 10 CFR 50.36(a), and not for the analyses and information in the SAR from which the technical specifications were derived. (However, a number of commenters acknowledged that the SAR is an important source of information about margins.) Further, commenters thought that the staff's view was too broad in asserting that a reduction in safety margin results when an acceptance limit is no longer met (as documented in the staff safety evaluation report or in the SAR). Many commenters believed that licensees should be able to use acceptance limits as defined by the NRC's Standard Review Plan (NUREG-0800) or regulatory guides instead of the SAR value.

(6) Role of 10 CFR 50.59 in Resolving Degraded and Nonconforming Conditions (and the Use of Compensatory Measures) (III.O)

A number of aspects of the guidance in this area drew comments. The two issues of greatest concern were (1) the position that a plant could not restart from any shutdown if a degraded or nonconforming condition involved a USQ and (2) the position that any compensatory measures had to be evaluated under 10 CFR 50.59 against the SAR-described condition, considering the nonconformance condition before the measures could be implemented. (On the basis of recent experience with nonconforming conditions and on the comments, the staff has modified its position, and proposes to issue a revision to Generic Letter (GL) 91-18 to make this guidance known to the public as soon as possible. See Attachments 2 and 2C.)

The Commission also received substantive comments in the following areas:

! "As Described" (III.E)

Most commenters did not object to the view that this phrase should be interpreted broadly when considering whether a change required evaluation. Nonetheless, some expressed concern that the tabulation of types of information presented in NUREG-1606 is much broader than that defined as "design bases" in 10 CFR 50.2. Thus, these commenters were concerned that such an interpretation would result in additional reporting, the need for evaluation of minor changes, and limitations on the ability to delete information from the SAR (when such processes are defined). As a specific example, some commenters raised the concern that if they wished to close a valve shown on a drawing as "open," they would have to perform a 10 CFR 50.59 evaluation. (In such an instance, the staff would conclude that if operation of the system with the valve in a "closed" position was already covered in procedures, no such evaluation would be necessary.)

! Accidents Previously Evaluated (III.H)

Several commenters stated that they thought external events (such as seismic events, winds, and floods) should be considered in terms of equipment malfunctions, rather than as accidents, as proposed by the staff. The outcome is the same in that changes to the facility that affect response to such events require evaluation; nevertheless, commenters thought this was a clearer description.

! Role of PRA in 10 CFR 50.59 Evaluations (III.M)

The staff's proposed guidance cautioned that licensees should not use probabilistic risk assessments (PRAs) for decisionmaking on whether changes involve USQs. Several commenters felt that for questions about increases in probability, this is *exactly* the method that *should be* used. Others said that PRA, if properly applied, can be useful in evaluating initiating events, as well as equipment reliability, and can give an additional dimension to deterministic evaluations. However, commenters agreed that the maturity level of PRA usage is such that it should not be the sole basis for making such USQ determinations. (The staff generally agrees that PRA can be a useful tool for evaluating changes, but not as for the sole basis for determining of the need for NRC approval.)

! Deletion of Information from the SAR (III.N)

The staff's guidance stated that there is no defined process for removing information from the SAR, when such changes are not necessitated as the result of a change to the facility or procedures. Some commenters stated that they thought such removal of information should be controlled by 10 CFR 50.59. Many others supported the need for some means by which licensees could remove "extraneous" details from the SAR, and some offered suggestions on criteria for making such determinations. Some comment letters proposed that the following types of information could be deleted:

— information not specifically required to be included by regulatory requirements (such as 10 CFR 50.34 or 10 CFR 50.71(e))

— information that was not (or was not believed to be) the basis for any commitment

— information that was not documented to be the basis for NRC acceptance in any safety evaluation report

— information covered by a more general commitment (such as a regulatory guide)

— information that does not strengthen or enhance the description or design basis of a safety-related structure, system, or component

— information that does not impact the reliability and accuracy of any future safety evaluation

Commenters also stated that they believed licensees should be allowed to remove duplicate information to clarify the SAR. (The staff does not view elimination of duplicate information as "deletion of information from the SAR," because it would still be present in the SAR.) Staff actions concerning this issue are discussed in the options presented in Attachment 3 to the this paper.

! Scope of 10 CFR 50.59 (IV.A)

In NUREG-1606, the staff also requested comment on policy options relating to the scope of 10 CFR 50.59 and on SAR updating. These options included (1) taking steps to bring important commitments, not presently in controlled documents, under regulatory control; (2) the possibility of changing the scope to refer to the "current licensing basis," rather than the SAR; (3) updating of the SAR to correct past omissions, such as those concerning the effects of new analyses; and (4) improving guidance for future updates.

The commenters overwhelmingly rejected the options mentioned by the staff. Commenters noted that commitment management processes, such as the NEI's "Commitment Management Guidelines," combined with NEI 96-07 guidance to consider documents other than the SAR in performing 10 CFR 50.59 evaluations, were sufficient to ensure changes are properly evaluated. In addition, commenters expressed concern that changes to staff practices or guidance on SAR updating should be conducted as a rulemaking. Commenters also stated that licensee responses to generic letters should not be included in the SAR unless the plant licensing basis was changed by regulation or license amendment.

ATTACHMENT 2C

DRAFT NRC GENERIC LETTER NO. 91-18, REVISION 1: INFORMATION TO LICENSEES REGARDING NRC INSPECTION MANUAL SECTION ON RESOLUTION OF DEGRADED AND NONCONFORMING CONDITIONS

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION
WASHINGTON, D.C. 20555-0001

September xx, 1997

NRC GENERIC LETTER NO. 91-18, REVISION 1: INFORMATION TO LICENSEES REGARDING NRC INSPECTION MANUAL SECTION ON RESOLUTION OF DEGRADED AND NONCONFORMING CONDITIONS

Addressees

All holders of operating licenses for nuclear power and non-power reactors, including those power reactor licensees who have permanently ceased operations, and all holders of non-power reactor licenses whose license no longer authorizes operation.

Purpose

The U.S. Nuclear Regulatory Commission (NRC) is issuing this generic letter to inform licensees of the issuance of a revised section of Part 9900, "Technical Guidance," of the NRC Inspection Manual. The revised section is entitled "Resolution of Degraded and Nonconforming Conditions." The revisions to this section of Part 9900 more explicitly discuss the role of the 10 CFR 50.59 evaluation process in the resolution of degraded and nonconforming conditions. The Part 9900 guidance on operability forwarded by Generic Letter (GL) 91-18 has not been revised. This letter is provided for information only; no specific action or written response is required.

Background

The previous version of NRC Inspection Manual, Part 9900, "Technical Guidance," on the Resolution of Degraded and Nonconforming Conditions, was issued for information in GL 91-18, on November 7, 1991. This guidance provided a process for licensees to develop a basis to continue operation or to place the plant in a safe condition and to take prompt corrective action. It contained a number of provisions that relate to the role of 10 CFR 50.59 and the basis for continued operation of a facility.

Section 4.3.2, "Changing the Current Licensing Basis To Satisfy an Appendix B Corrective Action," stated:

> A licensee may change the design of its plant as described in the FSAR in accordance with 10 CFR 50.59, at any time. Whenever such changes are sufficient to resolve a degraded or nonconforming condition involving an SSC [system, structure, or component] that is subject both to Appendix B and 50.59, they may be used in lieu of restoring the affected equipment to its original design. However, whenever such a change involves a unreviewed safety question (USQ) or change in a technical specification (TS), the licensee must obtain a license amendment in accordance with 10 CFR 50.90 **prior to**

> **operating** (emphasis added) the plant with the degraded or nonconforming condition...

Section 4.5.1, "Justification for Continued Operation (JCO) Background," stated:

> The license authorizes the licensee to operate the plant in accordance with the regulations, license conditions, and the TS. If an SSC is degraded or nonconforming but operable, the license provides authorization to operate and the licensee does not need further justification. The licensee must, however, promptly identify and correct the condition adverse to safety or quality in accordance with 10 CFR Part 50, Appendix B, Criterion XVI.

A footnote to the flow chart attached to the Part 9900 guidance stated:

> 50.59 may be used to make a change in a facility, as described in the SAR, which would resolve the condition adverse to safety or quality so that the degraded and nonconforming condition no longer exists. Delay or partial correction of conditions adverse to safety or quality is considered a change in facility or procedures and subject to 50.59 review.

The NRC Inspection Manual Part 9900 guidance, "10 CFR 50.59 - Interim Guidance on the Requirements Related to Changes to Facilities, Procedures, and Tests (or Experiments)," issued in April 1996, specifically refers to the Part 9900 attached to GL 91-18 for guidance concerning 10 CFR 50.59 in the resolution of degraded and nonconforming conditions.

As part of its reevaluation of the 10 CFR 50.59 process, the staff recognized that the guidance in GL 91-18 was not complete, and may in some respects be inconsistent. Therefore, the staff developed additional guidance on the application of 10 CFR 50.59 to the resolution of degraded and nonconforming conditions. The staff's proposed guidance was published for public comment, as part of draft NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, or Experiments)," on May 7, 1997 (62 FR 24947).

Description of Circumstances

The proposed guidance published for comment on May 7, 1997, discussed the application of 10 CFR 50.59 to implementation of compensatory measures, how "delay" should be interpreted, and how the guidance about obtaining a license amendment operating the facility with a condition involving a USQ should be interpreted. In this proposed guidance, the staff stated that implementation of compensatory measures required a 10 CFR 50.59 evaluation with respect to the condition described in the final safety analysis report (FSAR) and that the staff would consider delay to have occurred when a licensee has not implemented corrective action at the first available opportunity (considering need for analysis or parts, or the need to be in cold shutdown to complete the action), in any event not to exceed the next refueling outage. Finally, the staff proposed that when a licensee determined that resolution of a

nonconforming condition involved a USQ, the license amendment should be issued before the plant resumed operation from any shutdown (the NRC would not require a plant to shut down in such circumstances provided that SSCs required for operation were operable). Over the last several months, a number of nonconforming conditions have been identified at operating plants through licensee reviews and NRC inspections. Based on staff experience in dealing with these situations, the staff has concluded that a revision to the Part 9900 guidance, "Resolution of Degraded and Nonconforming Conditions," was appropriate.

Many of the comments received in response to the *Federal Register* notice stated that the position that should be applied is more consistent with the discussion in Section 4.5.1 of the existing Part 9900 guidance, that is, if SSCs are operable but degraded, the license provides authority for continued operation, and existence of a USQ, by itself, should not be an impediment to a plant's ability to resume operation.

Commenters noted that the policy of not requiring plant shutdown but preventing plant restart was arbitrary, and had no basis in safety. Commenters also suggested that delay in implementation of corrective action is a matter for enforcement of 10 CFR Part 50, Appendix B, and not for requiring a 10 CFR 50.59 evaluation. The commenters also stated that requiring a 10 CFR 50.59 evaluation of compensatory measures against the condition described in the safety analysis report (SAR) would essentially preclude licensee implementation of compensating actions that enhance safety when degraded or nonconforming conditions are found.

On the basis of the staff's continuing review of the issues associated with nonconforming conditions and with interpretations of 10 CFR 50.59 requirements, and of the public comments that were received in response to the *Federal Register* notice, the staff determined that it would be beneficial at this time to issue a revision to this Inspection Manual Chapter 9900 guidance, even before other aspects of potential guidance are resolved, because of the impacts on plant operation. Therefore, through this generic letter, the NRC is notifying addressees of the issuance of the attached NRC Inspection Manual guidance.

Discussion

As discussed in more detail in the attached guidance, the staff now concludes that the need to obtain NRC approval for the final resolution of a degraded or nonconforming condition does not affect the licensee's authority to continue operation (or restart from a shutdown), provided that necessary equipment is operable and the degraded equipment is not in conflict with any technical specification. Thus, Section 4.3.2 has been revised, and other conforming changes made, to note this change in staff guidance.

On July 21, 1997, the Nuclear Energy Institute (NEI) submitted to the NRC a guidance document, NEI 96-07 [Final Draft], "Guidelines for 10 CFR 50.59 Safety Evaluations." Part of this guidance relates to applicability of 10 CFR 50.59 to degraded and nonconforming conditions.

The specific guidance is:

> In the case of a nonconforming condition, there are three potential scenarios for addressing the condition:
>
> - If the condition is accepted "as-is" resulting in something different than described in the SAR or is modified to something different than described in the SAR, then the condition should be considered a change and subjected to a 10 CFR 50.59 safety evaluation unless another regulation applies (i.e., 10 CFR 50.55a).
>
> - If the licensee intends to restore the SSC back to its previous condition (as described in the SAR), then this corrective action should be performed in accordance with 10 CFR 50, Appendix B (i.e. in a timely manner commensurate with safety), and a 10 CFR 50.59 safety evaluation is not required.
>
> - If an interim compensatory action is taken to address the condition and involves a procedure change or temporary modification, a 10 CFR 50.59 review should be conducted and may result in a safety evaluation. The intent is to determine whether the compensatory action itself (not the degraded condition) impacts other aspects of the facility described in the SAR.

The staff finds this industry guidance acceptable with respect to the need for a 10 CFR 50.59 safety evaluation for degraded and nonconforming conditions. Therefore, the revised Part 9900 Inspection Manual guidance references this industry guidance.

As noted in the Part 9900 guidance, the NRC will take enforcement action if it determines that licensee corrective action (which may include submittal of a license amendment request) is not prompt, or that operability determinations are not sound. Enforcement action may also be taken for the circumstances that led to existence of the degraded or nonconforming condition.

This generic letter was not published for public comment because the issues covered by the revision were previously published for public comment in May 1997, and the staff's guidance is responsive to the comments received. This generic letter requires no specific action or response. If you have any questions about this matter, please contact the technical contact listed below.

Jack W. Roe, Acting Director
Division of Reactor Program Management
Office of Nuclear Reactor Regulation

Technical Contact: Eileen M. McKenna, NRR
(301) 415-2189
Internet: emm@nrc.gov

Attachments:
1. Inspection Manual Part 9900 Guidance, "Resolution of Degraded and Nonconforming Conditions"
2. List of Recently Issued NRC Generic Letters

NRC INSPECTION MANUAL

OTSB

PART 9900: TECHNICAL GUIDANCE

STS30DEG.TG

RESOLUTION OF
DEGRADED AND NONCONFORMING CONDITIONS

NOTE: GUIDANCE IS SHOWN IN RED-LINE/STRIKE-OUT VERSION FOR EASY COMPARISON WITH EXISTING (1991) VERSION OF THIS PART 9900 GUIDANCE. FINAL ISSUED VERSION WILL NOT CONTAIN THESE MARKINGS.

RESOLUTION OF
DEGRADED AND NONCONFORMING CONDITIONS

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RESOLUTION OF
DEGRADED AND NONCONFORMING CONDITIONS

1.0 PURPOSE AND SCOPE:

To provide guidance to NRC inspectors on resolution of degraded and nonconforming conditions affecting the following systems, structures, or components (SSCs):

(i) Safety-related SSCs, which are those relied upon to remain functional during and following design basis events (A) to ensure the integrity of the reactor coolant pressure boundary, (B) to ensure the capability to shut down the reactor and maintain it in a safe shutdown condition, or (C) to ensure the capability to prevent or mitigate the consequences of accidents that could result in potential offsite consequences comparable to the 10 CFR Part 100 guidelines. Design basis events are defined the same as in 10 CFR 50.49(b)(1).

(ii) All SSCs whose failure could prevent satisfactory accomplishment of any of the required functions identified in (i) A, B, and C.

(iii) All SSCs relied on in the safety analyses or plant evaluations that are a part of the plant's current licensing basis. Such analyses and evaluations include those submitted to support license amendment requests, exemption requests, or relief requests, and those submitted to demonstrate compliance with the Commission's regulations such as fire protection (10 CFR 50.48), environmental qualification (10 CFR 50.49), pressurized thermal shock (10 CFR 50.61), anticipated transients without scram (10 CFR 50.62), and station blackout (10 CFR 50.63).

(iv) Any SSCs subject to 10 CFR Part 50, Appendix B.

(v) Any SSCs subject to 10 CFR Part 50, Appendix A, Criterion 1.

(vi) Any SSCs explicitly subject to facility Technical Specifications (TS).

(vii) Any SSCs subject to facility TS through the definition of operability (i.e., support SSCs outside TS).

(viii) Any SSCs described in the final safety analysis report (FSAR).

This guidance is directed toward NRC inspectors who are reviewing actions of licensees that hold an operating license. Although this guidance generally reflects existing staff practices, application to specific plants may constitute a backfit. Consequently, significant differences in licensee practices should be discussed with NRC management to ensure that the guidance is applied in a reasonable and consistent manner for all licensees.

2.0 DEFINITIONS

2.1 Current Licensing Basis

Current licensing basis (CLB) is the set of NRC requirements applicable to a specific plant, and a licensee's written commitments for assuring compliance with and operation within applicable NRC requirements and the plant-specific design basis (including all modifications and additions to such commitments over the life of the license) that are docketed and in effect. The CLB includes the NRC regulations contained in 10 CFR Parts 2, 19, 20, 21, 30, 40, 50, 51, 55, 72, 73, 100 and appendices thereto; orders; license conditions; exemptions, and TS. It also includes the plant-specific design basis information defined in 10 CFR 50.2 as documented in the most recent FSAR as required by 10 CFR 50.71 and the licensee's commitments remaining in effect that were made in docketed licensing correspondence such as licensee responses to NRC bulletins, generic letters, and enforcement actions, as well as licensee commitments documented in NRC safety evaluations or licensee event reports.

2.2 Design Basis

Design basis is that body of plant-specific design bases information defined by 10 CFR 50.2.

2.3 Degraded Condition

A condition of an SSC in which there has been any loss of quality or functional capability.

2.4 Nonconforming Condition

A condition of an SSC in which there is failure to meet requirements or licensee commitments. Some examples of nonconforming conditions include the following:

1. There is failure to conform to one or more applicable codes or standards specified in the FSAR.

2. As-built equipment, or as-modified equipment, does not meet FSAR ~~design requirements~~descriptions.

3. Operating experience or engineering reviews demonstrate a design inadequacy.

4. Documentation required by NRC requirements such as 10 CFR 50.49 is not available or deficient.

2.5 Full Qualification

Full qualification constitutes conforming to all aspects of the current licensing basis, including codes and standards, design criteria, and commitments.

3.0 BACKGROUND:

A nuclear power plant's SSCs are designed to meet NRC requirements, satisfy the current licensing basis, and conform to specified codes and standards. For degraded or nonconforming conditions of these SSCs, the licensee may be required to take actions required by the TS. The provisions of Title 10 of the "Code of Federal Regulations" (10 CFR), Part 50, Appendix B, Criteria XVI, may apply requiring the licensee to identify promptly and correct conditions adverse to safety or quality. Reporting may be required in accordance with Sections 50.72, 50.73, and 50.9(b) of 10 CFR Part 50, 10 CFR Part 21, and the TS. Collectively, these requirements may be viewed as a process for licensees to develop a basis to continue operation or to place the plant in a safe condition, and to take prompt corrective action. Changes to the facility in accordance with 10 CFR 50.59 may be made as part of the corrective action required by Appendix B. The process displayed by means of the attached chart titled, "Resolution of Degraded and Nonconforming Conditions," recognizes these and other provisions that a licensee may follow to restore or establish acceptable conditions. These provisions are success paths that enable licensees to continue safe operation of their facilities.

4.0 DISCUSSION OF NOTABLE PROVISIONS

4.1 Public Health and Safety

All success paths, whether specifically stated or not, are first directed to ensuring public health and safety and second to restoring the SSCs to the current licensing basis of the plant as an acceptable level of safety. Identification of a degraded or nonconforming condition that may pose an immediate threat to the public health and safety requires the plant to be placed in a safe condition.

Technical Specifications (TS) address the safety systems and provide Limiting Conditions for Operation (LCOs) and Allowed Outage Times (AOTs) required to ensure public health and safety.

4.2 Operability Determinations

For guidance on operability see the Inspection Manual, Part 9900, "OPERABLE/OPERABILITY: ENSURING THE FUNCTIONAL CAPABILITY OF A SYSTEM OR COMPONENT," and see the Inspection Manual, Part 9900, "STANDARD TECHNICAL SPECIFICATIONS STS SECTION 1, OPERABILITY."

4.3 The Current Licensing Basis and 10 CFR 50, Appendix B

~~4.3.1 10 CFR 50, Appendix B~~

The design and operation of a nuclear plant is to be consistent with the current licensing basis. Whenever degraded or nonconforming conditions of SSCs subject to Appendix B are identified, Appendix B requires prompt corrective action to correct or resolve the condition. The licensee must establish a time frame for completion of corrective action. The timeliness of this corrective action should be commensurate with the safety significance of the issue. The time frame governing corrective action begins with the discovery of the condition, not with the time when it

is reported to the NRC. In determining whether the licensee is making reasonable efforts to complete corrective action promptly, NRC will consider whether corrective action was taken at the first opportunity, as determined by safety significance (effects on operability, significance of degradation) and by what is necessary to implement the corrective action. Factors that might be included are the amount of time required for design, review, approval, or procurement of the repair/modification; availability of specialized equipment to perform the repair; or the need to be in a hot or cold shutdown to implement the actions. The NRC expects time frames longer than the next refueling outage to be explicitly justified by the licensee as part of the deficiency tracking documentation. If the licensee does not resolve the degraded or nonconforming condition at the first available opportunity or does not appropriately justify a longer completion schedule, the staff would conclude that corrective action has not been timely and would consider taking enforcement action.

~~4.3.2 Changing the Current Licensing Basis to Satisfy an Appendix B Corrective Action~~

~~A licensee may change the design of its plant as described in the FSAR in accordance with 10 CFR 50.59 at any time. Whenever such changes are sufficient to resolve a degraded or nonconforming condition involving an SSC that is subject both to Appendix B and 50.59, they may be used to satisfy the corrective action requirements of Appendix B, in lieu of restoring the affected equipment to its original design. However, whenever such a change involves a unreviewed safety question (USQ) or change in a Technical Specification (TS), the licensee must obtain a license amendment in accordance with 10 CFR 50.90 prior to operating the plant with the degraded or nonconforming condition.~~

~~Further guidance on 10 CFR 50.59 is provided in the NRC Inspection Manual, Part 9900, "50.59 Changes, Testing, and Experiments."~~

4.4 Discovery of an Existing But Previously Unanalyzed Condition or Accident

In the course of its activities, the licensee may discover a previously unanalyzed condition or accident. Upon discovery of an existing but previously unanalyzed condition that significantly compromises plant safety, the licensee shall report that condition in accordance with 10 CFR 50.72 and 50.73, and put the plant in a safe condition.

For a previously unanalyzed condition or accident that is considered a significant safety concern, but is not part of the design basis, the licensee may subsequently be required to take additional action after consideration of backfit issues (see Section 50.109(a)(5)).

4.5 Justification for Continued Operation (JCO)

4.5.1 Background

The license authorizes the licensee to operate the plant in accordance with the regulations, license conditions, and the TS. If an SSC is degraded or nonconforming but operable, the license ~~provides authorization to operate and the licensee does not need further justification.~~establishes an acceptable basis to continue to operate and the licensee does not need to take any further actions. The licensee must, however, promptly identify and correct the condition adverse to safety or quality in accordance with 10 CFR Part 50, Appendix B, Criterion XVI.

The basis for this authority to continue to operate arises because the TS contain the specific characteristics and conditions of operation necessary to obviate the possibility of an abnormal situation or event giving rise to an immediate threat to public health and safety. Thus, if the TS are satisfied, and required equipment is operable, and the licensee is correcting the degraded or nonconforming condition in a timely manner, continued plant operation does not pose an undue risk to public health and safety.

Under certain defined and limited circumstances, the licensee may find that strict compliance with the TS would cause an unnecessary plant action not in the best interest of public health and safety. NRC review and ~~response~~action is required prior to the licensee taking actions that are contrary to compliance with the license conditions or TS unless an emergency situation is present such that 10 CFR 50.54(x) and (y) is applied. A JCO, as defined herein for general NRC purposes, is the licensee's technical basis for requesting NRC responses to such action.

4.5.2 JCO Definition

A Justification for Continued Operation[1] (JCO) is the licensee's technical basis for requesting authorization to operate in a manner that is prohibited (e.g., outside TS or license) absent such authorization. The preparation of JCOs does not constitute authorization to continue operation.

4.5.3 Items for Consideration in a JCO

Some items which are appropriate for consideration in a licensee's development of a JCO include:

- Availability of redundant or backup equipment
- Compensatory measures including limited administrative controls
- Safety function and events protected against

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[1]Regulations, generic letters, and bulletins may provide direction on specific issue JCOs, which do not require that they be submitted. Licensees may also use the JCO for situations other than for operating in a prohibited manner. The JCO term has been used in Generic Letters 88-07 on Environmental Qualifications of Electrical Equipment and 87-02 on Seismic Adequacy. Licensees should continue to follow earlier guidance regarding the preparation of JCOs on specific issues.

- Conservatism and margins, and
- Probability of needing the safety function.
- Probabilistic Risk Assessment (PRA) or Individual Plant Evaluation (IPE) results that determine how operating the facility in the manner proposed in the JCO will impact the core damage frequency.

4.5.4 Discussion of Industry-Type JCOs

Currently, some licensees refer to two other documents or processes as JCOs that are not equivalent to and do not perform the same function as the NRC-recognized JCO (as defined in 4.5.2). This is an acceptable industry practice and to the extent the industry JCO fulfills other NRC requirements, the JCOs will be selectively reviewed and audited accordingly.

In the first industry-type JCO, the licensee may consider the entire process depicted in the attached chart as a single JCO that includes such things as the basis for operability, PRA, corrective action elements, and alternative operations.

In the second industry-type JCO, the licensee may consider the documentation that is developed to support facility operation after the operability decision has been made as a JCO. This documentation can cover any or all of the items listed under "Interim Operation" on the attached chart.

Although the "JCO" is used differently by some licensees, the NRC concern is that the operability decision is correct, documentation of licensee's actions are appropriate, and submittals to the NRC are complete. The licensee's documentation of the JCO is normally proceduralized through the existing plant record system, which is auditable.

4.6 Reasonable Assurance of Safety

For SSCs that are not expressly subject to TS and that are determined to be inoperable, the licensee should assess the reasonable assurance of safety. If the assessment is successful, then the facility may continue to operate while prompt corrective action is taken. Items to be considered for such an assessment include the following:

- Availability of redundant or backup equipment
- Compensatory measures including limited administrative controls
- Safety function and events protected against
- Conservatism and margins, and
- Probability of needing the safety function.
- PRA or Individual Plant Evaluation (IPE) results that determine how operating the facility in the manner proposed in the JCO will impact the core damage frequency.

4.7 Evaluation of Compensatory Measures

In its evaluation of the impact of a degraded or nonconforming condition on plant operation and on operability of SSCs, a licensee may decide to implement a compensatory measure as an interim step to restore operability or to otherwise enhance the capability of SSCs until the final corrective action is complete. Reliance on a compensatory measure for operability should be an important consideration in establishing the "reasonable time frame" to complete the corrective action process. NRC would normally expect that conditions that require interim compensatory measures to demonstrate operability would be resolved more promptly than conditions that are not dependent on compensatory measures to show operability, because such reliance suggests a greater degree of degradation. Similarly, if an operability determination is based upon operator action, NRC would expect the nonconforming condition to be resolved expeditiously.

On July 21, 1997, the Nuclear Energy Institute (NEI) submitted to the NRC a guidance document, NEI 96-07 [Final Draft], "Guidelines for 10 CFR 50.59 Safety Evaluations." Part of this guidance relates to applicability of 10 CFR 50.59 to degraded and nonconforming conditions. With respect to the use of compensatory measures, the guidance states:

- If an interim compensatory action is taken to address the condition and involves a procedure change or temporary modification, a 10 CFR 50.59 review should be conducted and may result in a safety evaluation. The intent is to determine whether the compensatory action itself (not the degraded condition) impacts other aspects of the facility described in the SAR.

The staff concludes that this is an acceptable approach for dealing with compensatory actions within the context of a corrective action process.

In considering whether a compensatory measure may affect other aspects of the facility, a licensee should pay particular attention to ancillary aspects of the compensatory measure that may result from actions taken to directly compensate for the degraded condition. As an example, suppose a licensee plans to close a valve to isolate a leak. Although that action would temporarily resolve the leak, it has the potential to affect flow distribution to other components or systems, may complicate required operator responses, or could have other effects that should be evaluated before the compensatory measures are implemented. In accordance with 10 CFR 50.59, should the evaluation determine that implementation of the compensatory action itself would involve a TS change or an unreviewed safety question (USQ), NRC approval, in accordance with 10 CFR 50.90 and 50.92, is required prior to implementation of the compensatory action.

4.8 Final Corrective Action

The responsibility for corrective action rests squarely on the licensee. A licensee's range of corrective action could include (1) full restoration to the SAR-described condition, (2) NRC approval for a change to its licensing basis to accept the as-found condition as is, or (3) some modification of the facility other than restoration to the original FSAR condition. If corrective action is taken so that the degraded or nonconforming condition is restored to its original configuration, no 10 CFR 50.59 evaluation is required. The 10 CFR 50.59 process is

entered when the final resolution to the degraded or nonconforming condition is to be different than the established FSAR requirement. As this point, the licensee is planning (in a prospective sense) to make a change to the facility or procedures as described in the SAR. The proposed change is now subject to the evaluation process established by 10 CFR 50.59. A change can be safe, but can still require NRC approval. The proposed final resolution can be under staff review and not affect the continued operation of the plant, because interim operation is being governed by the processes of the operability determination and corrective action of Appendix B.

In two situations, the identification of a final resolution or final corrective action would trigger a 10 CFR 50.59 evaluation, unless another regulation applies (i.e., 10 CFR 50.55a): (1) when a licensee decides to change its facility or procedures to something other than full restoration to the FSAR-described condition, as the final corrective action, or (2) when a licensee decides to change its licensing basis as described in the SAR to accept the degraded or nonconforming condition as its revised licensing basis. This guidance is consistent with the July 21, 1997, revision of NEI 96-07.

Change to Facility or Procedures

The first circumstance is if the licensee plans for its final resolution of the degraded or nonconforming condition to include other change(s) to the facility or procedures in order to cope with the (uncorrected) nonconforming condition. Rather than correcting the nonconforming condition, the licensee decides to restore capability or margin by another change. In this case, the licensee needs to evaluate the change from the SAR-described condition to the final condition in which the licensee proposes to operate its facility. If the 10 CFR 50.59 evaluation concludes that a change to the TS or a USQ is involved, a license amendment must be requested, and the corrective action process is not complete until the approval is received, or other resolution occurs.

Change to Current Licensing Basis

The other situation is a final resolution in which the licensee proposes to change the current licensing basis to accept the as-found nonconforming condition. In this case, the 10 CFR 50.59 evaluation is of the change from the SAR-described condition to the existing condition in which the licensee plans to remain (i.e., the licensee will exit the corrective action process by revising its licensing basis to document acceptance of the condition). If the 10 CFR 50.59 evaluation concludes that a change to the TS or a USQ is involved, a license amendment must be requested, and the corrective action process is not complete until the approval is received, or other resolution occurs. In order to resolve the degraded or nonconforming condition without restoring the affected equipment to its original design, a licensee may need to obtain an exemption from 10 CFR Part 50 in accordance with 10 CFR 50.12, or relief from a design code in accordance with 10 CFR 50.55a. The use of 10 CFR 50.59, 50.12, or 50.55a in fulfillment of Appendix B corrective action requirements does not relieve the licensee of the responsibility to determine the root cause, to examine other affected systems, or to report the original condition, as appropriate.

In both of these situations, the need to obtain NRC approval for a change (e.g., because it involves a USQ) does not affect the licensee's authority to operate the plant. The licensee may make mode changes, restart from outages, etc., provided that necessary equipment is operable

and the degraded condition is not in conflict with the TS or the license. The basis for this position was previously discussed in Section 4.5.1.

ENFORCEMENT

If the licensee, without good cause, does not correct the nonconformance at the first available opportunity, the staff concludes that the licensee has failed to take prompt corrective action and, thus, is in violation of 10 CFR Part 50 Appendix B (Criterion XVI).[2] When the NRC concludes that corrective action to implement the final resolution of the degraded or nonconforming condition is not prompt, or that the operability determination is not valid, enforcement action (Notice of Violation, orders) will be taken. Enforcement action may include restrictions on continued operation.

Implementation of complete corrective action within a reasonable time frame does not mitigate the potential for taking enforcement action for the root causes that initially created the degraded or nonconforming condition or for violations of other regulatory requirements. The nonconforming condition may have resulted from (1) earlier changes performed without a 10 CFR 50.59 evaluation or (2) inadequate reviews; or may be a *de facto* change for which the facility never met the SAR description. The staff may determine that the "change" from the FSAR-described condition to the discovered nonconforming condition involved a USQ (or a TS change), and that enforcement action is appropriate for the time frame up to time of discovery.

5.0 REFERENCE

See attached charts ~~on next page~~titled, "Resolution of Degraded and Nonconforming Conditions."

END

[2]Since Appendix B is only applicable to safety-related SSCs, this approach could not be used if the delay in resolution of a nonconforming condition from the SAR involved only non-safety-related SSCs and did not affect any safety-related SSCs. However, NRC expects licensees to take corrective action for nonconformances with the SAR consistent with Criterion XVI in a time frame commensurate with safety.

RESOLUTION OF DEGRADED AND NONCONFORMING CONDITIONS

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OF DEGRADED AND NONCONFORMING CONDITIONS

ATTACHMENT 3

OPTIONS AND ALTERNATIVES FOR REGULATORY CHANGES

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OPTIONS AND ALTERNATIVES FOR REGULATORY CHANGES

INTRODUCTION

This attachment to the Commission paper describes the systematic process used by the U.S. Nuclear Regulatory Commission (NRC) staff in developing and analyzing approaches that would comprehensively integrate the large number of requirements, recommendations, and commitments emanating from recent lessons-learned reviews, the agency's action plan to improve the implementation of 10 CFR 50.59, and ongoing activities (that form a foundation for each of the options developed by the staff) into a cohesive plan of regulatory improvements. This attachment also presents the options (and related alternatives) for making these improvements.

INTEGRATION OF RECOMMENDATIONS FOR REGULATORY PROCESS IMPROVEMENTS

Since early May 1997, a dedicated, multidisciplinary team from the NRC's Office of Nuclear Reactor Regulation (NRR) has been systematically defining various approaches, including a range of possible actions and timing, for implementing changes that would result in effective regulatory improvements that are performed in a timely manner. The effort of the Integration Team has progressed through successive phases of development, including scoping, developing and refining options (and alternatives), analyzing options, and shaping a preferred option.

Scoping

During the scoping phase, the Integration Team worked to understand the boundaries of the project. Essential to the scoping phase was the clear identification of the body of requirements, recommendations, and commitments against that which the comprehensiveness of potential approaches would be tested. This "requirements set" includes actions derived from the following key documents:

- SECY-97-035, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, and Experiments)," February 12, 1997
- SECY-97-036, "Millstone Lessons Learned Report, Part 2: Policy Issues," February 12, 1997
- Staff requirements memoranda (SRMs) on SECY-97-035 and SECY-97-036, dated April 25 and May 20, 1997, respectively
- "Millstone Lessons Learned Report, Part 1: Review and Findings," September 1996
- Maine Yankee Independent Safety Assessment and Lessons Learned reports

Among these key documents and other source documents, such as transcripts from Commission meetings, the staff extracted well over 100 individual actions.

Also, as part of the scoping phase, the team developed problem and issue statements to help characterize the overall agency goal. The team then separated these statements into those

that were reasonably related to one another and those that were not. (The team did not direct its efforts toward resolving the problems and issues that were not interrelated; however, the team assured that they are on a path to resolution in separate forums). The team divided the related problems and issues into three categories on the basis of the most probable "owner" of the problem or issue (licensees, NRC, or shared ownership). From these statements, the team developed and later refined the following general goal statement:

GOAL

To improve the availability and control of essential design-bases information, as well as regulatory oversight of licensees' compliance with and changes to that design-bases information, and to ensure that licensees operate their facilities in the manner reviewed and approved by the NRC.

Another important part of the scoping phase was the team's identification of various constraints (scheduling, resource, management expectations, Commission goals, and process) expected to impact the eventual selection of an approach.

Development and Refinement of Options and Alternatives

In this phase, the Integration team separated the goal statement into component parts and created a model ("goal model") that identifies a combination of components or activities that could be used to test the thoroughness of a particular approach. The team noted that the model comprised activities that could be assigned among four areas:

- implementation of 10 CFR 50.59
- content of Safety Analysis Reports (SARs)[1] and compliance with the updating requirements of 10 CFR 50.71(e)[2]
- design bases
- NRC oversight of licensee commitments and other internal process improvements

The team eventually selected these areas as the categories within options under which it would group various activities (as will be explained later, Option 4 is an exception). The team also used the goal model for brainstorming a wide range of possible ways to satisfy a particular component of the model, and later used the brainstorming results to craft options and alternatives within options.

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[1]Unless otherwise indicated, references to the safety analysis report (SAR) denote the updated final safety analysis report (UFSAR) required by 10 CFR 50.71(e).

[2]More generally, this category considers what information is important to maintain, where it should be located, and what level(s) of control should be applied to that information.

Next, the team examined various ways to organize and depict the various regulatory changes available to the staff in the four areas noted above. Thus, the team decided to create several options and to arrange them to form a hierarchy of activities that generally increased in complexity, schedule duration, and resource impact from one option to the next. The result was a hierarchy of four options, each built on the foundation of specific ongoing activities (discussed further below). To a large extent, successive options built on the previous option. Nearly each option contains a set of activities addressing each of the four areas (10 CFR 50.59 implementation, SAR content and updating, design bases, and NRC oversight of licensee commitments and other related internal process improvements).

Analysis of Options

The Integration Team developed several evaluative tools for gauging the potential success of each option (relative to one another). These tools involve comparing the features of a particular option (and/or alternative within an option) against a set of criteria and rendering a consensus judgement as to how closely the overall option satisfies each criterion. The team identified three sets of criteria that could be used for these comparisons. The first set is the list of constraints (scheduling, resource, management expectations, Commission goals, and process) developed during the scoping phase and would be used for determining how severely the pursuit of a particular approach would be constrained and for identifying the most constraining factor(s). The second set comprises the problem and issue statements and would be used to approximate how effective an approach might be in resolving the problems and issues. The third set is a list of specific requirements (e.g., requirements in SRMs relating to SECY-97-035 and SECY-97-036), commitments, and recommendations and would be used to confirm that an approach is responsive to the needs.

The team piloted these tools on a set of options developed early on. The team then used the results during management briefings to demonstrate how the tools could be used. For example, the tools could be used to refine an option (by focusing on what type of activity could be added, or if an activity could be changed to fill the gaps in areas where an option may be weak). Similarly, the tools could be used to highlight particular constraints that could be reduced or eliminated.

Shaping a Preferred Option

The hierarchy of four options served as an outline for further refinement of the possibilities. While this outline showed an adequate spread of possibilities, it initially lacked specificity and did not depict the different ways (alternatives) in which specific activities could be accomplished under each option. The team expanded and refined Options 1 through 4 and packaged them with distinct boundaries as shown later in this attachment.

The staff recognized that in order to create the best option, it was necessary to select among the activities in Options 1 through 4 to shape the most comprehensive solution. The staff identified a conceptual approach, described (as Option 5) in the "Discussion" section of this Commission paper, that comprises risk-informed enhancements to existing regulatory processes in selected areas in the near term, and development of much broader risk-informed regulatory changes in the longer term. This conceptual approach has not yet been refined to the level of detail presented for Options 1 through 4. The staff will be developing the details for the approach, which will include more specific resource and schedule estimates and strategy for prioritization of the work within the NRC's operating plan, during the next several months.

ONGOING ACTIVITIES RELATED TO 10 CFR 50.59, SAR CONTENT AND UPDATING, DESIGN BASES, AND NRC OVERSIGHT OF LICENSEE COMMITMENTS AND OTHER RELATED INTERNAL PROCESS IMPROVEMENTS

As discussed above, the Integration Team noted that the goal model comprised activities that could be assigned among four areas (implementation of 10 CFR 50.59, content of SARs and compliance with the updating requirements of 10 CFR 50.71(e), design bases, and NRC oversight of licensee commitments and other related internal process improvements). In the process of developing and refining possible options and alternatives, the team established these four areas as the categories under which it would group various activities within options. The team identified a number of activities in each of the four categories that had been under way for some time. Many of these were begun several months before the issuance of SECY-97-035 and SECY-97-036 or the related Commission guidance (SRMs), while several others are addressed by SECY-97-036 and the SRMs. After ensuring that it was appropriate to continue implementing these ongoing activities, the team established these activities as a foundation upon which any future options would be based. In addition, the team decided that it would be appropriate to evaluate the results of these activities at appropriate point(s) in the future, in order to gain insights on the overall benefit of their implementation to the reactor licensing and oversight programs and to determine whether changes in direction would be advisable. The following subsections discuss each of the four categories of ongoing activities evaluated by the team:

10 CFR 50.59

Ongoing activities in the area of improving the implementation of 10 CFR 50.59 include development of staff-issued guidance (NUREG-1606) or NRC endorsement of industry-developed guidance (Nuclear Energy Institute's document, NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations"), as well as improved inspection guidance on the role of 10 CFR 50.59, specifically as it relates to resolving degraded and nonconforming conditions (Generic Letter 91-18, Revision 1).[3] (See Attachment 2 to this Commission paper for additional details on these efforts.) Ongoing activities in this area also include the eventual use of the improved implementation guidance and NRC inspection guidance, once available, to improve licensee implementation and NRC oversight of the 10 CFR 50.59 process.

Another element of ongoing activities in this area involves the possible need to give the NRC staff greater flexibility in determining the severity levels for certain apparent violations of 10 CFR 50.59. A more complete discussion of this activity appears in the "Discussion" section of this Commission paper.

SAR Update Requirements

[3]NUREG-1606, "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 (Changes, Tests, or Experiments) — Draft Report for Comment," April 1997. NEI 96-07 [Final Draft], "Guideline for 10 CFR 50.59 Safety Evaluations" (July 1997). Generic Letter 91-18, "Information to Licensees Regarding NRC Inspection Manual Section on Resolution of Degraded and Nonconforming Conditions," Revision 1.

Ongoing activities in this area are directed toward continuing the NRC's focus (during inspections and other oversight activities) on licensee compliance with the SAR updating requirements of 10 CFR 50.71(e), and continuing to monitor industry and licensee initiatives.

By memorandum dated January 25, 1996, the NRR issued short-term inspection guidance to the regional offices to supplement the existing level of SAR reviews that were accomplished during routine NRC inspections. The revised guidance required inspectors to verify selected SAR commitments by reviewing the applicable portions of the SAR during inspection preparation and verifying that the commitments had been properly incorporated into plant practices, procedures, and/or the plant design. The staff incorporated this guidance into NRC Inspection Manual Chapter 2515, "Light-Water Reactor Inspection Program — Operations Phase," which was issued on April 9, 1997.

The staff has since worked with the NRC Technical Training Center and the regions to ensure that inspection training courses continue the emphasis that senior NRR management has placed on the staff's use of the SAR during licensing and inspection activities. Additionally, during regional counterpart meetings in the regions and at several NRR Project Manager (PM) workshops, senior NRR management has emphasized the importance of consulting and verifying licensee compliance with the SAR during inspections and licensing activities. Guidance was developed and disseminated to the NRR projects staff. These activities are discussed in more detail under Millstone Lessons Learned Short-term Actions 3 and 16 in Attachment 1 to this Commission paper.

In October 1996, the Commission revised the NRC Enforcement Policy (NUREG-1600[4]) to address departures from the SAR. The revision included changes to address enforceability of the SAR and provided severity levels for violations of 10 CFR 50.59 and 10 CFR 50.71(e). To encourage licensees to identify and correct violations that are not normally identified through current surveillance and quality assurance activities, the revised policy provides for a 2-year period during which the NRC would not take enforcement action if the licensee identifies violations (up to and including Severity Level II) associated with the SAR through a voluntary initiative. The staff also made appropriate changes to the NRC Enforcement Manual (NUREG/BR-0195). This activity is also discussed under Millstone Lessons Learned Short-term Action 11 in Attachment 1 to this Commission paper.

Another ongoing activity involves NRC evaluation of the results from the industry's licensing-basis review initiative conducted in accordance with NEI 96-05, "Guidelines for Assessing Programs for Maintaining the Licensing Basis." The industry began this initiative in July 1996 as a means of providing additional assurance to the NRC that existing licensee programs are adequate to ensure that (1) licensees are operating their plants in conformance with their licensing basis, (2) licensees are adequately maintaining their licensing basis, (3) no differences exist between operating practices and the licensing basis that could result in a significant public health and safety concern, and (4) degraded and nonconforming conditions are documented in controlled tracking systems and resolved in a timely manner. Under this initiative, each licensee was to assess the programs in place to determine that its plants are operated in conformance with the licensing basis. To accomplish the assessment, each licensee was to sample SAR information, programs for processing changes to procedures and the plant that may impact the SAR, and changes that may not be governed by licensee

[4]NUREG-1600, "General Statement of Policy and Procedures for NRC Enforcement Actions."

programs. The NEI has since informed the staff that the initiative is essentially complete, and that the results will be provided to the staff in late 1997. The staff intends to analyze the results of this initiative and use the results to adjust future SAR inspection efforts and possibly issue a generic communication.

Design Bases

Ongoing activities in this area are directed toward improving industry-wide understanding and NRC oversight of plant design bases and related concerns.

One important activity involved the staff review of the plant-specific responses to the 10 CFR 50.54(f) letter on design-bases information (issued in October 1996) and how the staff is using the information submitted by licensees in response to that letter. The staff presented the results of that review in greater detail in SECY-97-160, "Staff Review of Licensee Responses to the 10 CFR 50.54(f) Request Regarding the Adequacy and Availability of Design Bases Information," dated July 24, 1997. Generally, the staff is using the results of its review to prioritize architect/engineer (A/E) design inspections and to provide input to the detailed plans for the design inspections (in the NRC Plant Performance Review process). Refer also to the discussion of Millstone Lessons Learned Short-term Actions 10 and 12 in Attachment 1 to this Commission paper.

The staff will also continue the existing enforcement policy related to exercising discretion regarding problems with engineering, design, and installation discrepancies identified through formal licensee design basis reconstitution programs.

In addition, the staff is working to publish a revision to NUREG-1022, "Event Reporting Guidelines for 10 CFR 50.72 and 10 CFR 50.73," Revision 1. One area where the staff is developing additional guidance involves the issue of reporting when the plant is outside its design basis. According to the present schedule, the staff will publish the revised NUREG in June 1998.

The staff is also monitoring the advent of industry initiatives in the area of design bases and encouraging interest in updating NUMARC 90-12, "Design Basis Program Guidelines," as a means of fostering better definition and understanding of design-bases information and reconstitution. Toward that end, the staff met with representatives of the NEI on July 10, 1997, to discuss issues related to design bases. At the meeting, the staff and the NEI discussed examples of the types of information that constitute design bases, as defined by 10 CFR 50.2, and other types of design-related information that may be contained in the SAR or other design documents. The NEI would like to reach some agreement with the NRC on these interpretations and how they reflect on reporting requirements.

NRC Oversight of Licensee Commitments and Other Related Internal Process Improvements

In this area, the staff has several actions related to improving the NRC's internal processes. Of these, the two most significant actions pertain to NRC oversight of licensee commitments that the NRC relies upon in making its regulatory decisions and improving guidance and direction to NRR PMs. The NRR's Associate Director for Projects Process Improvement Plan (ADP PIP) presently manages these actions and their accomplishment.

Regarding oversight of licensee commitments, the staff is developing process changes that will establish and implement effective means for identifying, tracking, enforcing, and verifying licensee commitments that the staff relies on. In a letter to the NEI dated January 24, 1996, the staff informed the industry that the NRC found the NEI guidance document, "Guideline for Managing NRC Commitments," dated December 20, 1995, to be acceptable. Further, the letter stated that the NRC will monitor licensees' implementation of the NEI guideline (or their alternative commitment control processes) in order to assess the need to promulgate staff guidance or rulemaking. As a followup to this pronouncement, the staff is currently preparing to conduct a series of audits of licensee programs for managing commitments made to the NRC. On the basis of the results of those audits, the staff will determine what additional actions are warranted. For additional details, see the discussions of Millstone Lessons Learned Short-term Actions 1, 2, 3, and 11 in Attachment 1 to this Commission paper.

This area also encompasses a number of ADP PIP action items, most of which have already been completed, that involve developing new or revised guidance for the PM Handbook. The staff recently revised the PM Handbook and converted the document to electronic form for use on the NRC's Local Area Network Home Page for easy accessibility and consolidation of PM guidance. In addition, the NRR Projects organization holds periodic workshops to provide training and guidance for PMs. Management expectations are also communicated in these forums and in memoranda to the Projects staff. See also the discussions of Millstone Lessons Learned Short-term Action 3 in Attachment 1 to this Commission paper.

OPTIONS AND ALTERNATIVES

The remainder of this attachment discusses Options 1 through 4 (and alternatives).

OPTION 1

OPTION 1

This option continues the ongoing actions discussed previously, as well as actions begun before the Commission issued the SRMs related to 10 CFR 50.59 (SECY-97-035) and the Millstone Lessons Learned Part 2 Report (SECY-97-036), and includes several actions requested by the SRMs. The ongoing actions provide near-term improvement in regulatory oversight of licensees' design-bases maintenance programs and changes to licensee facilities under 10 CFR 50.59.

This option is enhanced by the addition of a rule change to 10 CFR 50.59 to allow some flexibility regarding the probability and consequences of a change before it requires prior NRC approval. In addition, this option is enhanced by notifying the industry of NRC expectations with respect to implementation of 10 CFR 50.71(e). These enhancements are expected to improve licensee control of SAR information and maintenance of the design bases in the way the NRC had intended. As such, these enhancements fulfill the spirit of the SRMs by improving control of design-bases information and allowing negligible decreases to the safety margins in 10 CFR 50.59 evaluations.

In addition, this option uses information available to the staff to evaluate the licensees' implementation of 10 CFR 50.59 and 10 CFR 50.71(e), as well as the availability, accessibility, and control of design-bases information. On the basis of that evaluation, the staff would then be in a better position to make more informed decisions about actions needed in the longer term. As a result, this option would enable the staff to more fully implement Commission guidance on implementation of 10 CFR 50.71(e) (compared with the ongoing activities alone). Implementation of this option, however, may prove sufficient to obviate the need to pursue more resource-intensive and high-impact activities in the longer term.

This option requires additional resources to revise 10 CFR 50.59, but less than any of the other options. In return, this option would improve both NRC processes (mostly internal) and licensee processes (as a result of improved NRC oversight). In addition, this option should reduce both the regulatory and industry burdens because it would clarify the application of 10 CFR 50.59, particularly with regard to negligible increases in probability or consequences and the margin of safety as defined in the basis for any technical specification. However, bringing SAR content into conformance with the requirements of 10 CFR 50.71(e) may represent a significant burden for many licensees. This option would not provide for information in the SAR to be readily removed.

Implementation of 10 CFR 50.59

In Option 1, the staff would pursue rulemaking to more clearly convey to licensees which plant changes the NRC must review and approve under Section 50.59, to allow negligible changes in probability or consequences, and to clarify the statement in the rule "the margin of safety as defined in the basis for any technical specification." The staff would also develop guidance to improve the safety evaluations that licensees conduct to determine if a proposed change is safe. As noted in NUREG-1606, such safety evaluations by licensees are fundamental to support the implementation of 10 CFR 50.59. Thus, an additional activity associated with this option would involve developing guidance for screening the effects of a change, checking for any potential impact on interfacing systems, and considering risk insights in evaluating alternative changes. Such guidance could be developed independently by the staff, or in

cooperation with industry groups. The guidance would be made available for voluntary use by licensees.

The staff considered rulemaking alternatives for 10 CFR 50.59 (presented below) ranging from small changes in criteria for determinations regarding unreviewed safety questions (USQs) to approaches tied to changes in risk.[5] For each alternative, the staff has outlined the nature of the rule change, as well as associated considerations such as required resources, time frames for development and implementation, legal implications, and other factors. These alternatives relate to changes to the definition of a USQ, that is, defining the threshold for what constitutes a USQ:

(1) Change "probability...may be increased" to "probability...is increased."

(2) Change "probability...may be increased" to "probability...is more than negligibly increased." "Negligible" could be qualitative or quantitative, such as a finding that the measurable effect on the outcome of a safety function is less than a specified percentage or safety-assessment value.

(3) Change "consequences of accidents previously evaluated in the safety analysis report may be increased" to "consequences of accidents previously evaluated in the safety analysis report exceed established limits for the accident being evaluated."

(4) Clarify or modify in the rule itself that "margin of safety as defined in the basis for any technical specification" refers to meeting acceptance limits in the SAR.

(5) Replace the three existing criteria for determining when a change, test, or experiment involves a USQ with a criterion based upon continuing to meet acceptance limits as defined by either the Standard Review Plan (NUREG-0800) or the plant-specific bases in the SAR and staff safety evaluation.

These alternatives were discussed in Section IV of NUREG-1606 and, thus, have already been subjected to some degree of public comment.

The first two alternatives listed above require consideration of the following factors:

- The scope of rulemaking and supporting regulatory guidance and analysis is relatively small.

- Such changes would revise rule language to be more consistent with industry practice (as represented by the industry's existing guidance documents), yet still limit the amount of change in either probability or consequences to be very small. This alternative could be viewed as risk-informed in that very small increases in probability or consequences would not be significant to risk.

[5]Language similar to 10 CFR 50.59 also exists in 10 CFR 72.48 and 10 CFR 76.68. There may be merit in conforming rule changes to these sections if 10 CFR 50.59 is revised.

- Such changes would revise the rule language to accommodate staff views that negligible changes in probability or consequences pose little risk and do not warrant expenditure of staff resources to issue license amendments.

- Some development resources would be required to prepare guidance on qualitative or quantitative metrics for "negligible increases."

- The criteria established by these rule revisions would be less burdensome to licensees than existing criteria.

- Such changes would not resolve existing interpretation issues about margin of safety.

By contrast, USQ threshold alternatives (3) through (5) require consideration of the following factors:

- These alternatives would reduce confusion about when margins of safety are involved and more directly identify what changes have an impact on the basis for the staff's licensing decisions.

- The development of rules and guidance is more involved (as compared, for instance, to endorsing an existing standard or guideline) and will require more time to clearly delineate which acceptance limits fall within the language of the rule so that licensees will consistently and appropriately implement the rule.

- Some of the alternatives will allow licensees greater latitude for changes that increase consequences more than negligibly, but are still within limits. This raises a potential concern, however, about cumulative effects.

- Rule changes on margin of safety could be viewed as imposing new requirements, raising potential backfit concerns.

Those who commented on the rulemaking options discussed in NUREG-1606 generally believed that rulemaking was not necessary because the industry guidance positions were consistent with the rule. However, some stated that if the Commission does not change its interpretations regarding probability and consequence increases, rulemaking is needed because too many insignificant changes would be considered USQs.

The rulemaking on 10 CFR 50.59 would also include use of a term other than "unreviewed safety question" to designate conditions that warrant prior NRC approval of a change. Possible terms are "unreviewed licensing issue," "unreviewed regulatory question," "unapproved licensing basis change," and "licensing basis change." The term "unreviewed safety question" gives rise to confusion about "unreviewed" (by who), "safety question," and so forth. Also, the term "safety evaluation" has led some licensees to erroneously conclude that because a change is "safe," it cannot be a USQ. As part of such rule changes, the NRC could revise the language referring to "safety evaluation" to clarify that the determination of need for prior approval (USQ determination) is drawn from the licensee's safety evaluation of the change, but that the "licensing evaluation" is the documentation of this determination.

Compliance with SAR Update Requirements

The first task to be accomplished under Option 1 would be to inform the industry of the NRC's expectations regarding the content of the SAR. The staff has identified several possible methods; however, each method will state that the NRC expects all licensees to comply with 10 CFR 50.71(e). Specifically, licensees would be required to ensure that their SARs are updated to reflect changes to the design bases and to reflect the effects of other analyses performed since original licensing which should have been included under 10 CFR 50.71(e). The most direct method to convey this message would be to issue a letter to all licensees, pursuant to 10 CFR 50.54(f). This letter would inform licensees that the NRC expects them to update the SAR for the more risk-significant plant changes first. Moreover, licensees would be expected to include this new information in their next scheduled SAR update. This method may have backfit considerations.

Another method of informing the industry of the NRC's expectations would be to issue a separate generic communication, or include this information in another, related generic communication.

The final method of informing the industry would involve writing a letter to the NEI in which the staff would invite the industry to develop guidance for updating the SARs to comply with 10 CFR 50.71(e) and to include the more risk-significant changes first. This letter would request that the NEI develop the guidance within a specific time frame. The staff could work jointly with the NEI (thereby implementing Commission direction on Direction-Setting Issue 12 (DSI-12), "Risk-Informed Performance-Based Regulation," of the NRC's Strategic Assessment and Rebaselining Initiative), or the NEI could independently prepare the guidance and seek NRC review of the finished product.

The next action would involve the NRC issuing a generic communication that discusses the results of recent broad-based SAR inspections. In a memorandum dated January 25, 1996, NRR issued short-term inspection guidance to all regional offices to supplement the existing level of SAR reviews that were accomplished during routine NRC inspections. The revised guidance required inspectors to verify selected SAR commitments by reviewing applicable portions of the SAR during inspection preparation and verifying that the licensee properly incorporated the commitments into plant practices, procedures, and/or design. The staff subsequently incorporated this guidance into NRC Inspection Manual Chapter 2515 on April 9, 1997. In addition, in a memorandum to the Commission from James M. Taylor dated September 17, 1996, the staff reported the results of inspections performed during the period from January 25 through April 26, 1996, as well as the planned short- and long-term improvements in SAR compliance. This generic communication could also be used to inform licensees of the NRC's expectations regarding compliance with 10 CFR 50.71(e).

The final action to be accomplished under Option 1 would be an assessment of the results of the industry's licensing-basis review initiative conducted in accordance with NEI 96-05, "Guidelines for Assessing Programs for Maintaining the Licensing Basis." The industry began this initiative in July 1996 as a means of providing additional assurance to the NRC that existing licensee programs are adequate to ensure that (1) licensees are operating their plants in conformance with their licensing basis, (2) licensees are adequately maintaining their licensing basis, (3) no differences exist between operating practices and the licensing basis that could result in a significant public health and safety concern, and (4) degraded and nonconforming conditions are documented in controlled tracking systems and resolved in a timely manner.

Under this initiative, each licensee was to assess the programs in place to determine that its plants are operated in conformance with the licensing basis. To accomplish the assessment, each licensee was to sample SAR information, programs for processing changes to procedures and the plant that may impact the SAR, and changes that may not be governed by licensee programs. The NEI has since informed the staff that the initiative is essentially complete, and that the results will be provided to the staff in late 1997. The staff would analyze the results of this initiative and use the results to adjust future SAR inspection efforts and possibly issue a generic communication.

Design Bases

The staff recognizes that available information (gleaned from operating experience) may help the staff identify the need for specific regulatory actions. To better utilize this information, the staff is considering a focused evaluation of events (reported under 10 CFR 50.72 and 10 CFR 50.73) related to licensees operating their plants outside of the design basis. Through such an evaluation, the staff could identify any weaknesses in licensee or regulatory processes that might warrant improvement.

A second initiative under this option would involve reviewing previously issued generic communications with underlying design-bases issues. In particular, the staff would seek to determine whether any trends or patterns suggest why the issues arose, and whether changes to licensee or NRC processes are needed.

As discussed earlier, the staff has an ongoing activity to monitor industry interest in updating NUMARC 90-12, "Design Basis Program Guidelines." As part of Option 1, the staff would take a more active role in working with the NEI and other industry groups to define and reach a mutual understanding of design-basis information by revising NUMARC 90-12 or by developing staff guidance.

These evaluations would enable the staff to assess the effectiveness of the NRC and industry handling of design-bases issues. The staff would adjust its oversight in accordance with these evaluations.

NRC Oversight of Licensee Commitments and Other Related Internal Process Improvements

Same as in the discussion of ongoing staff activities discussed earlier in this attachment.

OPTION 2

OPTION 2

Option 2 includes some of the rulemaking activities in Option 1 but attempts to further improve established regulatory processes. Specifically, Option 2 provides an opportunity for licensees to remove unnecessary information from the SAR and to update the SAR with the more risk-significant information first, while bringing SAR content into conformance with the requirements of 10 CFR 50.71(e). This option will not permit removal of information required by 10 CFR 50.34. Risk information will be used only in evaluating the priority with which the information should be incorporated into the existing SAR. Implementation of this option may sufficiently improve SAR compliance to obviate the need to pursue more resource-intensive and high-impact activities in the longer term. Like Option 1, this option will allow the staff an opportunity to gather and evaluate more experiential data in order to make more informed decisions about where future improvements are needed and how they should be prioritized.

Like Option 1, it will give the NRC an opportunity to gather and evaluate more experiential data, in order to gain a better understanding concerning the extent of issues. This, in turn, will enable the staff to make more informed decisions on where future improvements are needed and how they should be prioritized.

Implementation of 10 CFR 50.59

This option includes the 10 CFR 50.59 rulemaking aspect of Option 1 to more clearly define the USQ. This option also responds to the Commission's request that the staff consider rule options related to the review process for USQs. A number of commenters on NUREG-1606 also expressed support for a process that would involve less of an administrative burden than a license amendment for changes that do not involve the technical specifications (TS) or license conditions. Consequently, staff actions related to this option include examining various review methods, including a letter approval, a form of prior notification, and prompt post-implementation notification.

In assessing this option, the staff considered the following factors:

- In general, the TS address aspects of plant operation that are most significant to public health and safety. Consequently, changes to the TS require a license amendment prior to implementation, regardless of the amount of change proposed.

- The staff needs assurance that licensees apprise the staff of all changes that potentially impact the licensing basis, and that unacceptable changes do not result.

- The staff and the public need to remain aware of changes to the facility or procedures as described in the SAR.

- Depending upon the USQ definition that exists, some changes may constitute USQs and, thus, require issuance of an amendment even though the changes may be temporary or of little safety or risk significance.

An alternative that the staff considered was a prior notification (negative consent) process; however, following discussions with the NRC's Office of the General Counsel on the viability of the approach, the staff decided not to pursue such an alternative.

The staff did not pursue alternatives involving NRC approval in the form of a letter (rather than a license amendment). At one time, Section 50.59 did provide an alternative method of staff authorization for changes that involved USQs, but did not involve significant hazards considerations. However, a rulemaking in 1974 revised 10 CFR 50.59 to specify that NRC approval is in accordance with 10 CFR 50.90 (license amendment).

One other possible process alternative would involve relying upon licensee programs to evaluate the safety of proposed changes (particularly if the licensee has developed and implemented the guidance discussed in Option 1) to maintain consistency with their licensing documents, with a post-implementation reporting process (more frequent than the present "annual" report). This alternative could include "real-time" updating (through electronic media) of the SAR once the change is implemented, with staff access to this document (with links to discussion concerning the basis for the change). This alternative involves less administrative burden on both the licensee and the staff, but could potentially result in implementation of a change that the staff later finds unacceptable. (Note that this potential already exists in the existing 10 CFR 50.59 process.) The Commission may wish to consider this alternative in the longer term, after addressing issues related to the completeness and accuracy of SARs or knowledge of design bases.

Compliance with SAR Update Requirements

This option is similar to Option 1 in that it includes some form of generic communication on the results of the SAR inspections and a review of the industry's licensing-basis review initiative (NEI 96-05, "Guidelines for Assessing Programs for Maintaining the Licensing Basis"). However, this option differs from Option 1 in that it includes more effort related to defining what information an SAR must include and, by corollary, what information licensees may remove from an SAR.

Once again, the staff has identified different methods of completing the task of ensuring that licensees include the correct information in their SAR. One method is to send a letter to the NEI in which the staff would state that it expects all licensees to comply with 10 CFR 50.71(e). Specifically, the NRC expects licensees to ensure that their SARs are updated to reflect changes to the design bases and to reflect the effects of other analyses performed since original licensing, which should have been included under 10 CFR 50.71(e). This letter would also state that the staff expects licensees to add the more important information first, and that there is a need to develop guidance for licensees to use in prioritizing the material to be added, as well as guidance on what material can be deleted. Risk information would be used in evaluating the priority for incorporation into the SAR, but not for determining whether the material should be in the SAR at all. To develop the guidance, the staff could offer to work with the NEI on developing this guidance (thereby implementing Commission direction on DSI-12) or allow the NEI to develop the guidance on its own and keep the staff informed of the industry's progress. The staff would then review the completed NEI guidance and issue some form of endorsement (either a regulatory guide or a letter to the NEI).

Another method would be to add to the generic communication concerning the results of the SAR inspections. The staff could use this vehicle to inform the industry of the staff's expectations, as stated above, and also to inform them that the staff is developing related guidance. The staff would then begin work on defining the information that must appear in an SAR and the criteria that licensees could use for removing information. The staff would use traditional engineering methods to determine the information to be included, and could rely on

previously completed studies (such as the accident sequence precursor program conducted by the NRC's Office of Analysis of Operational Data) or previously issued bulletins and generic letters to identify the more safety-significant structures, systems, and components (SSCs). The staff would also need to define the required level of detail for the information to be added to the SAR. As a guide for its analysis, the staff could either use the type of SSC or the type of information.

After completing its analysis, identifying the material that must be included in the SAR, and defining a process and criteria for removing unnecessary material, the staff would need to publish the results of the analysis. Once again, the staff has several alternatives for achieving this step. Depending on the complexity and the legal implications of the issues, it may be necessary to publish rule changes that clarify how the requirements of 10 CFR 50.71(e) are to be interpreted. If this is not considered necessary, the staff might publish a regulatory guide (RG) (possibly an update to RG 1.70) or some form of generic communication. In the extreme, the Commission could even elect to order all licensees to comply with the new requirements.

Design Bases

This option builds upon all of the activities in Option 1 (which includes conducting design-related inspections and monitoring industry update and implementation of NUMARC 90-12). In this option, however, the staff would develop guidance regarding design-bases issues, such as specifying the type of information to be considered as design-bases information.

The need for such guidance can be determined from the staff's experience in reviewing licensees' reports under 10 CFR 50.72 and 10 CFR 50.73 and analyzing generic communications with underlying design-basis issues. The staff could also conduct a survey of the NRC staff to identify the extent of the problems and what guidance is needed. In addition, the staff could work with the NEI and other industry groups to revise NUMARC 90-12 to ensure that it specifically changes industry guidance related to definition of design bases. Alternatively, the staff could develop such guidance on its own.

NRC Oversight of Licensee Commitments and Other Related Internal Process Improvements

In addition to the ongoing activities discussed earlier, this option would reinstitute the functional area of "Licensing" in the systematic assessment of licensee performance (SALP) process. This feature reflects the NRC's increased on compliance with the licensing basis. This change would cover licensee activities associated with maintaining the license, responding to discovered problems, handling interactions with the NRC on generic issues, and so forth. If the NRC proceeds with this option, it must be recognized that certain activities (such as a formal commitment management program) are not regulatory requirements and, thus, may not be inspected. However, licensee processes for maintaining conformance with license requirements merit consideration for inclusion in the SALP program.

OPTION 3

OPTION 3

This option includes actions that more fully embrace risk-informed approaches to existing regulatory processes. The actions added by this option primarily involve developing more extensive rule changes on 10 CFR 50.59 and issuing accompanying regulatory guidance, with other rule changes as needed to prescribe risk-informed requirements for SAR updates. This would bring the consideration of severe accidents more fully within the regulatory processes (resulting in major policy implications for other areas under 10 CFR Part 50). These actions are directed toward revamping the 10 CFR 50.59 process and improving industry's understanding of what information licensees need to maintain in the SAR. If this option is pursued, the NRC may also wish to perform some of the actions from Options 1 or 2 to achieve some improvements while the staff is developing the necessary rulemaking and guidance for a risk-informed process. Further, this option may require parallel regulatory processes that would permit licensees to choose which process they wish to use in order to avoid significant backfit issues with imposition of risk-informed approaches. This option would involve a substantial departure from the framework under which operating plants were licensed and, thus, would involve significant resource, schedular, and legal considerations.

This option builds on Options 1 and 2 in that it includes all of the actions related to Section 50.59 and SAR compliance. The actions related to design bases and NRC oversight of licensee commitments and other related internal process improvements are identical to those discussed under Option 2.

Implementation of 10 CFR 50.59

The staff believes that several alternatives exist to make the 10 CFR 50.59 process more "risk-informed." First, 10 CFR 50.59, as written, is a process governing changes to the facility as described in the SAR; thus, the process is risk-informed to the extent that the plant design and operation are risk-informed and that such aspects are described in the SAR. Accordingly, approaches to establish and modify license requirements contribute to making the change control processes risk-informed to the extent that such approaches explicitly consider risk. Draft Regulatory Guide DG-1061, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Current Licensing Basis," presents examples of such approaches. Updating the SAR to contain risk-significant information would also make the 10 CFR 50.59 process more risk-informed.

It must also be recognized, however, that the accidents and the SSCs analyzed in the SAR are based on design-basis events. Thus, the criteria for requiring staff approval consider the risk factors (probability and consequences) only for that set of design-basis accidents, not for the full range of possible accidents. Nonetheless, it should also be noted that the SAR includes descriptions of parts of the facility that could initiate plant transients or otherwise challenge safety systems. This is an important element in risk assessment, and changes to these parts also require evaluation.

The following paragraphs discuss three alternative methods for making the 10 CFR 50.59 process more risk-informed. It should be noted, however, that to be effective, most of these methods would need to be conducted in conjunction with changes to requirements concerning SAR contents, performance of a plant-specific probabilistic risk assessment (PRA), or other measures.

The first method would build upon the body of knowledge concerning the relative safety- or risk-significance of various SSCs which is being used in Maintenance Rule (10 CFR 50.65) implementation, graded quality assurance, and other activities. Changes to SSCs that are identified as being highly risk significant on the basis of these reviews would require prior NRC approval if the changes would result in any discernable effect on reliability or would involve a USQ (under whatever definition the NRC has established). Changes to other SSCs would only require prior NRC approval if the changes had more significant effects (e.g., if established acceptance limits would no longer be satisfied). This method represents a hybrid of traditional engineering and risk-informed approaches.

The second method would model that used for the plant designs recently certified by the Commission. A change control process similar to that established in 10 CFR Part 52 would be used to control key information related to the PRA (if performed) or the individual plant examination, or other beyond-design-basis information produced in response to Commission request. That is, a change would involve a USQ if it would substantially increase the probability and credibility of a particular severe accident that was previously reviewed and determined not to be credible, or if the change would substantially increase the consequences to the public of a particular severe accident that was previously reviewed. This method would take into account that the present 10 CFR 50.59 threshold may not be suitable for beyond-design-basis accidents, but would allow some degree of regulatory control over plant equipment and procedural changes associated with severe accidents. Such a rulemaking would be time consuming, particularly because it would involve a number of backfit issues associated with the possible need to require a PRA, licensee inclusion of certain PRA information in a controlled document (SAR or otherwise), and other requirements.

The third method would be to more fully translate the overall regulatory framework into a risk-based regime. Instead of an SAR as defined in 10 CFR 50.34, this approach would control (by a 10 CFR 50.59-type process) different information and would impose different criteria for prior NRC approval. Prerequisites for this method include performing a plant-specific PRA (at least Level 2), using methods acceptable to the NRC. In addition, when proposing a given change to its facility, a licensee would be required to evaluate the associated change in risk. If the result was less than a defined change in core damage frequency and large early release frequency, or consequences, the licensee could make the change without prior NRC approval. Otherwise, the change would fall under the provisions of a (modified) 10 CFR 50.59 process for staff review. Implementation of this method would require a major rulemaking effort with significant backfit considerations, and would require significant licensee investment in PRA development and consume significant staff resources for review of the PRA models and results. The staff therefore recommends that, if the Commission desires to pursue this method, it be established as a voluntary alternative to the existing regulation rather than a required approach. The complexity of this rulemaking also translates to a long time frame before it could be implemented and, thus, the Commission may wish to pursue other improvements in the interim.

Content of SARs and Compliance with Update Requirements

The major thrust of this option is a complete, top-down review of the form and content of the SAR. The staff would either work with the industry (through the NEI), thereby implementing Commission direction on DSI-12, or work by itself to perform this review. The goal is to start with a "clean sheet of paper" and to develop a risk-informed or risk-based SAR. This project would take longer to complete than the previously described options; therefore, the staff would need to consider whether to attempt to have licensees update their SARs while this effort was under way, or to forgo that effort until a new approach is developed.

A risk-informed approach could use risk ranking information developed by licensees for the Maintenance Rule and graded quality assurance. In addition, a totally risk-based approach would require each licensee to perform at least a Level 2 PRA, which must then be reviewed and approved by the staff. This option is obviously more resource intensive than the other options; however, it offers the benefit of focusing the SAR on risk-important information. It should also be noted that using a risk-informed or risk-based approach will probably increase the scope of accidents reviewed.

As the staff and/or the industry develop(s) the new approach to the SAR, the staff will have to examine the related regulations. Certainly, the staff will need to change the language of 10 CFR 50.71(e), and it may be necessary to change many other sections of 10 CFR Part 50 (e.g., 10 CFR 50.34).

Once the new approach and the new rule language are developed, the staff will promulgate the information to the industry. Depending on the magnitude and complexity of the changes, the staff may select any of several vehicles to communicate this information. One choice may be to publish the rule changes and an update to RG 1.70. Another method may be to issue an update to RG 1.70, along with some form of generic communication.

The final, major decision concerning this option is whether to make the new risk-informed or risk-based SAR approach mandatory for all licensees. The staff recognizes that some licensees who are close to the end of their licenses, and who decide not to renew their licenses, may not be interested in investing the necessary resources to pursue this option. It may be possible to write the new rule language in such a way as to offer two paths for licensees to follow. One path would be to maintain the *status quo*, and the other would be a risk-based path in which licensees could take advantage of their PRA results in a variety of areas.

Design Bases

Same as for Option 2.

NRC Oversight of Licensee Commitments and Other Related Internal Process Improvements

Same as for Option 2.

OPTION 4

OPTION 4

Option 4 includes an approach that would involve specifying what essential information from the licensing basis cannot be changed without prior NRC approval (instead of defining criteria in a change control process). To implement this option, the staff would need to define the content of a controlled document, thereby eliminating the need for the 10 CFR 50.59 evaluation process to determine when approval is needed. Similar to Option 3, the schedular, resource, and legal considerations are substantial for this option.

Since this option differs so radically from Options 1, 2, and 3, the presentation of this option does not follow the same pattern. Instead, the general discussion below addresses the issues related to 10 CFR 50.59, the SAR, and the design bases.

Definition of "Essential" vs "Important" Information

The first task in implementing this option would be to define what constitutes essential and important information. Functionally, **essential** information could be defined as information which, if changed, may measurably decrease the regulatory margin for protection of the public health and safety; thus, prior NRC review and approval would be required before licensees could implement such changes. Although the staff needs to study this definition further, essential information may describe the makeup or configuration of SSCs and procedures which, if changed, may increase the probability or consequence of an accident.

By contrast, **important** information could be defined as information outside the scope of **essential** information but within the plant's licensing basis. This information must be controlled by a regulated process. This set of information could describe the makeup or configuration of SSCs and the procedures which, if changed under a regulated control process, would not increase the probability or consequences of an accident.

The staff would develop criteria and guidance for identifying the essential information. These criteria could be similar to those used in the advanced reactor design certification process for designating material as belonging to Tier 1 or Tier 2. The process could use risk-informed methods, as well as existing programs (such as the Maintenance Rule or graded quality assurance).

Once the NRC develops the criteria and guidance, licensees will prepare a submittal that identifies the essential information for their facility and defines the location of that information. (The essential information could be located in a stand-alone document, or it could be part of another document such as the SAR. Wherever it is located, the essential information should be clearly identified.)

Control Mechanisms

The next task required to implement this option would be to define the new control mechanisms. Under this option, 10 CFR 50.59 reviews would not be required because the information needing NRC review would be predefined. Changes to essential information would require prior NRC review and approval, but licensees could make changes to non-essential (but important) information under a regulated control process without NRC review and approval.

Licensees could seek NRC approval for changes to essential information in a manner similar to the current 10 CFR 50.90 amendment process or a variation of that process. The staff could choose to have licensees update their essential information as it changes or on a periodic basis.

Because the NRC would need to be informed of changes to important information, the staff would need a notification process. Specifically, the staff would ask licensees to notify the staff as the changes are being made, through a periodic reporting mechanism, or in "real-time" through electronic media. In all cases, the staff would evaluate the effectiveness of the licensee's process for controlling changes to important information.

Advantages of Option 4

This option offers the following advantages over Options 1, 2, and 3:

- Option 4 defines the set of SSCs and procedures that are **essential** and, therefore, cannot be changed without regulatory review and approval. By defining this essential information, this option obviates the need for a review similar to that required by 10 CFR 50.59. This should lead to an overall increase in safety because risk-significant SSCs and procedures would be predefined.

- Option 4 heightens the visibility of **essential** SSCs and procedures. This visibility should lead to improved licensee control and better NRC oversight.

- The change control process for SSCs and procedures that are **important**, but not **essential**, would be more consistent because these items would be predefined. Because licensees would notify the NRC of changes to important information, NRC oversight of the changes would also be improved.

- In the long term, Option 4 should lead to a reduction in both licensee and NRC resource requirements because changes to non-essential items would be simplified.

Disadvantages of Option 4

Compared to Options 1, 2, and 3, this option has the following disadvantages:

- Option 4 does not take into account that the result of a change, not just the category of the SSC that is changed, can matter in regard to safety (e.g., extremely small changes in *essential* SSCs can be unimportant, whereas very large changes in *important* SSCs can be very significant).

- A large initial expenditure of resources is needed to develop clear descriptions of SSCs and procedures contained in the sets of **essential** and **important** information. This initial expenditure may not be offset by reduced expenditures expected in the longer term, especially for licensees nearing decommissioning.

- Rulemaking would be needed to change the existing 10 CFR 50.59 and 10 CFR 50.71(e) requirements, among other sections of 10 CFR Part 50 (such as 10 CFR 50.34), to allow licensees to follow Option 4. Option 4 also imposes significant backfit considerations because it is not necessary for regulatory compliance.

- Because some licensees may not choose to adopt Option 4, implementation of the actions in Options 1, 2, or 3, may also be required, thereby increasing the expenditure of staff resources.

ATTACHMENT 4

SCHEDULE AND RESOURCE ESTIMATES FOR PROPOSED COURSE OF ACTION

SCHEDULE AND RESOURCE ESTIMATES FOR PROPOSED COURSE OF ACTION

	Duration	Date
Part 50 Rulemaking (approx. 15 FTE)[1]		
Transmit Commission paper with ANPR		02/27/98
Commission approval (SRM issued)	+ 30 days	
Publish ANPR	+ 14 days	
Public comment period ends	+ 90 days	
Transmit Commission paper with rulemaking plan(s)	+ 90 days	10/15/98
Commission approval of rulemaking plan	+ 30 days	
Transmit Commission paper with draft rules and guidance and associated analyses/assessments (regulatory, NEPA, Paperwork Reduction Act, backfit)	+ 17 mos.[2]	04/00
Commission approval (SRM issued)	+ 30 days	
Publish draft rule and guidance for public comment	+ 14 days	
Public comment period ends	+ 120 days[3]	
Transmit Commission paper with final rule, guidance, etc.	+ 8 mos.[4]	06/01
Commission approval (SRM issued)	+ 30 days	
Publish final rule, guidance, and NRC inspection procedure	+ 45 days	
Complete NRC staff training (inspectors and PMs)	+ 90 days	

[1]The staff will further refine its budget estimates and resource impacts for FY 1999 and beyond and provide that information with the ANPR.

[2]Dependent on extent of rule changes. Estimate considers completing ACRS and CRGR reviews before Commission review begins.

[3]Longer public comment period provided due to the expected more extensive rule changes.

[4]Dependent on extent of public comments and changes to draft rule.

SCHEDULE AND RESOURCE ESTIMATES FOR PROPOSED COURSE OF ACTION

	Duration	Date
A. Guidance on Applicability of 10 CFR 50.59 to Degraded and Nonconforming Conditions (4 staff weeks)		
Transmit Commission paper with revised Generic Letter 91-18 (includes revised inspection guidance)	____	09/97
Publish revised Generic Letter 91-18 and inform NRC staff, including regions, of change in agency practice	+ 14 days	9/22/97
Complete NRC staff training (inspectors and PMs)	+ 90 days	
B. Enforcement Policy Changes to Allow More Flexibility in Evaluating 10 CFR 50.59 Violations (6 staff weeks)		
Transmit Commission paper with draft policy revisions	____	12/15/97
Commission approval (SRM issued)	+ 30 days	
Publish final policy revisions; issue EGM	+ 14 days	02/01/98
Complete NRC staff training	+ 90 days	

SCHEDULE AND RESOURCE ESTIMATES FOR PROPOSED COURSE OF ACTION

	Duration	Date
C. 10 CFR 50.71(e) Implementation Guidance (1.5-2 FTE)[5]		
Commission paper with proposed approach, draft guidance, and draft enforcement policy changes relating to use of enforcement discretion to internal review committees	____	10/17/97
Transmit Commission paper with proposed approach, draft guidance, and draft enforcement policy changes relating to use of enforcement discretion to Commission	+ 75 days	12/30/97
Commission approval (SRM issued)	+ 30 days	
Publish draft guidance and enforcement policy changes for public comment	+ 45 days	03/15/98
Public comment period ends	+ 60 days	05/15/98
Commission paper to internal review committees to incorporate changes based on comments	+ 60 days	
Transmit Commission paper with final guidance	+ 60 days	09/15/98
Commission approval (SRM issued)	+ 30 days	
Publish final guidance, enforcement policy changes, and interim NRC inspection procedure	+ 45 days	12/30/98
Complete NRC staff training (inspectors and PMs) on interim inspection procedure	+ 90 days	
End of 2-year enforcement discretion; issue final NRC inspection procedure	+ 21 mos.	12/30/00
Complete NRC staff training (inspectors and PMs)	+ 90 days	

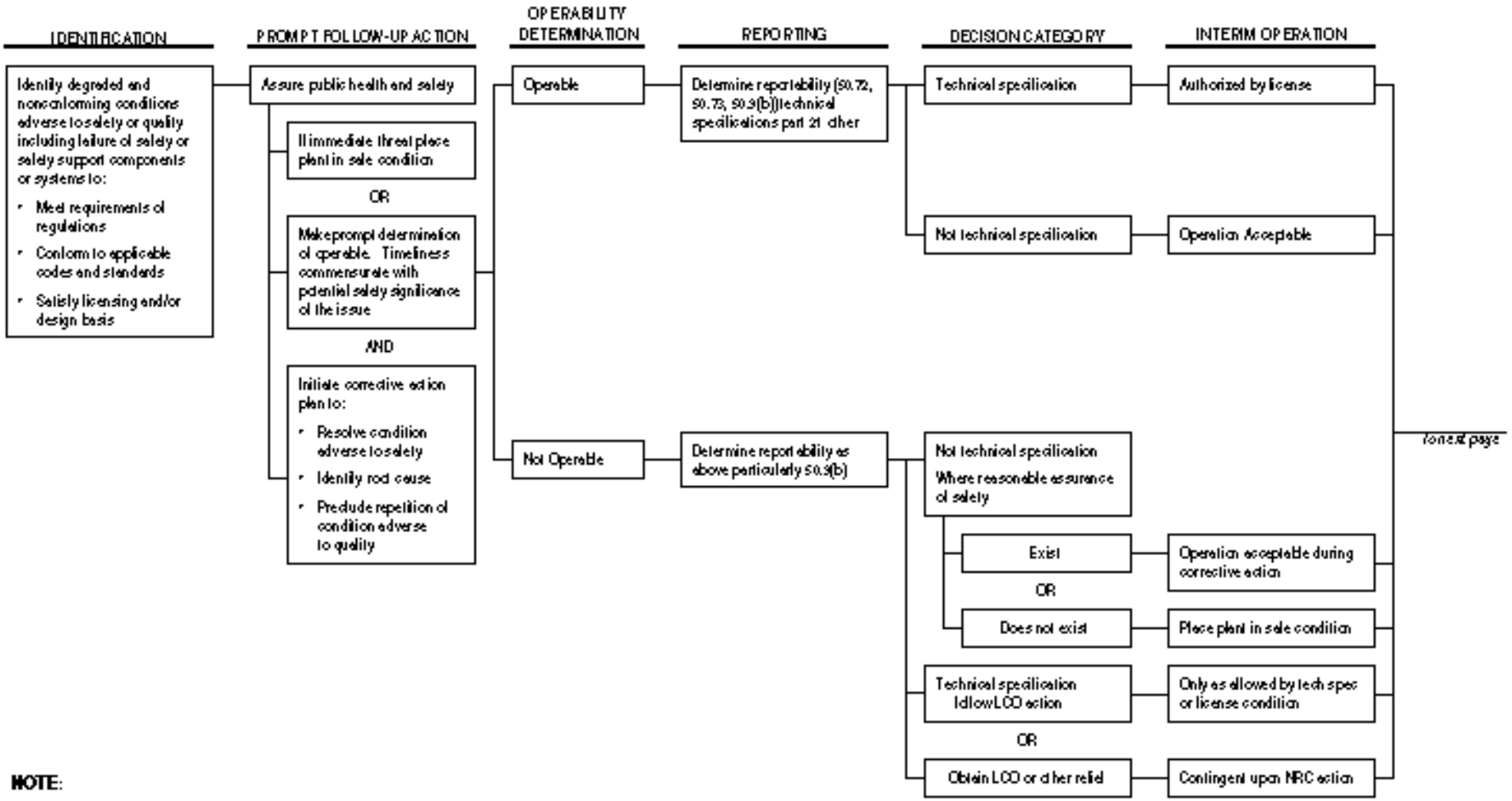
[5]Dependent on extent of risk prioritization guidance and backfit analysis.

SCHEDULE AND RESOURCE ESTIMATES FOR PROPOSED COURSE OF ACTION

	Duration	Date
D. 10 CFR 50.59 Rulemaking (3-4 FTE)		
Paper to internal review committees	____	11/15/97
Transmit Commission paper with draft rule and guidance and associated analyses/assessments (regulatory, NEPA, Paperwork Reduction Act, backfit)	+ 30 days	12/15/97
Commission approval (SRM issued)	+ 30 days	
Publish draft rule and guidance for public comment	+ 14 days	01/30/98
Public comment period ends	+ 75 days	04/15/98
Paper to internal review committees	+ 60 days[6]	
Transmit Commission paper with final rule, guidance, etc.	+ 60 days	08/15/98
Commission approval (SRM issued)	+ 30 days	
Publish final rule, guidance, and interim NRC inspection procedure	+ 45 days	11/01/98
Complete NRC staff training (inspectors and PMs)	+ 90 days	

[6]Dependent on extent of public comments received.

RESOLUTION OF DEGRADED AND NONCONFORMING CONDITIONS



NOTE:

Bulletins and generic letters, among others may provide guidance specific to an issue but counter to the generally accepted approach herein. Examples of deviations from the above approach include generic letter 88-07 on environmental qualification of electrical equipment and generic letter 87-02 on seismic adequacy (See use of JCO)

RESOLUTION OF DEGRADED AND NONCONFORMING CONDITIONS