February 12, 1997 SECY-97-035

FOR: The Commissioners

FROM: Hugh L. Thompson, Jr. /s/
Acting Executive Director for Operations

SUBJECT: PROPOSED REGULATORY GUIDANCE RELATED TO IMPLEMENTATION OF 10 CFR 50.59 (CHANGES, TESTS AND EXPERIMENTS)

PURPOSE:

To request Commission approval to seek public comment on the attached proposed regulatory guidance, given the need for and importance of consistent implementation of 10 CFR 50.59. The proposed regulatory guidance reaffirms existing regulatory practice in many areas; clarifies the staff's expectations and positions in areas where industry practice or position differs from the staff's expectations; and establishes guidance in areas where previous guidance did not exist for implementation of 10 CFR 50.59.

SUMMARY:

The staff has documented its regulatory positions on a number of issues related to the implementation of Section 50.59 of Title 10 of the Code of Federal Regulations (10 CFR 50.59) and proposes to seek public comment on this guidance. The proposed regulatory guidance reaffirms existing regulatory practice in many areas; establishes new guidance in areas where previous guidance did not exist; and, clarifies the staff's expectations and positions in areas where industry practice or position differs from the staff's expectations for implementation of 10 CFR 50.59. This paper also briefly discusses some policy issues related to potential rulemaking for 10 CFR 50.59 for which the staff will provide recommendations to the Commission at a later time.

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BACKGROUND:

Section 50.59 of Title 10 of the *Code of Federal Regulations* (10 CFR 50.59) defines the conditions under which reactor licensees may make changes to their facilities or procedures without prior NRC approval. The licensee determines whether a change meets the criteria of 10 CFR 50.59 and may be made without prior NRC approval. Section 50.59 is thus a regulatory threshold, determining when NRC prior approval of a change is needed, rather than a safety or acceptability test.

In 1995, recognition that Millstone Unit 1 had conducted refueling outages in a manner outside its design basis, as reflected by the analysis and assumptions in its updated safety analysis report (SAR), led to questions about the regulatory framework that authorizes licensees to make changes to their facilities without prior NRC approval (see memoranda from Chairman Jackson to James M. Taylor dated October 27, 1995, and November 30, 1995). As a result, the staff initiated a review of the 10 CFR 50.59 process to identify short- and long-term actions to improve implementation and oversight of the process. The staff efforts and action plan are described in memoranda from James M. Taylor to Chairman Jackson dated December 15, 1995, and April 15, 1996 (as modified by memorandum dated August 20, 1996). In summary, the staff found that difficulties with the day-to-day use of the 10 CFR 50.59 process arise when meanings of the rule language are not clear and, therefore, the staff and licensees have different interpretations, and different expectations for implementation, of the rule.

In 1989, the industry issued a document, NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations," to help licensees perform 10 CFR 50.59 evaluations. While the staff concluded that the evaluation process established in NSAC-125 is generally sound, the staff was unable to endorse the document because of some inconsistencies between specific implementation guidance and the language of 10 CFR 50.59, such as that related to increases in probability or consequences of postulated accidents. Many licensees use NSAC-125 as the basis for their 10 CFR 50.59 programs. On August 13, 1996, the Nuclear Energy Institute (NEI) issued Draft NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations," which is a slightly revised version of NSAC-125.

By memorandum to the Commission dated September 19, 1996, the staff forwarded Part 1 of the Millstone Lessons-Learned Task Group Report, in which the staff assessed NRC’s regulatory programs and processes in light of the Millstone issues,

identified problems and recommended actions. Part 2 of the Millstone Lessons-Learned Task Group Report, being forwarded to the Commission by separate correspondence, addressees policy issues and recommendations pertaining to the licensing basis, the content and revision of the SAR, commitments, and design bases. The matters addressed by Part 2 of the Millstone Lessons-Learned Task Group Report and the 10 CFR 50.59 policy issues addressed in the attached report are linked because both relate to the content and use of the SAR, and the control of changes to the facility and procedures.

DISCUSSION:

The staff and the industry have more than 30 years of experience with implementation of 10 CFR 50.59 and, although specific 10 CFR 50.59 guidance documents may be few, a reasonable body of related documents exists that has shaped the implementation of 10 CFR 50.59. The staff has identified implementation concerns with only a small subset of the total situations that licensees evaluate under 10 CFR 50.59. The overall approach of permitting changes (without prior NRC approval), that do not erode the basis of the NRC's licensing decision, has provided needed flexibility and, where implemented properly, has been and continues to be successful in preserving safety margins.

Although the staff has not endorsed NSAC-125, it has concluded, as discussed in the April 15, 1996, memorandum from James M. Taylor to Chairman Jackson, that NSAC-125 has given the nuclear power industry a reasonable foundation to establish a process that will, in most instances, produce effective evaluations related to changes to plant design or procedures. Changes of significance are highly likely to be identified by the licensee through implementation of the NSAC-125 guidance. Inspection results have confirmed that the quality of the evaluations of changes has improved since licensees began implementing the NSAC-125 guidance. However, the NSAC-125 guidance is not a requirement for any licensee, and each licensee develops its own program for performing the required evaluations under 10 CFR 50.59.

In accordance with the staff's 10 CFR 50.59 action plan, the staff has examined a number of issues that have arisen over the past several years, during its review of NSAC-125 and during its inspections, to determine (1) whether additional guidance would provide more clarity to the rule itself or (2) whether the specific language of the rule should be modified. The results of

this review are discussed in Attachment 1 to this Commission paper.

In Section III of Attachment 1, the staff discusses a number of the provisions of the rule for which the staff proposes to issue guidance. The issues are generally presented in order of increasing regulatory impact. For example, the first several issues are those for which the staff position and the industry position are similar, and the impact of the guidance will not be significant. On later issues the staff and industry positions are different and implementation of the staff position could have a significant effect on current implementation practices. Each issue or concern contains a reference to the specific rule language, a summary of the regulatory issue or concern, the industry position, and the staff position. For each of these issues, the staff proposes to issue regulatory guidance and intends to modify its inspection guidance, following receipt and consideration of public comments.

In Section IV of Attachment 1, the staff discusses two policy issues about potential rulemaking to enhance the regulatory effectiveness of the section 50.59 regulation: (1) a revision of the rule to better define the scope of the rule, and (2) a revision of the criteria that define when an unreviewed safety question exists. (This part of the report would not be issued for public comment at this time because there are other policy issues that are related to those affecting 10 CFR 50.59 that are included in the Part 2 Millstone Lessons-Learned Task Group Report upon which the staff intends to provide further information to the Commission at a later date).

The staff guidance associated with some of the more significant of the implementation issues are summarized below. Further details are provided in Attachment 1.

Significant Regulatory Issues and Proposed Regulatory Guidance

1. Application of 10 CFR 50.59 to the Resolution of Degraded and Nonconforming Conditions

The applicable regulation for dealing with degraded or nonconforming conditions is 10 CFR Appendix B, Criterion XVI which requires, among other things, that licensees take "prompt" corrective action. The staff measures the promptness with which corrective action is taken against the safety significance of the issue. Generic Letter 91-18, "Information to Licensees Regarding Two NRC Inspection Manual Sections on Resolution of Degraded and Nonconforming Conditions and On Operability," described actions to be taken for safety, operability and reportability when licensees discover degraded or nonconforming conditions. While this guidance addresses 10 CFR 50.59 in some respects, there are aspects that should be clarified.

There are two regulatory questions associated with the application of 10 CFR 50.59 to the discovery of a degraded or nonconforming condition that affects the facility or procedures described in the SAR, if immediate corrective action is not performed: (1) Under what circumstances and how quickly should a 10 CFR 50.59 evaluation be performed for a nonconforming condition? (2) What is the appropriate course of action when the result of the 10 CFR 50.59 evaluation determines that the nonconforming condition involves an unreviewed safety question (USQ)? The answer to these questions can become more complex if the licensee makes other changes to the facility or procedures (i.e., compensating actions) as a result of the nonconforming condition.

The staff has determined that a 10 CFR 50.59 evaluation is required in the following circumstances:

(1) When a licensee plans to implement compensatory actions, such as to satisfy operability requirements, until such time as the plant can be restored to the original design bases or an alternative solution is implemented. Such compensatory actions are viewed as the licensee "making changes to the facility or procedures as described in the safety analysis report," and thus require a 10 CFR 50.59 evaluation against the FSAR-described condition before they are implemented.

(2) When a licensee intends to implement a final resolution for a degraded or nonconforming condition other than full restoration. If a licensee needs to change the design bases contained or referenced in the safety analysis report, the licensee must evaluate the final resolution against the criteria in 10 CFR 50.59 and determine if an unreviewed safety question exists.

(3) When a discovered nonconforming or degraded condition is not permanently resolved at the first available opportunity. The NRC has concluded that delay beyond the first available opportunity is in essence a de facto change to the facility that should be evaluated under 10 CFR 50.59. If the fix is planned for the next available opportunity, and that opportunity has not presented itself because the plant needs to be in a hot or cold shutdown, there has not been adequate time for design, review, approval or procurement, or specialized equipment to accomplish the repair is unavailable, delay in implementation of the corrective action is acceptable if the licensee is making reasonable efforts to resolve the matter promptly. Under these conditions, assuming operability can be demonstrated, operation in a degraded or nonconforming condition may continue up to the next outage of reasonable duration and timing to effect the corrective action. If, however, such an outage occurs and the licensee does not fix the degraded or nonconforming condition, the staff would conclude that the issue is no longer simply part of an Appendix B corrective action process, but that the licensee has decided to continue the de facto change, which will require a prompt 10 CFR 50.59 determination. The key point is failure to restore the degraded or nonconforming condition promptly, despite the opportunity to do so. The staff position for corrective action that does not require an outage is similar, that is, if not corrected by the next opportunity of reasonable duration and timing, the staff would conclude that a de facto change had occurred and that a prompt 10 CFR 50.59 evaluation is required.

Otherwise, no 10 CFR 50.59 evaluation is required regarding the

discovery of a degraded or nonconforming condition that is being appropriately resolved consistent with 10 CFR Part 50 Appendix B, Criterion XVI.

The second question focuses on the course of action to follow when an existing condition, which was required to be evaluated under 10 CFR 50.59, involves a USQ. The inspection program guidance forwarded by GL 91-18 says that when the licensee changes its licensing basis (to accept a condition as-is) and a USQ is involved, staff approval (in the form of a license amendment) is required prior to operating the plant with the degraded or nonconforming condition.

The staff position is that a plant currently operating with a condition involving a USQ would not normally be required to shutdown, provided that the licensee has determined that all necessary equipment is operable and that the

licensee expeditiously (i.e., within days) submits its application for a license amendment. However, the staff would not allow plant startup unless the condition is corrected or staff approval is received.

2. Definition of Reduction in Margin of Safety as Defined in the Basis of any Technical Specifications (TS)

There are two regulatory issues related to application of the margin of safety in assessing the impact of plant changes. One issue is the point from which the reduction in margin should be measured or assessed. The other issue is where a licensee should look within the licensing basis to find the margins. The rule language itself is not definitive about the appropriate interpretations.

In determining what changes represent a reduction of the margin of safety, it should be recognized that the technical specifications and the accident analyses on which they are based, provide assurance that the response of the plant to various design basis accidents and transients is acceptable. The NRC concludes that a reduction of margin of safety has occurred when an acceptance limit is no longer met as a result of a proposed change, test, or experiment. Acceptance limits are specific values, conditions or range of parameters within which the licensee had proposed to operate the facility and which the NRC had accepted during its review of a license application. These values are derived from the plant-specific design bases analyses reviewed by the NRC. If a staff acceptance limit was not explicitly stated in the license or staff safety evaluation, the acceptance limit is the SAR calculated value.

The staff has concluded that any plant change or change in the established licensing basis that results in the plant design bases being outside the bounds of what the staff had found acceptable is an unreviewed safety question and should be submitted for staff review. Further, the staff concludes that the safety analysis report and supporting analyses, as well as the staff safety evaluation, not just the Bases section of the technical specifications, should be reviewed in determining whether a margin of safety as defined in the basis for any TS has been reduced.

3. Increase in Probability or Consequences

When assessing whether a change results in an increase in the probability of an accident or malfunction, the regulatory issue is interpreting what is meant by the 10 CFR 50.59 language of "may be increased". The staff position is that even uncertainty

about whether there is an increase in the probability of an accident or malfunction would result in the change involving a USQ. The staff also recognizes that the capability to determine such changes in probability at the time the rule was written and today are different, and that this interpretation does not take into account risk significance. This is an area that relates to a policy issue discussed later concerning the USQ threshold.

The regulatory issue related to increases in consequences centers on whether an USQ exists if a change results in any increase in radiological consequences above those reported in the safety analysis report. In certain instances, industry guidance would permit a licensee to determine that a USQ is not involved even though the radiological consequences associated with a change exceed the values reported in the SAR. The staff position is that the rule requires that any increase in consequences above that "previously evaluated in the safety analysis report" be deemed a USQ. The staff concludes that the industry guidance does not comply with the rule and therefore, licensees who follow the industry guidance on this issue could be subject to enforcement action.

4. Licensee Practice of Deleting Information from Safety Analysis Reports

The regulatory issue centers around whether a licensee could delete from its FSAR information that the licensee might consider to be unneeded (in content or level of detail) or unimportant to safety. This is not the same situation as when the FSAR is being appropriately revised as part of the periodic updating required by 10 CFR 50.71(e). There is no established policy, regulation, or guidance that governs the removal of information from safety analysis reports when the removal of information is not related to appropriately reviewed and approved changes to the facility or procedures described in the safety analysis report. Currently, the staff position is that licensees may not remove material from safety analysis reports unless the material is changed as a direct result of a change to the facility or procedures. In Part 2 of the Millstone Lessons-Learned Task Group Report, questions about the need to issue guidance that clearly identifies the types of information that should be in the SAR (or added as part of the updating process) are being considered. This review may result in determinations about what information (if any) that is presently in the SAR is not needed, and therefore, whether there is a need for a process to allow deletion of information.

It should be noted that should the staff issue regulatory guidance, the staff will take into account the Small Business

Regulatory Enforcement Fairness Act and any other applicable requirements.

Policy Issues

During its review of the implementation of 10 CFR 50.59, the staff identified two areas where it felt that rulemaking could be effective in resolving some of the issues discussed above. The two areas are: 1) the scope of 10 CFR 50.59, and 2) the criteria that define an unreviewed safety question.

1. Scope of 10 CFR 50.59

The policy question centers around whether the current scope of 10 CFR 50.59, in referring only to the SAR, is sufficient to include all information that should be subject to the regulatory control of the 10 CFR 50.59 process.

A written 10 CFR 50.59 safety evaluation is required when changes to the facility or procedures as described in the SAR are made, or tests and experiments not described in the SAR are conducted. Thus, the 10 CFR 50.59 evaluation process controls changes to that part of the plant design and operation that is described in the SAR.

The requirements for periodic updating of the safety analysis report, contained in Section 10 CFR 50.71(e) were neither implemented nor enforced in a manner to ensure that the effects of all new analyses were included in the SAR. Thus, while the facility or its operation may have been modified since initial licensing in response to new requirements or safety issues, these modifications may not have been added to the SAR, so that future changes to these parts of the facility or procedures would be subject to the 10 CFR 50.59 process.

Policy issues concerning the content and use of the SAR and licensing basis are discussed in further detail in the Part 2 Millstone Lessons-Learned Task Group Report. As discussed in that paper, the staff plans to consider these policy issues in an integrated fashion and will respond at a later time with recommendations.

2. Unreviewed Safety Question (USQ) Threshold

The policy question associated with the threshold for a USQ is related to the possible redefinition of the term "unreviewed safety question." Rulemaking to clarify the definition of USQ could reduce uncertainty about when a USQ is involved and might also eliminate the need for review of some changes that have only

a minor effect on the "licensing basis" considered by the staff, but that meet the present USQ definition.

If a change does not involve a USQ (or involve a change to the technical specifications), the licensee may proceed to make the change, and there may be up to 2 years before such a change not involving a USQ must be reported to the NRC. On the other hand, for changes involving a USQ, a license amendment must be submitted and approved, before the change can be implemented. These processes are appropriate for changes that may be significant, but can be burdensome for changes that might be found to meet the USQ definition (as presently interpreted), but that have little true safety significance.

Policy options could include: (1) a revision of the USQ criteria to permit changes involving negligible increases in probability or consequences to be accomplished without NRC review, (2) redefinition of the margin of safety criterion to codify the staff position relating to acceptance limits and basis to more clearly establish those conditions where prior staff approval would be required. However, as mentioned above, the staff will be evaluating a number of policy issues in an integrated fashion, and providing recommendations to the Commission.

CONCLUSION:

The 10 CFR 50.59 process is a significant element of the framework for nuclear power plant regulation that provides licensees with needed structure and flexibility to make changes to facilities and procedures that do not erode the basis of the NRC's licensing decision; and, when implemented properly, has been and continues to be successful in preserving the design bases and safety margins at operating plants. However, as a result of the staff's analysis of experience with the 10 CFR 50.59 process, the staff has identified areas where implementation of the process would benefit from additional clarifications of guidance. Thus, the staff concludes that existing regulatory guidance should be clarified and revised, as discussed in Attachment 1, to further reduce differences in interpretation of rule language and expectations of the process. Because the proposed regulatory guidance may modify or expand upon existing interpretations of section 50.59, the staff believes it is important to make its positions on these issues publicly available as early as possible and to seek input from the public and the industry. Therefore, the staff proposes to publish the discussion and the proposed regulatory guidance contained in Sections I through III of Attachment 1 for public

comment (Attachment 2 is the draft *Federal Register* notice). Following the staff review of the public comments, the staff will publish final regulatory and inspection guidance and further consider rulemaking if appropriate. Resources to publish the final regulatory and inspection guidance are included in the budget. Resources (approximately 3-5 FTE) to conduct a rulemaking for 10 CFR 50.59 are not in the budget but will be addressed when staff provides final recommendations to the Commission.

For the policy issues contained in Section IV of Attachment 1, the staff plans to develop integrated recommendations on these matters as well as on those that are discussed in the Part 2 Millstone Lessons-Learned Task Group Report and to provide a report to the Commission at a later date.

COORDINATION:

The Office of the General Counsel has reviewed this paper and has no legal objection.

This paper has been coordinated with the Office of the Chief Financial Officer which has not resource objection.

The Chief Information Officer has reviewed this paper for potential information management impacts and has no objection to the staff recommendations.

The Committee to Review Generic Requirements was not requested to review this proposed guidance pending receipt of public comments. Any changes in industry guidance or requirements will be subject to 10 CFR 50.109 backfit review before final issuance.

RECOMMENDATION:

That the Commission approve issuance of the proposed regulatory guidance related to implementation of 10 CFR 50.59 (not including discussion of possible policy issues and options) for a 60-day public comment period.

original /s/ by

Hugh L. Thompson, Jr.
Acting Executive Director
for Operations

Attachments: 1. Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59
2. Draft Federal Register Notice

Draft Federal Register Notice

Attachment 2

[7590-01-P]

NUCLEAR REGULATORY COMMISSION

Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59 "Changes, Tests or Experiments" - Notice of Availability and Request for Comment

The Nuclear Regulatory Commission has issued for public comment a staff document that presents proposed regulatory guidance and staff interpretations regarding implementation of 10 CFR 50.59. Section 50.59 defines the conditions under which reactor licensees may make changes to the facility or procedures as described in the safety analysis report (SAR) and the conduct of tests or experiments not described in the SAR without prior NRC approval. Changes (or tests) involving a change to the technical specifications or an unreviewed safety question require staff approval by a license amendment before implementation. The NRC has been evaluating the need to develop or clarify guidance on aspects related to 10 CFR 50.59 over the last several months. This document, entitled "Proposed Regulatory Guidance Related to Implementation of 10 CFR 50.59" presents the results of the staff's review. The proposed regulatory guidance reaffirms existing regulatory practice in many areas; clarifies the staff's expectations and positions in areas where industry practice or position differs from the staff's expectations for implementation of 10 CFR 50.59; and establishes guidance in areas where previous guidance did not exist. The document is being issued to seek comment on whether the proposed regulatory guidance is clear and whether there are other areas in which guidance would be useful. Following review of public comments, NRC will determine whether to issue a regulatory guide or to take other action. Any changes in industry guidance or requirements will be subject to 10 CFR 50.109 backfit review before issuance.

The comment period ends [60 days from publication]. Comments received after that date will be considered to the extent practical. Submit written comments on the staff document to the Chief, Rules Review and Directives Branch, U.S. Nuclear Regulatory Commission, Washington D.C. 20555-0001. Copies of comments received may be examined at the NRC Public Document Room, 2120 L Street NW, Washington DC.

Comments may be submitted electronically, in either ASCII text or WordPerfect format (version 5.1 or later) by calling the NRC Electronic Bulletin Board on FedWorld. The bulletin board may be accessed using a personal computer, a modem, and one of the commonly available software packages, or directly via Internet.

If using a personal computer and modem, the NRC subsystem on FedWorld can be accessed directly by dialing the toll free number: 1-800-303-9672. Communication software parameters should be set as follows: parity to none, data bits to 8, and stop bits to 1 (N,8,1). Using NSAI or VT-100 terminal emulation, the NRC NUREGs and RegGuides for Comment subsystem can then be accessed by selecting the "Rules Menu" option for the "NRC Main Menu." For further information about options available for NRC at FedWorld, consult the "Help/Information Center" from the "NRC Main Menu." Users will find the "FedWorld Online User’s Guides" particularly helpful. Many NRC subsystems and databases also have a "Help/Information Center" option that is tailored to the particular subsystem.

The NRC subsystem on FedWorld can also be accessed by a direct dial phone number for the main FedWorld BBS, 703-321-3339, or by using Telnet via Internet, fedworld.gov. If using 703-321-3339 to contact FedWorld, the NRC subsystem will be accessed from the main FedWorld menu by selecting the "Regulatory, Government Administration and State Systems", then selecting "Regulatory Information Mail." At that point, a menu will be displayed that

has an option "U.S. Nuclear Regulatory Commission" that will take you to the NRC Online main menu. The NRC Online area also can be accessed directly by typing "/go nrc" at a FedWorld command line. If you access NRC from FedWorld's main menu you may return to FedWorld by selecting the "Return to FedWorld" option from the NRC Online Main Menu. However, if you access NRC at FedWorld by using NRC's toll-free number, you will have full access to all NRC systems but you will not have access to the main FedWorld system.

If you contact FedWorld using Telnet, you will see the NRC area and menus, including the Rules menu. Although you will be able to download documents and leave messages, you will not be able to write comments or upload files (comments). If you contact FedWorld using FTP, all files can be accessed and downloaded but uploads are not allowed; all you will see is a list of files without descriptions (normal Gopher look). An index file listing all files within a subdirectory, with descriptions, is included. There is a 15-minute time limit for FTP access.

Although FedWorld can be accessed through the World Wide Web, like FTP that mode only provides access for downloading files and does not display the NRC Rules menu. For more information on NRC bulletin boards, call Mr. Arthur Davis, Systems Integration and Development Branch, U.S. Nuclear Regulatory Commission, Washington DC 20555, telephone (301)415-5780, e-mail AXD3@nrc.gov.

A free single copy of the staff report may be requested by those considering public comment by writing to the U.S. Nuclear Regulatory Commission, ATTN: Distribution and Mail Services Section, Washington DC 20555-0001, or by fax at (301)415-2280. Telephone requests cannot be accommodated.

Copies of the draft report are also available for review in the NRC Public Document Room, 2120 L Street, NW (Lower Level), Washington DC 20555-0001.

The report is electronically available for downloading from the Internet at: 'http://www.nrc.gov/ (Name to be assigned).' However, comments cannot be provided electronically by this means; see above discussion about the NRC BBS for electronic filing of comments.

For more information on this document contact Ms. Eileen McKenna, telephone (301) 415-2189; e-mail EMM@nrc.gov.

Dated at Rockville, Maryland, this ___ day of February 1997.

For the Nuclear Regulatory Commission

Thomas T. Martin
Director, Division of Reactor Program Management
Office of Nuclear Reactor Regulation

PROPOSED REGULATORY GUIDANCE RELATED TO IMPLEMENTATION OF 10 CFR 50.59

NOTE: In this report, cross-references are provided to the Part 2 Millstone Lessons-Learned report, and from Section III (Implementation Guidance) to Section IV (Policy Issues). These references are included for the convenience of the Commission during the review process. Prior to public release of the guidance for comment in accordance with the staff recommendation (if approved), the staff will review such references to determine if they should be modified or deleted.

Attachment 1

TABLE OF CONTENTS

I. INTRODUCTION

Section 50.59 of Title 10 of the Code of Federal Regulations (10 CFR 50.59) allows licensees the discretion to make changes to their facilities (or procedures) without prior NRC approval. Specifically, 10 CFR 50.59, in paragraph (a), states that the holder of a license authorizing operation[1] of a production or utilization facility may make changes in the facility as described in the safety analysis report (SAR), make changes in procedures as described in the SAR, and conduct tests or experiments not described in the SAR without prior Commission approval unless the proposed change, test, or experiment involves a change to the technical specifications (TS) incorporated in the license, or involves an unreviewed safety question (USQ). A proposed change, test or experiment shall be deemed to involve a USQ: (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the SAR may be increased, (ii) if a possibility for an accident or malfunction of a different type than any evaluated previously in the SAR may be created, or (iii) if the margin of safety as defined in the basis for any TS is reduced.

The licensee's determination for each modification of the facility that an unreviewed safety question (USQ) does not exist[2] provides confidence that the bases on which NRC issued a

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[1] On July 29, 1996, 10 CFR 50.59 was revised to extend applicability of the rule provisions to reactor licensees that have permanently ceased operations, and thus, who may no longer have a license authorizing operation.
It should also be noted that provisions similar to 10 CFR 50.59 are contained in sections of the regulations applicable to other types of facilities, e.g., Part 72, "Independent Storage of Spent Nuclear Fuel," and Part 76, "Certification of Gaseous Diffusion Plants."

[2]Changes to the facility which involve a change to the Technical Specifications also require prior approval by the NRC through a license amendment. For purposes of this paper, the staff's

license to operate the facility are preserved. It is thus a regulatory threshold to determine when NRC prior approval of a change is needed, rather than a safety or acceptability test. The text of the rule is given as an appendix.

In 1989, the industry issued a document, NSAC-125, "Guidelines for 10 CFR 50.59 Safety Evaluations," to help licensees perform 10 CFR 50.59 evaluations. While NRC concluded that the evaluation process established in NSAC-125 is generally sound, NRC was unable to endorse it because of some inconsistencies between the guidance and the language of 10 CFR 50.59. Many licensees use NSAC-125 as the basis for their 10 CFR 50.59 programs. On August 13, 1996, the Nuclear Energy Institute (NEI), formerly the Nuclear Utilities Management Resources Council (NUMARC), issued Draft NEI 96-07, "Guidelines for 10 CFR 50.59 Safety Evaluations," which is a slightly revised version of NSAC-125. On October 24, 1996, NEI submitted "point papers" on selected topics relative to 10 CFR 50.59 implementation.

Recognition that Millstone Unit 1 had conducted refueling outages in a manner outside its design basis, as reflected by the analysis and assumptions in its updated SAR, led to questions about the regulatory framework that authorizes licensees to make changes to their facilities without prior NRC approval (see Memoranda from Chairman Jackson to James M. Taylor dated October 27, 1995 and November 30, 1995). As a result, the staff initiated a review of the 10 CFR 50.59 process to identify short- and long-term actions to improve implementation and oversight of the process. The staff efforts and action plan are described in memoranda from James M. Taylor

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focus is on those changes that involve an USQ because this has been the area which has posed most of the implementation differences.

to Chairman Jackson dated December 15, 1995, and April 15, 1996 (as modified by memorandum dated August 20, 1996). In summary, the staff found that in spite of the industry efforts to establish guidance for 10 CFR 50.59 implementation, some confusion over the specific meaning of specific terms in the rule continues to exist and, therefore, the staff and licensees have different interpretations and different expectations for implementation of the rule.

In accordance with the action plan, a staff task group performed a review of 10 CFR 50.59. The review covered the regulation itself (including the statements of consideration for the rulemaking), past staff and legal guidance regarding 10 CFR 50.59, guidance from outside entities, such as NSAC-125 and Draft NEI 96-07, and current problems with 10 CFR 50.59. The objective of the review was to determine what issues need to be resolved (via rulemaking or guidance), and to provide guidance, if possible, regarding the use of 10 CFR 50.59. The task group considered issues that deal with the scope of the rule, i.e., when a licensee must perform a 10 CFR 50.59 evaluation as well as those related to how a 10 CFR 50.59 evaluation should be performed and whether an unreviewed safety question is involved.

Each of the issues that the task group evaluated is discussed in greater detail in this report. Section III discusses issues where the staff would propose to issue guidance. Section IV discusses issues that could involve rulemaking to implement.

As a separate initiative, a task group was formed to conduct an overall lessons-learned review that considered the findings from all of the staff activities resulting from the issues at Millstone, including the 10 CFR 50.59 action plan. Many of the findings from these activities were related to the staffs' and

licensees' abilities to identify, retrieve, and properly use information on and off the docket. The lessons-learned task group concluded that (1) the concepts of current licensing basis and design bases are not clearly understood by some licensees and NRC staff; (2) both licensees and staff have difficulty identifying and locating bases documents; and (3) bases documents are not always appropriately used in NRC licensing and inspection activities and in licensee design and facility changes. In its various reviews the staff has found that some information that should be in updated FSARs has not been included. It has also found that some information, which the staff has relied on in ensuring that licensees are in compliance with new rules and in approving licensing actions or other licensing activities, is not in documents that are subject to any regulatory control for changes the licensee may subsequently make.

The Millstone Lessons-Learned Task Group (MLLTG) prepared its report in two parts. The first part consisted of a staff level review with recommendations in the areas of inspection, licensing, enforcement, and licensee reporting, submitted to the Commission by memorandum dated September 19, 1996. The Part 2 report evaluates the findings of Part 1 and discusses policy issues and recommendations pertaining to licensing basis, the SAR, and design bases. The report discusses the major policy issues from the perspectives of licensee responsibilities and from NRC internal practices. Short-term, interim actions are identified as well as longer-term actions that address underlying shortcomings in several regulations. The staff will develop detailed plans to accomplish the actions necessary to implement the recommendations after receiving the Commission's guidance. The matters being addressed by the Part 2 Millstone Lessons-Learned task group report and the 10 CFR 50.59 policy issues are linked because both relate to the

content and use of the SAR and control of changes to the facility or procedures.

The NRC has also published a revision to its General Statement of Policy and Procedure for Enforcement Actions (Enforcement Policy) to address issues associated with departures from the Final Safety Analysis Report. This revision was published on October 18, 1996 (61 FR 54461). In particular, this revision provides additional guidance developed to address severity levels to categorize violations of 10 CFR 50.59 and 50.71(e) and reporting requirements, application of the corrective action factor, use of enforcement discretion for violations involving old design issues, and applying enforcement discretion to increase sanctions in this area.

II. RELATIONSHIP OF REVIEW OF CHANGES FOR EFFECTS ON SAFETY AND FOR 10 CFR 50.59 EVALUATION PURPOSES

In evaluating a proposed activity, a licensee is responsible for determining that the change, test or experiment is safe. In fact, this is the first step that must be completed. Only after a licensee has determined that a proposed change, test or experiment is safe, does the question of the need for NRC approval arise. A change can be safe, but still require review by NRC.

As noted above, the 10 CFR 50.59 evaluation is for the purposes of determining whether prior NRC approval of a change, test or experiment is needed. This document focuses on the section 50.59 evaluation process as this was the scope of review requested and is the area in which a number of implementation issues have been identified. The intent in providing guidance

on 10 CFR 50.59 evaluations is, in part, to address the review process in broad terms so that the effects (safety and regulatory) of a proposed change are fully considered by the licensee and their evaluation is not limited because of the existence of (or lack of) certain words in a safety analysis report. Therefore, initial screening reviews of various activities that might involve a change are particularly important; if something is not viewed as being a change, a process for review of its effects on the plant will not be implemented.

Determinations of when a change is "safe" need to be based on such factors as compliance of the change with regulations, license conditions, and applicable codes and standards, consideration of guidance such as the NRC's Standard Review Plan (which references Regulatory Guides, consensus standards and other information), and risk significance. Configuration management, quality assurance, onsite review committee approvals, and procedures, all play an important role in assuring adequate review of all changes such that safety is maintained.

Section 1 of NSAC-125, the industry guidance document, makes a similar distinction, stating:

> *The nuclear plant change process involves a two step safety analysis. One step is a determination that the change is safe. The other step is to determine if there is a Technical Specification change or an unreviewed safety question. However, the questions that define an unreviewed safety question are so fundamental to determining if a change or test is safe that the two steps are not independent...Assuming an activity has been analyzed and determined to be safe,*

a check for an unreviewed safety question is required.

In other words, the two steps, while closely related, are not the same. Determining the safety of a change or test is not the same as determining, under 10 CFR 50.59, whether a change must be submitted to NRC for approval prior to implementation.

III. DISCUSSION OF REGULATORY ISSUES OR CONCERNS

As part of its review of the rule under the established action plan, the staff evaluated a number of the provisions of the rule to determine (1) whether additional guidance would provide more clarity to the rule itself or (2) whether the specific language of the rule should be modified. The task group identified a number of issues that are discussed in greater detail in this Section and in Section IV of this report. The issues are presented in order of increasing regulatory impact. For example, the first set of issues are those for which the staff position and the industry position are similar and the impact will not be significant. The later issues are issues where the staff and industry positions are different and implementation of the staff position could have a significant effect on current implementation practices. Each issue or concern presented below contains a reference to the specific rule language, a summary of the regulatory issue or concern, the industry position, and the staff's proposed position. The staff plans to issue regulatory and inspection guidance following review of public comment.

III.A Definition of change

III.A.1 Rule language

The holder of a license authorizing operation of a production or utilization facility may (i) make changes in the facility as described in the safety analysis report, (ii) make changes in the procedures as described in the safety analysis report, and (iii) conduct tests or experiments not described in the safety analysis report, without prior Commission approval, unless the proposed change, test, or experiment involves a change in the technical specifications incorporated in the license or an unreviewed safety question. [10 CFR 50.59(a)(1)]

III.A.2 Statement of Issue or Concern

The staff is not aware of any specific issue or concern with existing guidance; however, implementation issues arise where an activity is not considered to be a change, for example, a replacement that is similar but not identical, and which was not evaluated. Thus, the staff believes there may be a need for a more complete definition of change.

III.A.3 Industry Position or Guidance

NSAC-125 and recently received NEI 96-07 (which proposes modifications to NSAC-125) contain some discussion about what would constitute a change under this rule. For instance, the industry guidance states that temporary changes to a facility should be evaluated to determine if an unreviewed safety question exists. Examples of temporary modifications include jumpers and lifted leads, temporary shielding on pipes and equipment, temporary blocks and bypasses, temporary supports or other equipment used on a temporary basis.

III.A.4 NRC Position or Guidance

NRC does not have any published guidance that defines those actions that constitute a "change" governed by the requirements of 10.CFR 50.59. The staff has interpreted "change" to include any modification or replacement of something, whether temporary or permanent, with something that is not identical to the original in design requirements. Additions (e.g., new systems or structures, procedural steps) and subtractions (e.g., abandoning a system or component in place) are also changes for purposes of determining whether the facility or procedures have been affected.

In deciding whether the activity being contemplated is a change, rather than maintenance or an activity already reviewed, the licensee needs to consider questions including, but not limited to the following: (a) whether components described in the SAR are removed, or their function is altered, or substitute (i.e., not identical) components are utilized, or changes are made as the result of a maintenance activity; (b) whether the activity would affect redundancy, diversity, separation, the probability or consequences of a loss of a non-safety system, physical interactions, seismic qualification, quality classification, missile or flooding protection, fire protection, environmental qualification, high energy line break, or masonry walls; (c) whether equipment is disabled, or a system, structure or component (SSC) is removed from service for maintenance that is part of the licensing basis but that is not addressed by TS Limiting Conditions for Operation (unless the effects were previously considered in the SAR or safety evaluation report (SER)); (d) whether the change involves lifted leads, temporary lead shielding, temporary blocks or bypasses, temporary supports or other equipment used on a temporary basis, which should be evaluated if not already considered in the SAR; (e) whether the activity requires

deviation from a SAR procedure or puts the plant in a condition where it functions differently from its SAR description.

Changes to SSCs not explicitly described in the SAR also need review because they have the potential for affecting the function of SSCs which are explicitly described. Changes which alter the design, function, or method of performing the function of a SSC, as described in the SAR, are within the scope of 10 CFR 50.59.

Further, when evaluating a change, the licensee must also consider not only operation of the facility after the change is in place, but also possible effects while the change is being made. For example, system lineups or other configuration changes while a modification is in progress may involve a USQ even though operation with the completed change would not.

III.B Definition of Facility

III.B.1 Rule Language

> *The holder of a license authorizing operation of a production or utilization facility may (i) make changes in the facility as described in the safety analysis report, [10 CFR 50.59(a)(1)]...*

III.B.2 Statement of the Issue or Concern

In practice, there have been issues concerning whether facility refers only to physical plant equipment, or whether it also includes associated design requirements. Thus, the issue is whether a more complete definition of facility is appropriate.

III.B.3 Industry Position or Guidance

Neither NSAC-125 nor NEI 96-07 contain a definition of what would constitute a facility as used in this rule.

III.B.4 NRC Position or Guidance

The staff understanding is that "facility," as used in 10 CFR 50.59 is an abbreviated form of "utilization or production facility." A "utilization facility" or a "production facility" is defined in 10 CFR 50.2; in particular, a utilization facility is a "nuclear reactor." The staff views the term "facility" to include (1) all systems, structures, and components; (2) the requirements for their design, construction, and operation; and (3) the design bases[3] and safety analysis information associated with those SSCs that are described in the SAR.

III.C Definition of Procedures

III.C.1 Rule Language

[3] In section 50.2, Design Bases is defined as that information which identifies the specific functions to be performed by a structure, system or component of a facility, and the specific range of values chosen for controlling parameters as reference bounds for design. These values may be (1) restraints derived from generally accepted "state of the art" practices for achieving functional goals, or (2) requirements derived from analysis (based on calculation and/or experiments) of the effects of a postulated accident for which a structure, system or component must meet its functional goals.

The holder of a license authorizing operation of a production or utilization facility may (i) make changes in the facility as described in the safety analysis report, (ii) make changes in the procedures as described in the safety analysis report, [10 CFR 50.59(a)(1)]...

III.C.2 Statement of the Issue or Concern

The staff is not aware of any specific issue or concern with existing industry guidance; however, in practice, there have been questions as to whether procedures includes descriptions of system operation, or controls on processes that are not characterized as "procedures."

III.C.3 Industry Position or Guidance

Neither NSAC-125 nor NEI 96-07 contain a specific definition of what constitutes a procedure as used in this rule. However, Section 4.1.2 of both of these documents state that procedures are not limited to merely those items specifically identified as procedures (e.g., operating, chemistry, system, test, surveillance, and emergency plan), but that procedures include anything described in the safety analysis report that defines or describes activities or controls over functions, plant configuration, tasks reviews, tests, or safety review meetings. If changes to these activities or controls are made, such changes qualify as changes to procedures as described in the safety analysis report, and the changes would be governed by the requirements of 10 CFR 10.59.

III.C.4 NRC Position or Guidance

The staff defines "procedures" to include those procedures outlined, summarized or completely described in the SAR and also items not specifically identified as procedures, but which define or describe activities or controls over functions, plant configurations, tasks, reviews, tests, or safety review meetings. This includes procedures on initial operations, organizational information, and modes or sequences of plant operation. Changes that would result in system operation in a way that deviates from the way the system operation is described in the SAR (in words or by drawings), should be considered as a change in procedure.

Emergency Operating Procedures (EOP) include operator actions associated with response to design basis events, which are described in the SAR, but also address operator actions for scenarios which are outside the design basis and which may not be described in the SAR. The rule would require evaluation under 10 CFR 50.59 only for those procedures or parts of procedures in which the operator actions are described in the SAR. In practice, the operator actions in the EOP for design basis accidents and for severe accidents are interwoven and therefore it would be very difficult to change EOPs only with respect to the portions described in the SAR. The subject of sufficiency of SAR content is discussed in Section IV.A.

Specific licensee programs, such as emergency preparedness plans, security plans and quality assurance plans have change control processes explicitly established by regulation (in 10 CFR 50.54) even though the plans may also be referenced by the SAR. These specific change control processes are considered applicable to the plans rather than the 10 CFR 59 process because the 10 CFR 50.54 processes generally contain more restrictive reporting requirements and different criteria for determining when prior staff approval is needed. Note, for

instance, that 10 CFR 50.54(a)(3) states that each licensee may make a change to a previously accepted quality assurance program description included or referenced in the Safety Analysis Report, provided the change does not reduce the commitments in the program descriptions previously accepted by the staff.

III.D Definition of Test or Experiment

III.D.1 Rule Language

> *The holder of a license authorizing operation of a production or utilization facility may ... (iii) conduct tests or experiments not described in the safety analysis report, without prior Commission approval [10 CFR 50.59(a)(1)]...*

III.D.2 Statement of the Issue or Concern

There have been implementation issues concerning whether particular evolutions, which may have used existing procedures to some extent, were "tests" requiring evaluation. Clarification of which tests or experiments fall under the requirements of 10 CFR 50.59 could be helpful.

III.D.3 Industry Position or Guidance

Neither NSAC-125 nor NEI 96-07 contain a specific definition of what constitutes a test or experiment as used in this rule.

III.D.4 NRC Position or Guidance

The staff has not previously published specific guidance on the definition of a test or experiment. Existing 9900 inspection

guidance on 10 CFR 50.59 (1984) says: "This pertains to the performance of an operation not described in the SAR which could have an adverse effect on safety-related systems." In order to meet the requirements of the rule, the staff position is that any tests or experiments not described in the SAR need to be evaluated to determine if a USQ (or a TS change) is involved.[4] The staff considers a test or experiment to be a special procedure for a particular purpose or an evolution performed to gather data. Some examples of when a test or experiment is not described in the SAR, and thus requires evaluation, are: (1) if a test previously described in the SAR will be done in a different way from that described in the SAR or (2) if tests are done to verify the adequacy of modifications such that the tests could be considered a replacement for preoperational or startup tests that formed the basis for NRC's acceptance of the adequacy of the SSC.

III.E Definition of "as described"

III.E.1 Rule Language

> *The holder of a license authorizing operation of a production or utilization facility may (i) make changes in the facility <u>as described</u> in the safety analysis report, (ii) make changes in the procedures <u>as described</u> in the safety analysis report*

[4] In 50.34(a)(4) and (b)(4), it is noted that the FSAR is to include analysis and evaluation of design and performance of SSCs with the objective of assessing risk to public health and safety resulting from operation of the facility and determination of the margins of safety during normal operations, and the adequacy of SSCs for prevention of accidents and mitigation of consequences. Therefore, an inadequate evaluation of such a test or experiment would be a violation of more than minor severity if the test or experiment as conducted affected these factors.

[10 CFR 50.59(a)(1)]...

III.E.2 Statement of the Issue or Concern

The regulatory concern is the degree to which a system or component needs to be described in a safety analysis report in order to have any changes to it evaluated under the provisions of 10 CFR 50.59. Specifically, some instances have arisen where a licensee concluded that a change did not require a 10 CFR 50.59 evaluation because the specific aspect of the SSC being changed was not explicitly discussed in the SAR.

III.E.3 Industry Position or Guidance

NSAC-125 and NEI 96-07 do not contain specific instructions on this issue, but do provide some general guidance. More specifically, the industry guidance recommends that safety evaluations be performed for changes to the facility that affect the design, function, or method of performing the function of a structure, system, or component described in the safety analysis report either by drawing, text, or other information relied upon by the NRC. It also recommends that changes to structures, systems, or components that are not explicitly described in the safety analysis report have the potential for affecting structure, systems, or components that are in the safety analysis report and, therefore, should be evaluated under 10 CFR 50.59.

III.E.4 NRC Position or Guidance

Existing guidance in NRC Inspection Procedure 37001 states that a change to the facility or procedures as described in the SAR requires a written 10 CFR 50.59 safety evaluation "only if both the SSC or procedure being changed is described in the most

recently updated SAR and the *SAR description of the SSC or procedure being changed* would be affected by the change." (Emphasis added). Considering the intended function of 10 CFR 50.59, the staff now concludes that if the change affects any SSC as described in the SAR (not just the SSC that is being directly changed) such that the FSAR description is no longer accurate, then a 10 CFR 50.59 evaluation is required. For example, so-called indirect or secondary effects of a change need to be considered. An SSC that itself is not described in the SAR can affect others that are--if a change to one part of the facility results in some other change to "the facility as described in the SAR", the first change is within the scope of 10 CFR 50.59. The change could also be at a level of detail that is not explicitly described in the SAR, but could affect a function or SSC that is described. Therefore, the staff will revise its inspection guidance to reflect this position.

The staff concludes that a broad interpretation of the phrase "as described" is appropriate when evaluating proposed changes under 10 CFR 50.59. The staff definition of the phrase includes words, phrases, models, assumptions, pictures, graphs, and figures that represent the system, structure or component of interest. Therefore, the staff concludes, for the purposes of 10 CFR 50.59, that the information in the FSARs that presents the purpose, quality, kind, number, condition, function, operation, use, design, or material of systems, structures or components are captured by the language of the rule. The above type of information for systems, structures and components that are included in the FSAR are considered part of the design basis, and subject to evaluation, that is, they are within 10 CFR 50.2 and 50.59.

III.F Definition of Final Safety Analysis Report

III.F.1 Rule Language

> *The holder of a license authorizing operation of a production or utilization facility may (i) make changes in the facility as described in the safety analysis report, (ii) make changes in the procedures as described in the safety analysis report, and (iii) conduct tests or experiments not described in the safety analysis report, without prior Commission approval [10 CFR 50.50(a)(1)]...*

III.F.2 Statement of the Issue or Concern

The regulatory concern centers around the specific information (content and level of detail) that should be included in a licensee's safety analysis report. The issue here is whether there is regulatory clarity related to the content of the safety analysis report and what information should be included as part of SAR updates.

III.F.3 Industry Position or Guidance

In NSAC-125, the guidance defines the content of the safety analysis report as that information defined by 10 CFR 50.34(b). NSAC-125 further states that the FSAR is to be a living document and is periodically updated to incorporate the information defined by 10 CFR 50.71(e). The staff is unaware of any proposals by the industry to change the content of the safety analysis reports from that defined by the regulations (refer to section III.N for discussion about potential for deleting information from the SAR).

III.F.4 NRC Position or Guidance

The Safety Analysis Report (SAR) as referred to in 10 CFR 50.59 is the final SAR as described in 10 CFR 50.34(b), as modified by updates[5] in accordance with 10 CFR 50.71(e). In accordance with 10 CFR 50.34(b), the SAR is that part of the application providing technical information. The SAR contains information that describes the facility, sets forth the facility's design bases and limits on its operation, and presents a safety analysis (The full text of 10 CFR 50.34(b) is provided in Appendix B). The SAR also includes information on site evaluation factors, information on organizational responsibilities, administrative controls, and plans for conducting normal operations and for coping with emergencies. Note that the SAR includes documents that are referenced as part of the description, but not documents merely listed as references. The SAR description includes the text, tables, figures and drawings.

The rule requires all information described in the SAR be evaluated to see if the change would make the information in the SAR no longer true or accurate and to determine whether a change in TS or a USQ is involved. A SAR may contain certain information, such as the population distribution[6] outside of the

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[5] Note that 50.59 applies to production and utilization facilities, a category that includes nonpower reactors. The update rule in 50.71(e) says "Each person licensed to operate a nuclear power reactor pursuant to the provisions of 50.21 or 50.22 of this section shall update periodically... the FSAR."

A recent rule change (July 29, 1996, 61 FR 39278) added Section 50.71(f) which extended applicability of 10 CFR 50.71(e) to power reactors undergoing decommissioning. This change also specified that only Sections 50.71 (a), (c), and (d) apply to nonpower reactors no longer authorized to operate.

[6] The Statement of Considerations for the rule change that added 50.71(e) states: "Minor differences between actual and projected population figures or other such changes in the site environment need not be reported unless the conclusions of safety analyses relative to public health and safety are affected and the licensee has prepared new analyses as a result of NRC

reactor site, which may not fit under Section 50.59 or otherwise be specifically controlled under section 50.54.

Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants, LWR Edition," and the Standard Review Plan (NUREG-0800) provide additional clarification of the information that is to be included in the safety analysis report and that is necessary to support a licensing review; however applications for at least half of the operating plants were submitted before these documents were issued and thus may not be consistent with this guidance.

Section 50.71(e) requires the SAR to be updated and submitted to NRC at regular intervals not to exceed 2 years; as stated in the rule, updates are to include the effects of changes to the facility, safety evaluations performed by the licensee, and new analyses performed at Commission request. Thus, as part of the periodic updates, the staff would expect licensees to include facility or procedure changes required as a result of additions to the licensing basis such as through regulations and orders. Examples where updates to the SAR would have been expected include changes resulting from issues such as Anticipated Transients without Scram, station blackout, and inter-system loss-of-coolant accidents.

Since updates may be submitted at two year intervals, at any given time, the SAR version last submitted to the staff will be out of date, as changes have been made, but not incorporated in the SAR in the periodic update cycle. For purposes of conducting 10 CFR 50.59 evaluations, a licensee needs to

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requirements." Thus, while changes to such information are not subject to 50.59, the general requirement in 50.71(e) to maintain the FSAR current may necessitate updating of the FSAR to reflect new information on site environs.

consider not just the SAR update as last submitted, but also any changes already made, whether under 10 CFR 50.59 or 10 CFR 50.90, that will be reflected in the UFSAR[7] when it is resubmitted under 10 CFR 50.71(e). (NSAC-125 guidance acknowledges this point on p.4-1).

III.G Industry Use of a Screening Process

III.G.1 Rule Language

None

III.G.2 Statement of the Issue or Concern

Screening is a practical approach that many licensees use to determine which changes require further analysis under 10 CFR 50.59, and which can proceed without further review. A number of NRC inspections have identified incomplete or hasty screening such that changes that should have been evaluated were not.

III.G.3 Industry Position or Guidance

Some licensees employ a screening approach to determine which changes require further analysis under 10 CFR 50.59, and which can proceed without further review. Typically, a screening process will determine if there is a change to the plant, whether the change affects the SAR descriptions, and whether the change would involve a change to the TS or be a USQ.

[7] There is no explicit regulatory requirement for a licensee to update the SAR on a day-to-day basis as changes are made. As a practical matter for purposes of implementing section 50.59, a licensee needs some process to take into account changes that have already been implemented in the facility or procedures (even if not yet reflected in the UFSAR); otherwise, a subsequent 10 CFR 50.59 evaluation may be based on inaccurate or incomplete information.

Preliminary industry guidance related to 10 CFR 50.59 screening processes was included with the October 24, 1996 letter from NEI.

III.G.4 NRC Position or Guidance

The staff believes that all proposed changes or modifications, wherever in the plant, need to be considered to determine whether a 10 CFR 50.59 evaluation is required. This does not mean all changes will require an analysis under 10 CFR 50.59. If a licensee uses a screening process, the process must be rigorous enough to actually identify those changes which will require a 10 CFR 50.59 evaluation. Screening processes should consider such factors as discussed in the sections discussing Change (Section III.A), and Test or Experiment (Section III.D), and "as described" (section III.E). A number of NRC inspections have identified examples of incomplete or hasty screening. The problem is attributed to a lack of understanding on the part of licensees relating to the scope of application of the 10 CFR 50.59 rule. For example, if a licensee believes that the scope includes only those SSCs specifically mentioned in the SAR, and not an SSC absent from the SAR but that has the potential for affecting the function of those SSCs specifically mentioned, then the licensee could prematurely conclude that the SSC being changed is not within the scope of the rule and that a 10 CFR 50.59 evaluation is not necessary. Thus, individuals performing such activities need accessible records of the SAR, changes already made that have not been included in the SAR, and other reference documents, as well as appropriate training on the scope of 10 CFR 50.59.

Under 10 CFR 50.59(b), the licensee must maintain records of such written evaluations for changes to the facility or procedures to the extent that these changes constitute changes

"as described in the SAR", that is, if the change is considered to be within the scope of the rule. There are no requirements in 10 CFR 50.59 to retain records of licensee evaluations performed to determine whether a "change" is within the scope of 10 CFR 50.59. While not specifically required by 10 CFR 50.59, documentation of screening evaluations might constitute records of activities affecting quality or safety and therefore fall under the documentation requirements established by 10 CFR Part 50 Appendix B.

III.H Definition of Accident Previously Evaluated

III.H.1. Rule language

> *A proposed change, test or experiment shall be deemed to involve a USQ (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the SAR may be increased, (ii) if a possibility for an accident or malfunction of a different type than any evaluated previously in the SAR may be created, or (iii) if the margin of safety as defined in the basis for any TS is reduced. [10 CFR 50.59(a)(2)].*

III.H.2 Statement of Issue or Concern

The staff is not aware of any specific issue or concern with the current industry definition of the term "accident previously evaluated." However, as discussed in the issue concerning completeness of the SAR (section IV.A), not all accidents previously evaluated for a particular plant may be included in its SAR.

III.H.3 Industry Position or Guidance

NSAC-125 notes that the accidents previously evaluated should include not only those events for which the plant was originally designed or analyzed, but also those added to the licensing basis and reflected in the updated SAR.

III.H.4 NRC Position or Guidance

NRC does not have any published guidance that defines accidents previously evaluated. The staff position is that accidents previously evaluated in the SAR include those anticipated transients and design basis accidents evaluated in the SAR (so-called Chapter 15 events), as well as events described in the SAR which the plant is designed to endure, such as earthquakes, fire, flood, high winds, tornados, missiles, offsite hazards and high energy line breaks. This should also include events or conditions added to the design and licensing basis through regulations and orders such as anticipated transient without scram and station blackout. Further, to the extent that plant features or procedures needed for response to other conditions, such as severe accidents, fuel handling accidents or heavy loads, are described in the SAR, the accidents previously evaluated would refer to those postulated conditions which those features were intended to prevent or mitigate.

Some confusion has been reported with respect to whether the April 1996 9900 interim Inspection Manual guidance on 10 CFR 50.59 limited accidents previously evaluated to those analyzed in Chapter 15 of the SAR. This guidance referred to Design Basis Events, which in context was meant to refer to those

accidents for which the plant must withstand the event and meet specified acceptance criteria, as opposed to severe accidents which might be considered from a risk perspective. This guidance did not exclude events such as earthquakes, missiles, winds, flooding which are also part of the design basis. The staff will clarify this guidance.

Further, while the scope of accidents and transients is generally consistent between the staff position and industry guidance, the staff recognizes that SARs as presently written may not include all such events. As noted in Part 1 of the Millstone Lessons-Learned Task Group report, not all licensees have interpreted the FSAR update requirements to require that information on such events be added to the FSAR. Thus, the SAR may not include all accidents previously evaluated for that facility.

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

III.I.1 Rule Language

> *A proposed change, test or experiment shall be deemed to involve a USQ (i) if the probability of occurrence or the consequences of an accident or <u>malfunction of</u>*

equipment important to safety previously evaluated in the SAR may be increased, or (ii) if a possibility for an accident or malfunction of a different type than any evaluated previously in the SAR may be created [10 CFR 50.59(a)(2)]...

III.I.2 Statement of Issue

The NRC and industry have had differing views concerning when a malfunction is of a different type, in particular to what level (system, component), and whether it is the cause of the malfunction or the effect on the rest of system performance. The staff's position on malfunction focuses not only on whether the effects of the malfunction are bounded by the analysis but also on whether there is a different cause.

III.I.3 Industry Position or Guidance

The term "malfunction" is defined in NSAC-125 as *the failure of structures, systems and components to perform the safety functions described in the SAR.*

A NUMARC/EPRI report TR-102348, Guideline on Licensing Digital Upgrades, suggested that to determine if a new type of malfunction has been created, the licensee should look for "any new types of system-level failures that would result in effects not previously considered in the FSAR."

III.I.4 NRC Position or Guidance

The staff believes that a more complete definition of "malfunction" than what is contained in NSAC-125 is *an undesired response of equipment, for example, failure to operate, inadvertent operation, operation in an unexpected*

manner, operation with less than rated capacity, and failure to perform function as designed.

Since structures, systems, and components which are not safety-related may be within the scope of 10 CFR 50.59, the NSAC-125 definition of "malfunction", which limits malfunctions to safety functions, should not be interpreted to mean that only safety-related functions are considered candidates for malfunction. Failure of a structure, system, or component to perform its intended function, even if that function is not specifically safety-related, should be evaluated to determine if the failure will have an effect on the proper operation of equipment within the scope of 10 CFR 50.59.

Note that 10 CFR 50.59 refers to malfunction of equipment "important to safety." In the SAR, malfunctions are evaluated for equipment that can initiate accidents and transients, as well as for equipment intended to mitigate the consequences of accidents. Therefore, in considering the scope of equipment for which malfunctions should be addressed, the licensee must address not only safety-related equipment, but also other equipment that may be relied upon such that safety-related equipment performs its intended functions and equipment that can initiate accidents and transients. Generally, the equipment important to safety for a particular plant is determined as part of the licensing reviews, and the malfunctions are evaluated in the SAR to the extent that they affect plant safety.

In determining whether a malfunction is of a different type than any evaluated previously in the safety analysis report, some licensees believe they need to consider only the results and not the mode of failure (as suggested in TR-102348). The staff provided clarifications concerning TR-102348 in Generic

Letter 95-02. Specifically, the staff's position was that the "system-level" failure should be malfunction of the equipment being modified. As stated in GL 95-02, it is the digital equipment replacing the analog equipment, rather than the otherwise unchanged system of which that equipment is a part, that is to be analyzed to see if a malfunction of a different type could be created.
In considering malfunctions of equipment, the staff would recommend that this be done at the component level. However, for some SSC, the evaluation of malfunctions discussed in the SAR may well have been only at the train or overall system level.

Further, in determining whether a malfunction is of a different type, the licensee needs to consider not only the effect of the malfunction on equipment or plant response but also what causes the malfunction. If the proposed activity could lead to a different initiator, or involves a failure mode of a different type than the types previously evaluated, then the failure results from a malfunction of a different type (and involves a USQ), even though the accident may be the same. Section 4.2.6 of NSAC-125 gives as an example, *"replacement of a mechanical control system on equipment important to safety with a digital control system that can potentially fail in a different mode".* For example, if a pressure transmitter using mechanical linkage is replaced with an oil-filled transmitter, oil loss is now a failure mechanism which might result in a type of failure at the output of the transmitter that did not exist previously, and therefore was never analyzed. This is a new type of malfunction, and should need staff review. If a digital trip system is now being used, and software failure is a new failure mode, staff review is also required. Further, the mode of component failures, particularly electrical equipment and

rotating equipment, can have a negative effect on connected components or on components in close physical proximity.

III.J Licensee Implementation of Modifications Associated with Technical Specifications

III.J.1 Rule Language

> *The holder of a license...who desires...(2) to make a change in the facility or the procedures described in the safety analysis report or to conduct tests or experiments not described in the safety analysis report, which involve...a change in technical specifications, shall submit an application for amendment of his license... [10 CFR 50.59(c)]*

III.J.2 Statement of the Issue or Concern

This regulatory issue relates to situations where a licensee is implementing modifications, whether on its own initiative or in response to Commission requirements and technical specifications will need to be modified as a result of the modification. In some cases the licensee has implemented the modification, without staff review, and subsequently requested a license amendment to add or modify the TS requirements to conform with the implemented modification.

III.J.3 Industry Position or Guidance

The staff is unaware of any industry position in this area.

III.J.4 NRC Position or Guidance

The staff has not previously published guidance on this topic. Section 50.59 states that a change to the facility that would involve a change to the technical specifications requires prior approval from the NRC. Therefore, the staff concludes that where technical specifications are involved with a planned modification, such that staff review of the associated TS will be required, staff approval of the proposed modification (and TS) must occur before the ongoing modification is implemented.

III.K Need for Plant-Specific 50.59 Evaluations When Implementing Generic Modifications

III.K.1 Rule Language

None

III.K.2 Statement of the Issue or Concern

A licensee may be considering a change to the facility that is similar to one that has either (1) already been made at another operating plant (following staff review), (2) is in response to an NRC communication, or (3) was subject to NRC review on a generic basis (such as through a topical report). In some cases a licensee has not performed a review under 10 CFR 50.59 to determine if staff review of their proposed change was necessary based on a licensee conclusion that the change was already found acceptable at other facilities.

III.K.3 Industry Position or Guidance

The staff is unaware of any industry guidance on this issue.

III.K.4 NRC Position or Guidance

The staff has not previously published guidance on this issue. The 10 CFR 50.59 process allows an individual licensee to make changes to its facility without prior approval under specified conditions. NRC involvement and approval of plant changes for other plants does not relieve a licensee of its responsibility to evaluate proposed changes for their facility in accordance with 10 CFR 50.59. An NRC safety evaluation for a facility modification proposed in response to a generic (or plant-specific) issue is not sufficient to conclude that implementation of the modification does not involve a USQ. The NRC evaluation does not normally address the broader implications of a licensee’s proposal upon the facility as a whole, but rather focuses on the acceptance criteria related to the safety issue itself.

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

III.L.1 Rule Language

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

III.L.2 Statement of the Issue or Concern

In some instances licensees have determined that existing TS requirements are not the "lowest functional capability or

performance levels of equipment required for safe operation of the facility," as defined in Section 50.36(c)(2), "Limiting Conditions for Operation." This situation may have resulted from a reanalysis, discovery of unexpected system degradation or response, or other information. In these instances, the licensee implemented administrative limits to ensure that the performance levels, with these administrative limits, met the safety requirements. The regulatory issue is whether there is a need to provide additional guidance that defines the actions that a licensee should undertake and whether the failure of the licensee to request a technical specification change to modify the existing technical specifications constitutes a violation of 10 CFR 50.59 or some other regulatory requirement.

III.L.3 Industry Position or Guidance

The staff is unaware of any industry guidance in this area.

III.L.4 NRC Position or Guidance

The staff has not published guidance that specifically addresses this topic. The staff position is that upon discovering such conditions, the licensee should take the appropriate action to put the plant in a safe condition (such as by imposing more conservative administrative limits), and also take action (such as requesting a license amendment) so that the TS represent the minimum requirements. The circumstances should also be reviewed for reportability under 10 CFR 50.72 and 10 CFR 50.73 with respect to operation outside the design basis. Failure to seek such approval could be considered as a failure of a licensee to take prompt corrective action and would be inconsistent with Criterion XVI (Corrective

Action) of Appendix B to 10 CFR Part 50. The staff has taken enforcement action on this basis for such situations. A violation of 10 CFR 50.59 could be involved if the licensee had made a change to the facility or procedures that resulted in the TS no longer being adequate.

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

III.M.1 Rule language

The rule does not directly refer to or address the use of PRA in 10 CFR 50.59 evaluations. It does, however, address probabilities and consequences of accidents, which can be evaluated with PRA techniques.

III.M.2 Statement of Issue or Concern

The issue is whether and how PRA techniques may be used in 10 CFR 50.59 evaluations. The staff is not aware of any specific issue or concern with the current industry practice and the use of PRA in such evaluations appears to have been limited. The issue is being discussed because of other initiatives under the PRA Implementation Plan, and interest in risk-informed regulation.

III.M.3 Industry Position or Guidance

The industry guidance (NSAC-125) notes that PRA is a tool that may be used in evaluating the safety of proposed changes, but

is not necessary for addressing the requirements of 10 CFR 50.59, which are deterministically based.

III.M.4 NRC Position or Guidance

The NRC currently does not have any published guidance on the role of PRA in 10 CFR 50.59 evaluations. However, as a general matter, for the foreseeable future, essentially all use of PRA in regulatory applications will require NRC staff review, in particular, for those applications which emphasize numerical results.

Section 50.59 is a regulatory test of whether a change falls within the licensing envelope reviewed and approved by the staff, not a test of its safety or risk significance. The reference point for evaluation of a change is the FSAR. The FSAR analyses are typically deterministic and are based on a set of postulated design basis events and the single failure criterion. By contrast, a typical analysis utilizing PRA would employ all current and documented information available on the probability of initiating events and the availability and reliability of the facility systems, system configurations, and procedures as needed. PRA analyses of accident sequences consider more than a single failure. Thus, in general, the staff concludes that PRA is not suitable as a decision-making tool for 10 CFR 50.59 evaluations. However, as PRA is more fully integrated into the regulatory process (i.e., through risk-informed license amendments), its role in 10 CFR 50.59

evaluations will naturally increase. The discussion below provides further perspective.

PRA techniques are increasingly being used to provide risk insights into the design and operation of nuclear facilities. The acceptability of PRA results depends not only on the application of the techniques (e.g., assumptions and models) and the quality of the data, but on how the results are interpreted and used in the decision-making process. PRA logically and quantitatively relates the performance of parts to the performance of the whole. For example, applied to a nuclear power plant, it may be used to analyze component and system unavailabilities together with initiating event frequencies to obtain core damage frequencies.

In general, applying PRA in 10 CFR 50.59 evaluations would be associated with unreviewed safety question determinations. Where PRAs were used as part of the basis for a previous licensing decision (as documented in the safety analysis report), facility changes that increase the related initiating event frequencies or equipment unreliability or accident consequences would constitute unreviewed safety questions.

With respect to more traditional topics where PRA was not used in the licensing basis, PRA results and risk insights would play no direct role in the evaluation of potential unreviewed safety questions. However, information regarding changes in initiating event frequencies and equipment reliability estimates can be used in answering the 10 CFR 50.59 questions related to unreviewed safety question determinations. Further, information underlying the PRA models can be used to address the 10 CFR 50.59 questions relating to new accidents and accident consequences.

III.N Licensee Practice of Deleting information from Safety Analysis Reports

III.N.1 Rule Language

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

III.N.2 Statement of the Issue or Concern

The regulatory issue centers around whether a licensee could delete information that the licensee might consider to be unneeded (in content or level of detail) or unimportant to safety from its FSAR. This is not the same situation as when the FSAR is being revised as part of the periodic updating required by 50.71(e).

III.N.3 Industry Position or Guidance

The industry believes that a licensee may remove non-safety relevant information from the safety analysis report through a disciplined program that documents the rationale for the change and the supporting evaluations are retained by the licensee.

III.N.4 NRC Position or Guidance

The staff recognizes that there is no established policy or guidance with respect to removal of information from the FSAR not associated with changes to the facility or procedures. The staff position is that licensees may not remove material from safety analysis reports unless the material is changed as

a direct result of a change to the facility. Section 50.59 addresses the process for the licensee to make changes to the facility or procedures as described in the SAR, and 10 CFR 50.71(e) addresses FSAR updating requirements such that the updated FSAR reflects accurate information and includes the effects of changes to the plant. Together, these rules govern the process for changing the plant and then updating the FSAR description to correspond. For example, if a licensee removes a system (where such removal is a change to the facility as described in the SAR), a 10 CFR 50.59 evaluation would be performed to determine if the removal involved a USQ. If not (and if no TS change would be involved), the system may be removed, and the next FSAR update submitted would reflect system removal. Following issuance of a license amendment, the FSAR might need to be updated to conform. Another way the FSAR may be changed is if a licensee revises its licensing basis ("as described in the SAR"), to accept a nonconforming condition as the new licensing basis. The SAR description must be modified as a result of the change to correspond with the change to the licensing basis that has occurred to the facility.

However, there is no established process for how a licensee might remove information under other circumstances. Since the FSAR is the primary document on which the NRC based its safety review for licensing, the removal of information from the FSAR has the potential to affect this basis and subsequent 10 CFR 50.59 evaluations.

Inherent to a policy of permitting a licensee to remove FSAR information is a determination that the information was not needed to support the licensee’s application or the staff’s safety evaluation documenting the acceptability of the licensee’s application. Section 50.34 lists the information

that is to be contained in the SAR. Regulatory Guide 1.70 (Standard Format and Content of SAR), and the Standard Review Plan (NUREG-800) provide some understanding about what information is necessary to support a licensing review; however, applications for at least half of the currently operating plants were submitted before these documents were issued. Some plants were licensed with FSARs consisting of just a few volumes; other FSARs are many times larger, with much more detail. In evaluating the earlier applications, the staff may have relied on information located in other documents; later SARs might have more detail in certain respects than was absolutely required for the staff's review.

The standards that should apply to "removal of information" from the SAR are not clear. If one says to apply the 10 CFR 50.59 criteria, what is the "change" to be evaluated to determine if a USQ is involved? If the facility or its operation is not affected (which would appear to be the case if the change is deletion of SAR text or figures), how could there be a USQ (or even a TS change)? On the other hand, if the licensee subsequently changes the part of the facility (which is no longer described in the SAR) in such a way that a USQ is involved, there is the potential regulatory concern in that the basis for licensing may be undermined by the licensee's actions.

Even if removal of information not associated with "facility or procedures" were not a concern for 10 CFR 50.59, it might still be of concern from the perspective of the completeness and accuracy of the SAR. Generic Letter 80-110, in answer to a question on whether information no longer applicable to an operating plant could be eliminated, stated "Information pertaining to programs described in the original FSAR with amendments, such as the initial training program and the

preoperational test program, should be submitted as part of the initial updated FSAR for completeness. The intent here is to locate previously submitted information in one document."

Therefore, the staff position is that licensees may not delete information from the SAR unless the material is changed as a direct result of a change to the facility or procedures made in accordance with 10 CFR 50.59 or 10 CFR 50.90. In Part 2 of the Millstone Lessons-learned task group report, questions about the need to issue guidance that clearly identifies the types of information that should be in the SAR (or added as part of the updating process) are being considered. This review may result in determinations about what information (if any) that is presently in the SAR is not needed, and therefore, whether there is a need for a process to allow deletion of information.

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

III.O.1 Rule Language

There are no provisions within 10 CFR 50.59 that define how 10 CFR 50.59 applies to the circumstances when a licensee identifies a degraded or nonconforming condition. As a general matter, the applicable regulation for dealing with this circumstance is 10 CFR Appendix B, Criterion XVI which requires, among other things, that licensees take "prompt" corrective action.

III.O.2 Statement of the Issue or Concern

There are two regulatory questions, associated with 10 CFR 50.59, related to how a licensee should proceed when a licensee discovers a degraded or nonconforming condition that involves

the facility or procedures described in the SAR: (1) Under what circumstances and how quickly should a 10 CFR 50.59 evaluation be performed for a nonconforming condition? (2) What is the appropriate course of action when the result of the 10 CFR 50.59 evaluation determines that a USQ is involved? The answer to the first question can become more complex if the licensee makes other changes to the facility or procedures (i.e., compensating actions) as a result of the nonconforming condition.

III.O.3 Industry Position or Guidance

Some industry positions can be found in an NEI letter to the NRC dated October 24, 1996. In this letter, NEI concluded that 10 CFR 50.59 applies to the evaluation of the final change to resolve the nonconforming or degraded condition. In addition, NEI concluded that if the nonconforming condition is to be corrected by changing the condition of the structure, system, or component so that no change to the design or licensing basis is required, then no change control process is applicable. The letter noted that temporary changes are subject to the same controls as permanent changes. The NEI letters also concluded that 10 CFR 50.59 evaluations are required for situations allowed to remain uncorrected for extended periods of time and noted that the definition of "extended" was a key issue.

III.O.4 NRC Position or Guidance

Recent inspections of conformance of plants with their FSARs has surfaced a number of discrepancies and the role of the 10 CFR 50.59 evaluation process in the resolution of such conditions warrants clarification.

10 CFR 50.59 is a process by which a licensee reviews proposed changes before they are implemented to determine whether prior NRC approval is needed. The treatment of existing conditions that are found to be nonconforming with the safety analysis report or the design bases as it relates to the need for regulatory approval is not defined in 10 CFR 50.59.

The staff distributed regulatory guidance (Generic Letter 91-18) to licensees that described actions to be taken for safe operation, operability and reportability when licensees discovered degraded or nonconforming conditions. While this guidance addresses 10 CFR 50.59 in some respects, there are aspects that should be clarified. The Generic Letter 91-18 guidance is premised upon a licensee taking prompt corrective action consistent with the requirements of 10 CFR Part 50 Appendix B, Criterion XVI. Nonconforming conditions are to be managed and tracked in a system subject to Appendix B so that there is documentation and accountability until they are resolved. In resolving such nonconforming conditions in accordance with Appendix B (specifically, Criterion XVI, Corrective Action), the condition is to be promptly corrected, commensurate with its safety significance[8].

In addition, Section 4.3.2 of the 9900 Inspection Manual Chapter (IMC) guidance on Resolution of Nonconforming Conditions, forwarded by GL 91-18, states:

> *A licensee may change the design of its facility 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*

[8] While Appendix B may not be literally applicable to FSAR discrepancies that are not safety-related, the concept of corrective action commensurate with safety significance would still apply.

involving an SSC that is subject to both 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.

Therefore, a 10 CFR 50.59 evaluation is required when the licensee decides to accept the nonconforming condition rather than to restore the plant to its FSAR-described condition. NRC inspection manual guidance on nonconforming conditions also notes that a delay in implementing corrective actions requires a 10 CFR 50.59 evaluation. What is meant by "delay" however is not clear. If the licensee plans to restore the discovered condition, what is a reasonable time to complete such a repair and what other actions should a licensee take? If a licensee has determined that the equipment is operable, even though degraded, it may not be considered appropriate or necessary to insist that the plant shut down to repair a degraded condition or to submit a license amendment for a condition that will be resolved soon. On the other hand, to permit a plant to operate for a long period of time, without staff review of a condition that might meet the USQ criteria[9], might also be unreasonable.

Resolution of degraded or nonconforming conditions is also related to reporting requirements and enforcement. De facto[10]

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[9]This conflict is heightened by the recognition that if the licensee had planned the action (i.e., to put the facility in the nonconforming condition), prior staff approval through a license amendment would have been required.

[10]As discussed in the recently issued revision to the NRC Enforcement Policy (61 FR 54461), October 18, 1996, "10 CFR 50.59 is also used to form the basis for citations where the facility or procedures never met the description in the FSAR. These changes represent de facto changes from the FSAR." As further discussed in the Enforcement Guidance Manual (NUREG/BR-0195), NRC takes the position that a licensee's failure to install equipment as originally described in the FSAR constitutes a change to the facility that was actually licensed.

changes may be violations of 10 CFR 50.59 and if they involve a USQ, such violations are classified under the Enforcement Policy as a Severity Level III violation. The policy also establishes provisions for enforcement discretion with respect to old design issues when circumstances warrant. The recently approved revision to the enforcement policy states that failure either to promptly undertake corrective action or to perform a 10 CFR 50.59 evaluation is considered to be "inadequate corrective action" with respect to mitigation of the penalty. Note that this discussion concerning licensee actions is focused on steps to take upon discovery of the condition. A licensee may also be subject to enforcement action for the root causes that led to the degraded or nonconforming condition.

According to 10 CFR 50.72 and 10 CFR 50.73, a licensee must report: (i) a condition of the plant being seriously degraded; (ii) a condition that results in the plant being in an unanalyzed condition that significantly compromises plant safety; (iii) a condition outside the design basis of the plant; or (iv) the plant is in a condition not covered by the plant’s operating and emergency procedures. As discussed in Part 1 of the Millstone Lessons-Learned report, some clarification of the relationship of these requirements is appropriate.

To clarify the implementation of 10 CFR 50.59 as it applies to the resolution of degraded or nonconforming conditions affecting the SAR, the staff has determined that a 10 CFR 50.59 evaluation is required in the following circumstances:

(1) When a licensee plans to implement compensatory actions, such as to satisfy operability requirements, until such time as the plant can be restored to the original design bases or an alternative solution is implemented. Such compensatory actions

are viewed as the licensee "making changes to the facility or procedures as described in the safety analysis report," and thus require a 10 CFR 50.59 evaluation against the FSAR-described condition before they are implemented.

(2) When a licensee intends to implement a final resolution for a degraded or nonconforming condition other than full restoration. If a licensee needs to change the design bases contained or referenced in the safety analysis report, the licensee must evaluate the final resolution against the criteria in 10 CFR 50.59 and determine if an unreviewed safety question exists.

(3) When a discovered nonconforming or degraded condition is not permanently resolved at the first available opportunity. The NRC has concluded that delay beyond the first available opportunity is in essence a de facto change to the facility that should be evaluated under 10 CFR 50.59. If the fix is planned for the next available opportunity, and that opportunity has not presented itself because the plant needs to be in a hot or cold shutdown, there has not been adequate time for design, review, approval or procurement, or specialized equipment to accomplish the repair is unavailable, delay in implementation of the corrective action is acceptable if the licensee is making reasonable efforts to resolve the matter promptly. Under these conditions, assuming operability can be demonstrated, operation in a degraded or nonconforming condition may continue up to the next outage of reasonable duration and timing to effect the corrective action. If, however, such an outage occurs and the licensee does not fix the degraded or nonconforming condition, the staff would conclude that the issue is no longer simply part of an Appendix B corrective action process, but that the licensee has decided

to continue the de facto change, which will require a prompt 10 CFR 50.59 determination. The key point is failure to restore the degraded or nonconforming condition promptly, despite the opportunity to do so. The staff position for corrective action that does not require an outage is similar, that is, if not corrected by the next opportunity of reasonable duration and timing, the staff would conclude that a de facto change had occurred and that a prompt 10 CFR 50.59 evaluation is required.

Otherwise, no 10 CFR 50.59 evaluation is required regarding the discovery of a degraded or nonconforming condition that is appropriately resolved consistent with 10 CFR Part 50 Appendix B, Criterion XVI.

The second question focuses on the course of action to follow when an existing condition, which was required to be evaluated under 10 CFR 50.59, involves a USQ. (Note: this discussion assumes the condition or SSC in question does not involve a TS change; IMC 9900 guidance exists for handling such situations by means of notices of enforcement discretion. That process specifically excludes situations involving unreviewed safety questions). The inspection program guidance forwarded by GL 91-18 says that when the licensee changes its licensing basis (to accept a condition as-is) and a USQ is involved, staff approval (in the form of a license amendment) is required prior to operating the plant with the degraded or nonconforming condition. However, elsewhere in the guidance, statements are made that if SSC are operable, plant operation may continue.

The staff position is that a plant currently operating with a condition involving a USQ would not normally be required to shutdown, provided that the licensee has determined that all necessary equipment is operable, and that the licensee

expeditiously (i.e., within days) submits its application for license amendment. The staff would not allow plant startup unless the condition is first corrected or staff approval is received.

III.P Definition of Increase in the Probability of Occurrence

III.P.1 Rule Language

> *A proposed change, test or experiment shall be deemed to involve a USQ (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the SAR may be increased [10 CFR 50.59(a)(2)]...*

III.P.2 Statement of Issue or Concern

The issue involved with this topic is whether negligible increases (or uncertainty about increases) must be considered to involve a USQ. Further, there is the question about the extent to which "compensating effects" may be considered. The NRC and industry positions are not consistent in this area.

III.P.3 Industry Position or Guidance

When making the determination of whether an accident is more probable than it was prior to the change, NSAC-125, in Section 3.4, divides "accident" into categories. For PWRs, these are Normal Operations, Incidents of Moderate Frequency, Infrequent Incidents, and Limiting Faults. NSAC-125 goes on to state "*Changes that result in a change from one frequency class to a more frequent class are examples of changes that increase the*

probability of occurrence. However, this is not to say that changes within a category may not result in an increase in the probability of occurrence of an accident if there is a clearly discernable increase or trend."

NSAC-125 guidance also stated that where a change in probability is so small or the uncertainties in determining whether a change in probability has occurred are such that it cannot be reasonably concluded that the probability has actually changed (i.e., there is no clear trend towards increasing the probability), the change need not be considered an increase in probability.

Draft NEI-96-07 replaced this language with language similar to that contained in the NRC's interim 9900 inspection guidance about compensating actions (see below). Specifically, the guidance says compensating effects, such as administrative controls, may be acceptable to offset increases in probability or consequences (or reductions in margin of safety) if the compensating effects outweigh the potential increase.

III.P.4 NRC Position or Guidance

Section 50.59 uses the term "may be increased," and therefore, any increase, however slight, will trigger an unreviewed safety question and thus require staff review. Accordingly, the staff's position is that the language of 10 CFR 50.59 (probability <u>may be increased</u>) indicates that any uncertainty or doubt about whether an increase, even a negligible one, has occurred should lead to the conclusion that a USQ is involved.

In Generic Letter 95-02, the staff provided some perspective on USQ determinations related to analog-to-digital replacements. The letter states:

> If during the 10 CFR 50.59 determination there is uncertainty about whether the probability or consequences may increase, or whether the possibility of a different type of accident or malfunction may be created, the uncertainty should lead the licensee to conclude that the probability or consequences may increase or a new type of malfunction may be created. If the uncertainty is only on the degree of improvement, the digital system will provide, the modification would not involve an unreviewed safety question.

The staff also recognizes that the meaning of "probability" could be considered in the context of the licensing approach in the time frame when 10 CFR 50.59 was promulgated and FSARs for current plants were prepared. Until recently, with a few exceptions, estimates of accident and equipment malfunctions were qualitative, inferred from deterministic considerations and engineering judgment, and were not explicitly discussed in the SAR. Generally the staff considered accident and transient probabilities in a broad sense, as for instance, frequent (anticipated operational occurrences), or infrequent (postulated accidents).

Although PRA and associated methodologies now provide a means for quantitative calculation of changes in probability, such results, in general, cannot be used as a basis for regulatory decisions without appropriate standards for the particular application and proper interpretation of results. The qualitative estimates of probability were a factor in evaluating what consequences were accepted for the accident or malfunction in question: high probability/low consequences (e.g., no fuel damage) or low probability/higher consequences (still within acceptable dose limits). Under such a framework, negligible increases (i.e., not worth considering) could not

have affected the staff's safety basis for licensing, and would not have been considered to result in a USQ under past practices. In the context of probability, the word "may" suggests that to conclude that a USQ is not involved, the evaluator must have confidence in the judgment (reasonable assurance) that no increase has occurred. However, with the present rule language, the above staff position must be followed to be in compliance with the rule.

The Part 9900 inspection manual guidance on 10 CFR 50.59, issued on April 9, 1996, states that the staff has found compensating effects such as administrative controls acceptable in offsetting uncertainties and increases in probability of occurrence or consequences of an accident previously evaluated or reductions in margin of safety, provided the negative impact is negligible, and is clearly outweighed by the compensatory actions. Present staff conclusions about the concept of compensating effects or actions are discussed in section III.V.

III.Q Increase in Probability Still Within Design Basis

III.Q.1 Rule Language

> *A proposed change, test or experiment shall be deemed to involve a USQ (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the SAR may be increased; or (ii)if a possibility for an accident or malfunction of a different type than any previously evaluated in the safety analysis report may be created...*
> *[10 CFR 50.59(a)(2)]...*

III.Q.2 Statement of Issue or Concern

The issue is whether changes in a facility that might result in a reduction in the capability of the facility from its previous condition to a level that still exceeds the minimum design requirement should be viewed as increasing the probability of an accident previously evaluated (or as creating a new type of accident).

III.Q.3 Industry Position or Guidance

Section 3.5 of NSAC-125 discusses the probability of occurrence of an accident, stating:

> *For example, a change that does either of the following is a change that increases the probability of occurrence of a malfunction of equipment important to safety:*
>
> *Degrades below the design basis the performance of a safety system assumed to function in the accident analysis.*
>
> *Increases challenges to safety systems assumed to function in the accident analysis such that safety system performance is degraded below the design basis...*

Thus, the guidance takes into account the design basis in determining whether an increase in probability has occurred.

With respect to the creation of an accident or malfunction of a different type, the guidance states that if a change is made such that a scenario previously not considered as part of the design basis (because of such low probability), becomes credible, it should be considered as creating the possibility of an accident of a different type.

III.Q.4 Current NRC Position or Guidance

The severity of certain design basis events that a plant must demonstrate it can withstand often have a probabilistic underpinning (for instance, the magnitude of an earthquake, wind speed, external missiles, etc.) Further, certain accidents may have been considered sufficiently unlikely that protection from their effects was not required ("outside the design basis"). In these instances, a design basis has been established for the facility which thus defines the "accidents previously evaluated." Unless the change makes this design basis event more likely (as compared to making some beyond design-basis event more likely), the change would not involve an increase in probability of an accident previously evaluated. As to creating an accident of a different type, this would arise only if the change made an accident previously considered as outside the design basis, on a probabilistic basis, now within the probability range that established the design basis. Otherwise, the staff does not believe that such changes should be determined to involve USQs if the design basis is still satisfied.

Examples:
(a) A plant is designed to withstand its design-basis earthquake; part of the basis for selection of the particular

earthquake is occurrence likelihood. A plant may have capability beyond that required to withstand this earthquake. A change that reduces the capability somewhat, but which still meets the design basis, need not be considered as an increase in probability (or consequences) of an accident previously evaluated.

(b) The design basis for a plant with respect to tornado missiles is that safety-related equipment be designed to withstand impacts of missiles of particular characteristics. The selection of the tornado speed for the plant had a probabilistic basis. In evaluating a change, the licensee concluded that while a piece of safety-related equipment would no longer be able to withstand the design basis missile, the change was acceptable because the probability of damage was less than 10E-7 (this probability was the cutoff for the design basis speed). The staff did not agree that a USQ was not involved because the design basis requirement for physical protection was not met. (Note: had the design basis been that the probability of damage from missiles be less than 10E-7, then the change noted would still have met the design basis, and would not be an increase in probability of an accident previously evaluated).

(c) Protection from the effects of a turbine missile is not required if the probability of generation is below specified values. Changes that might increase the probability of generation from the existing level to a level that is still below the specified criteria would not create a new type of accident, or increase the probability of an accident previously evaluated.

III.R Definition of Increase in Consequences

III.R.1 Rule Language

> *A proposed change, test or experiment shall be deemed to involve a USQ (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the SAR may be increased [10 CFR 50.59(a)(2)]...*

III.R.2 Statement of Issue or Concern

The issue centers on when it should be concluded that an increase in consequences has occurred, specifically, whether there is a USQ if there is any increase in the radiological consequences from the value(s) reported in the SAR for the accidents/malfunctions evaluated. The NRC and industry have different positions on this issue.

III.R.3 Industry Position or Guidance

For increases in consequences, the guidance provided in NSAC-125 and Draft NEI-96-07 would allow determination that no increase in consequences has resulted from a change if the radiological consequences associated with such a change exceed the values reported in the SAR but are still within the acceptance limits specifically addressed by the staff in its safety evaluation report.

With respect to a potential increase in the consequences, the consequence generally considered is release of radiation (other types of "consequences," such as changes in pressure, thermal conditions, are traditionally evaluated as potential reductions in margin of safety). Further, NSAC-125 states that onsite dose is considered to the extent it restricts access or impedes mitigation.

III.R.4 NRC Position or Guidance

The language in 10 CFR 50.59, is "consequences of an accident...previously evaluated in the safety analysis report may be increased." Therefore, the staff concludes that the dose calculated in the SAR should be considered as the threshold for when an increase in consequences (and thus a USQ) results. Further, failure to comply with this position could result in enforcement action.

The staff also notes that for radiological consequences associated with accidents evaluated in the SAR, the staff SER is generally based upon independent calculations performed by the staff, using the data provided by the license applicant. The staff’s assumptions on such parameters as decontamination factor may be different from licensee assumptions. Thus, the staff does not generally approve the methods or results of the SAR analysis, but finds the consequences of the accident acceptable if the staff-calculated results meet the applicable acceptance guidelines (Part 100 or SRP values which may be less for particular types of accidents). This fact would make it more difficult to allow licensee consideration of the NRC acceptance value (see discussion on Margin of Safety) as the benchmark for determining whether the increase is within the bounds of what the staff has previously reviewed and accepted, even if the rule language would allow such an interpretation.

The staff agrees that "consequences" refers to radiological consequences, with other results of accidents/malfunctions being addressed under margin of safety. In a letter to NUMARC dated May 10, 1989, the staff provided its view that "consequences" should be in terms of dose to either onsite or offsite persons that would likely result from any accident or equipment malfunction associated with the proposed change.[11] The staff concludes onsite doses must be considered to the extent they were considered before in the accident analysis (such as to show compliance with GDC 19).

III.S Definition of Reduction in Margin of Safety

For the issue of margin of safety, there are two related questions; Item III.S discusses margins as it relates to the point from which the reduction in margin should be measured or assessed. Item III.T discusses margin as it relates to where a licensee should look within the licensing basis to find the margins.

III.S.1 Rule Language

> *A proposed change, test or experiment shall be deemed to involve a USQ ... (iii) if the margin of safety as defined in the basis for any TS is reduced. [10 CFR 50.59(a)(2)]*

III.S.2 Statement of Issue or Concern

The question for this issue is the reference point for determining when a reduction in margin of safety has occurred. In general, the NRC position and industry guidance are

[11]Control of doses from routine operations is in accordance with 10 CFR Part 20.

consistent. However, the rule language itself is not definitive about the appropriate interpretation.

III.S.3 Industry Position or Guidance

NSAC-125 guidance states that a reduction in margin of safety has occurred if an acceptance limit (value previously reviewed and approved by the staff) is no longer met as a result of a change. It further states that to find the acceptance limit, one must determine the original licensing basis of the parameter in question. In making the judgment on whether the margin is reduced, the decision should be based on physical parameters which can be observed or calculated.

In its discussion of margin of safety and acceptance limits, NSAC-125 states that the acceptance limit is "the value at which the confidence level in the integrity of the barrier decreases."

III.S.4 NRC Position or Guidance

In determining what changes represent a reduction of the margin of safety[12], it should be recognized that the technical specifications and the accident analyses on which they are based, provide assurance that the response of the plant to various design basis accidents and transients is acceptable. Acceptance limits are specific values, conditions, or range of parameters within which the licensee has proposed to operate the facility and which the NRC has accepted during its review of a license application. These values are derived from the

[12] The determination of whether a change is an unreviewed safety question when there are changes in radiological consequences is discussed in section III.R with respect to 10 CFR 50.59(a)(2)(i), not as a margin of safety determination.

plant-specific design bases analyses reviewed by the NRC and are found in the plant-specific FSAR (unless a different value is explicitly established in the NRC safety evaluation as the acceptance limit), and may in some cases, be found in the "BASES" section for individual technical specifications.

Margin, as it is generally used in the NRC regulatory process, refers to the difference between actual conditions and minimum requirements. A reduction in margin suggests that one is considering a difference between two values. Thus, in understanding the concept of a reduction in "margin of safety", it is helpful to discuss some specifics as follows.

1) Failure point

This is the point at which failure is assumed to occur. This number is arrived at by using physical properties of the item; for example, the type of steel used in a pipe and the thickness of the pipe walls, derated for weld quality, etc., would determine the pressure the pipe could take before bursting or cracking. In engineering practice, there is generally not a single failure point, but an uncertainty band. Good engineering practices tend to result in the adoption of a lower-bound strength associated with a failure occurrence probability, and therefore by nature the failure point is not an exact number. The characterization in NSAC that the acceptance limit is the value at which the confidence level decreases is more appropriately called a failure boundary or failure point uncertainty, and may have little to do with the actual limit accepted by the staff during the review of the SAR and accident analysis. In some instances, regulatory limits have been established (in regulations, Codes, or TS)

for a parameter that sets the lower uncertainty bound on the failure range.

2) Acceptance limit

Acceptance limits are specific values, conditions, or range of parameters within which the licensee has designed, and proposes to operate its facility and which the NRC has accepted during its review of a license application. These values are derived from the design bases analyses contained in the SAR and reviewed by the NRC. An acceptance limit is the value which has been approved by the staff for the parameter of interest. (Whether this value is a maximum or a minimum is, of course, dependent on the type of variable being discussed.) This value is whatever the staff has approved during the licensing process and will be found in the plant-specific SAR value unless a different value was explicitly documented in the staff safety evaluation, and may in some cases be found in the Bases section of the TS. Further, these acceptance limits would not necessarily equate to the acceptance criteria in the Standard Review Plan because different limits may have been established for the plant during the staff’s review.

3) Maximum SAR value

This value is based upon physical properties of the plant and assumed conditions prior to and during an accident or anticipated transient. It is the extreme (highest or lowest) value the parameter involved is calculated to reach during the accident or anticipated transient as documented in the SAR. Depending on how the SAR and SER were written, this number may be the same as the "Acceptance Limit". For

example, this could be as high as pressure within the pipe is expected to get during an accident.

To evaluate whether an unreviewed safety question is involved, it is necessary first to determine whether or not a margin of safety, as defined in the basis for any technical specification, is involved. If so, the effects of the proposed change on this margin of safety must be assessed. Identifying all potentially affected technical specification safety margins involves more than just reviewing the Bases sections of technical specifications initially thought to be applicable. The licensee needs to determine the potential effects of the proposed change on:

-the capability and availability of structures, systems, and components (SSC) to perform their designed, intended, or specified function(s), and

- the way operator actions credited by the safety analyses are performed.

The licensee should identify every safety analysis for the plant that takes credit for the performance of the potentially affected function(s) or operator actions, and that also supports the bases of technical specifications. (If none of the affected analyses support the basis of a technical specification, then a reduction in margin of safety pursuant to 10 CFR 50.59 would not be involved).

Next, the licensee should evaluate the effect of the proposed change on the results of each such analysis and the applicable acceptance limits for each analysis. If the effect on the analyses of the proposed change would cause this value to be exceeded, then the proposed change would involve a reduction in the margin constituting an unreviewed safety question.

The NRC had previously issued inspection manual chapter (IMC) Part 9900: 10 CFR Guidance concerning 50.59 (April 1996) which states:

> *"For the purpose of performing evaluations in accordance with 10 CFR 50.59, the margin of safety should normally be considered the difference between the regulatory limit (i.e., the limit specified by the regulations or technical specifications) and the value of the parameter reviewed and approved by the staff as part of the licensing basis for the plant. Proposed changes that would affect margins beyond the regulatory limit (e.g., the margin between the TS Limit and the assumed system failure point) would most likely require an exemption from the regulation or a license amendment, and are by definition, not within the scope of 10 CFR 50.59."*

In essence, this guidance subdivides the margin of safety that NSAC-125 describes by providing a bound below the failure point (and above the acceptance limit) when such a regulatory limit is defined. In the case of containment pressure, there may not be a regulatory limit. A change that results in a parameter exceeding the acceptance limit (i.e,. the value previously approved by the NRC, as documented in the SAR, unless an explicit acceptance value is specified in the SER) towards either a regulatory limit or the failure point is a reduction in a margin of safety and thus involves an unreviewed safety question.

Accordingly, for purposes of this criterion, a reduction of margin of safety as defined in the basis for any technical specification will be deemed to have occurred when an acceptance limit is no longer met as a result of a proposed

change, test, or experiment. If the staff's acceptance limit in the safety evaluation is explicit, the licensees can consider the values in the staff safety evaluation as a reference for determining the "acceptance limit", rather than being limited only to values contained in the plant safety analysis report. If the staff's acceptance limit is not explicit, the "acceptance limit" is the value as reported in the SAR.

III.T Information That Establishes the Basis for any Technical Specification

III.T.1 Rule language

> *A proposed change, test or experiment shall be deemed to involve a USQ ... (iii) if the margin of safety as defined in the basis for any TS is reduced. [10 CFR 50.59(a)(2)]*

III.T.2 Statement of Issue or Concern

The issue is the appropriate reading of the words "basis for any TS", and whether it refers solely to the BASES section, defined as a summary statement of the bases or reasons for such specifications, in accordance with 10 CFR 50.36(a), or whether the phrase should be interpreted to mean the SAR (which includes the design bases and safety analyses).

Both the NRC position and industry guidance state that basis for any TS should be interpreted as being read more broadly than the BASES section of the TS.
The rule itself is not definitive about the appropriate interpretation of the language, as discussed below.

III.T.3 Industry Position or Guidance

NSAC-125 recommends that licensees look beyond the BASES section of the TS, such as by reviewing the SAR, in considering whether a reduction in margin has occurred. It is noted that not all licensees have adopted the guidance that "basis for any TS" be understood to include documents such as the SAR and SER and not just the BASES section of the TS.

III.T.4 NRC Position or Guidance

The NRC has not published specific guidance on how "basis for any TS" should be interpreted, although some information has been provided, as discussed below.

The rule itself does not specifically address what is meant by "margin of safety as defined in the basis for any TS." This part of the USQ definition in 10 CFR 50.59 was added at the same time that 10 CFR 50.36 was revised to require that each applicant provide "a summary statement of the bases or reasons for such specifications...in the application but [they] shall not become part of the technical specifications." These summary statements are typically maintained as a supporting document to the TS. Thus, some have interpreted "basis" as referring to these summary statements. The other view is that "basis" should be read to refer to 10 CFR 50.34(b)(2) and (b)(4), the descriptions and analyses that are in the FSAR. The staff has acknowledged that the TS BASES sections do not

consistently define margins of safety, even in qualitative terms.

A USQ is involved if the margin of safety as defined in the basis for any technical specification is reduced. However, in general, the BASES sections of the technical specifications are not written in such a manner that the safety margin is explicitly identified. The history of development of Sections 50.34 and 50.36 suggests that the SAR, as supplemented by the staff SER, is where the basis for any technical specifications are defined, and that the BASES section of the TS is just a summary. The TS specify the equipment that must be available and the initial plant conditions necessary to meet the assumptions in the safety analyses. This relationship to the safety analyses means that the basis for the TS and thus the associated margin-of-safety definitions are found in the analyses as described in the updated SAR and NRC SERs. TS BASES sections usually summarize the reasons for each specification, but in only a few cases actually define an associated margin of safety. Therefore, the BASES sections may be helpful, but should not be relied upon as the only reference in a margin-of-safety evaluation because they usually lack sufficient detail.

Thus, the staff concludes that other information, such as the SAR and supporting analyses, and the staff safety evaluation, should be reviewed in determining whether a margin of safety as defined in the basis for any TS has been reduced.

It should be noted that the interim IMC 9900 inspection guidance on
10 CFR 50.59 says that NSAC-125 guidance is broader than the rule regarding where a licensee must look to find a margin of safety in that it recommends looking beyond the TS BASES. This

guidance also says that in determining whether the margin of safety has been reduced, the licensee should first look in the BASES section and that any reduction in that margin must be considered a USQ. It further says that if the TS BASES do not specifically address the margin of safety, then the SAR, the SER and other licensing basis documents should be reviewed. The staff intends to modify this guidance to reflect the conclusion that the "basis for any TS" is broader than just the BASES section.

III.U Determination of Unreviewed Safety Questions When Licensees Use New Methods (Analysis methods, assumptions) to Evaluate Plant Changes or Conditions

III.U.1 Rule language

The rule contains no specific language on analysis methods or assumptions. The rule refers only to changes to facility or procedures as described in the safety analysis report. This topic is related to the definition of a change.

III.U.2 Statement of issue or Concern

The regulatory issue centers around how and when a licensee may use new methods or assumptions to demonstrate that a change to the facility or procedures does not involve a USQ.

III.U.3 Industry Position or Guidance

The NSAC-125 guidance discusses how licensees should treat changes in methodology in Section 3.8. The guidance states that if the specific methodology for computing the bounding limit, or for combining uncertainties was submitted to the NRC in support of the licensing action, reductions in margins

associated with this methodology would constitute an unreviewed question. In other cases, the guidance says the licensee should apply the same methodology, with and without the proposed change, when evaluating a change to determine its effect upon the margin of safety.

This issue is also discussed in the October 1996 point papers. The position described in that document in summary is:

> The methodology assessment should consider whether or not the codes, input assumptions, etc. were part of the original licensing submittal and whether or not that is documented in the SER. If it was part of the submittal and the change in methodology by itself reduces the margin of safety, it should be considered an USQ. If the methodology was not submitted, a comparison of the physical change using the old and new methodology should be made to determine if a reduction in margin of safety exists.

III.U.4 NRC Position or Guidance

NRC has not published any guidance that specifically addresses the use of new methods and assumptions. New methodology or analysis assumptions must be used carefully in recalculating limits or consequences to show that no increase in consequences has occurred or that a margin of safety has not been reduced. Since each method used for analysis has assumptions, approximations, and other uncertainties, one method will not necessarily produce a result compatible with that of another methodology. Also, NRC acceptance of the facility may have been based on certain conservatisms in the analysis method or assumptions. Thus, if the methodology (code, assumptions) are described in the SAR, a change to the methodology would require

a 10 CFR 50.59 evaluation. If new methods or assumptions are necessary to demonstrate that consequences have not increased or that the margin of safety is not reduced as a result of a change, it is likely that a USQ is involved with that change. In other words, the change by itself would affect consequences or margin and it is only consideration of other factors that makes the net effect on the analysis be no increase (or no reduction).

A licensee may be able to show that a proposed change does not involve a USQ by reducing certain operating ranges (when such changes still meet requirements). However, if in order to show that a proposed change does not involve a USQ a licensee introduces new assumptions not previously credited in its SAR, as for instance, scrubbing through the suppression pool, credit for containment overpressure for NPSH, etc., a USQ may be involved.

This is not to say that new methodology should not be used in other instances. As the knowledge base increases and computing power increases, new methods of analysis will more accurately predict the actual plant response than old methods. In making a 10 CFR 50.59 determination that a USQ is not involved as a result of a change, the results of two calculations are being compared. If the two calculations are the results of two different methodologies, the comparison is not valid. Therefore, the staff position is that a new methodology may be used for evaluating plant changes under 10 CFR 50.59 if two conditions are satisfied. First, the new methodology must be a valid methodology for the type of calculation being performed, for instance, a method that has been previously reviewed and approved by the staff for calculations of this type (to the extent that such approval of methods was previously required). Second, in order to judge the effect of a change, test, or

experiment, the analysis must be done for the cases of before and after the change and both analyses must be performed with the same methodology. The comparison is then valid, and could be used to show that no USQ is involved and thus that the change can be done by the licensee without prior staff review.

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

III.V.1 Rule language

The rule does not use the terms "compensating effects" or "compensatory measures." The connection to the rule is related to how a licensee defines the "change" to be evaluated under 10 CFR 50.59.

III.V.2 Statement of Issue or Concern

The regulatory concern centers around a licensee’s process for evaluating whether changes require staff review. Specifically, this issue focuses on a process that would permit a licensee to bundle or integrate a series of plant changes into one "change" on which a licensee could then make a determination that the integrated "change" was or was not an unreviewed safety question. In this approach, the individual plant changes would not be evaluated.

III.V.3 Industry Position or Guidance

The NSAC-125 guidance refers to compensating effects in the sections that discuss increases in probability by indicating that a change that results in safety system performance being degraded below the design basis without compensating effects,

would involve a USQ. The guidance also says that compensating effects such as changes to administrative controls may be used to offset an increase or trend in the probability of accident of moderate frequency.

Draft NEI 96-07 includes language that suggests that two independent changes can offset each other such that no net increase in probability or consequences (or reduction in margin) has occurred.

Further, the October 1996 NEI point paper contains additional discussion about consideration of "bundling" related changes such that any individual aspects of the change that might result in an increase are offset by other parts of the change.

III.V.4 NRC Position or Guidance

The interim IMC Part 9900 guidance on 10 CFR 50.59 says that the staff will accept compensating effects, such as administrative controls, as part of a change to offset a potential increase in probability (or reduction in margin), provided the "increase" (or "reduction") is negligible, and the compensatory action(s) "clearly outweighs" the increase (in probability or consequences) or reduction (margin of safety) of the change. However, the NRC position on "compensating effects" or the use of compensatory measures has evolved from the position published in this inspection guidance because this guidance may be contrary to the language of the rule. The present staff position is as follows:

Section 50.59 establishes a process to assure that changes to a facility or the procedures would preserve the design bases, functions and margins of safety established during the licensing process. Elements of a proposed change that are

linked with each other in accomplishing the required functions or in establishing the design bases for systems or structures are considered as a single change.

The current staff position is that the use of compensatory measures actions has no unique meaning for planned changes under 10 CFR 50.59. Licensees use compensatory measures or actions in certain situations to deal with a degraded or nonconforming condition at the plant. These measures are only of short duration and provide a licensee a basis for continued operation until such time as a licensee determines the final resolution of the degraded or nonconforming condition. However, these actions redefine the way the plant will be operated from that previously described in the plant safety analysis or other license amendment applications. Thus, such compensatory actions are viewed by the staff as a licensee "making changes to the facility or procedures," and thus require a 10 CFR 50.59 evaluation against the FSAR-described condition before they are implemented.

The industry guidance related to compensating effects may result in circumstances where a licensee may be subject to enforcement actions. For instance, when a licensee makes two changes to the same piece of equipment these separate changes would be considered as elements of the same change. However, if a licensee makes a change in one component or system to offset changes made in another system or component and would attempt to consider those changes as an integrated change for the purpose of 10 CFR 50.59, the staff believes that such situations may result in enforcement action against the licensee. The effect of any change must be evaluated against each of the USQ criteria separately - that is, an increase in probability cannot be "compensated" by additional mitigation capability. There may be instances where linking elements of a

change may be appropriate. A test for linking elements of proposed changes is interdependence. If a proposed change to a system or component requires a subsequent change in another system or component, the changes are linked. ("Required" should be interpreted with respect to function or performance of the system or component, not that the first change, absent the subsequent change, would involve a USQ). However, if a change to a system or component can be made without affecting other systems or components, then the proposed changes are separate changes under 10 CFR 50.59.

IV. POLICY ISSUES

Section III presented proposed staff positions and guidance on a wide range of issues related to the implementation of 10 CFR 50.59. In developing its positions and guidance, the staff took into account the explicit language of the rule. However, the staff identified a few issues that were of such importance to the regulatory effectiveness of the 50.59 regulation that revisions to the existing rule should be considered. The specific issues are (1) a revision of the rule to better define the scope of the rule, and (2) a revision of the criteria that define when an unreviewed safety question exists. The specific issues and impacts associated with a policy decision to pursue rulemaking in each of these areas is presented in greater detail below.

IV.A Scope of Section 50.59

A.1 Statement of Issue

The issue is whether the current scope of 10 CFR 50.59, in referring only to the SAR, is sufficient to include all information that should be subject to the regulatory control of the 10 CFR 50.59 process.

A.2 Industry Position

Given the varying levels of detail in the SAR, and the recognition that some important safety information is located in licensee documents other than the SAR, industry guidance recommends that licensee review these other documents when making changes in accordance with 10 CFR 50.59.

A.3 Discussion of NRC Position and Options

Changes to the facility or procedures as described in the SAR, or conduct of tests and experiments not described in the SAR, require a written 10 CFR 50.59 safety evaluation. Thus, the 10 CFR 50.59 evaluation process controls changes to that part of the plant that is described in the SAR. As discussed in the sections on SAR and on deleting information from the SAR, all of the design bases or other information that the staff would want to have subject to evaluation may not be contained in existing plant SARs.

Plant SARs vary in depth and completeness. In general, the level of detail of information contained in an SAR for later facility applications was much greater than that for the earlier licensed plants. Thus, tying the scope of 10 CFR 50.59 to the SAR results in uneven application of 10 CFR 50.59. For some plants, the SAR contains additional detail about the facility and margins in the design, which under the terms of the rule, is within the scope of 10 CFR 50.59, even though it would not be captured under 10 CFR 50.59 control at other plants. Further, in accordance with 10 CFR 50.71(e), periodic updates of the FSAR are to be submitted to reflect the effects of changes made to the facility, safety evaluations performed by the licensee and analyses of new safety issues performed at Commission request. As discussed in Parts 1 and 2 of the MLLTG report concerning "current licensing basis", 10 CFR 50.71(e) was neither implemented nor enforced in a manner to ensure that the effects of all new analyses were included in the SAR. Thus, while the facility may have been modified since initial licensing to cope with additional accidents or events, these modifications may not have been added to the SAR, such that future changes to these parts of the facility might not be appropriately constrained by the 10 CFR 50.59 process. Examples of such issues include station blackout, anticipated transients without scram, control of heavy loads and fuel handling

accidents. Thus, the SAR may not include all accidents previously evaluated for the facility. Further, plant features or procedure changes developed to provide ability to cope with severe accidents (beyond the design basis accidents) may also not be part of the SAR, and thus would not be subject to the regulatory control of 10 CFR 50.59. Parts 1 and 2 of the MLLTG report discuss the issue of completeness of the SAR, and updating requirements in more detail.

In considering options on the scope, the fundamental issue is whether to change 10 CFR 50.59 to refer to something other than the SAR (such as "licensing basis"), or to change requirements such that the SAR contains all of the information over which the NRC wishes to have the controls provided by 10 CFR 50.59. Some possible approaches are listed below; options relating to the contents of the SAR and licensing basis are also discussed in the Part 2 Millstone Lessons-Learned Task Group Report.

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

(2) revise 10 CFR 50.59 to reference the "licensing basis" instead of "SAR", and develop a definition of licensing basis that includes all the information that the staff wishes to subject to the control of the 10 CFR 50.59 process. Such a change could bring the other information that is not presently contained in the SAR, but that is part of the licensing basis as it would be defined, within

the scope of 10 CFR 50.59. If this option were followed, a definition of licensing basis, and other changes to Part 50 would be needed.

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

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

A.4 Impacts for the NRC

If rulemaking is undertaken for the issue of SAR contents and scope of section 50.59, there would be significant impacts on the staff. A rulemaking would take at least two years, and require staff resources on the order of 3-5 FTE. Since such rulemaking would be focused on reporting requirements (SAR), and licensee review processes, the impact on safety is difficult to assess. Thus, there are questions as to whether a regulatory analysis could be developed that would justify the resource implications for the industry in light of the safety improvements.

IV.B Unreviewed Safety Question Threshold

B.1 Statement of the issue:

The broad goal of the use of the unreviewed safety question threshold established in 10 CFR 50.59 is to identify any change in the facility or procedures from its SAR description that has the potential to move the plant in an unsafe direction. In the context of 10 CFR 50.59 language, however, the question is whether any increase (or even any uncertainty as to whether there has been an increase) in probability or consequences of an accident or malfunction, creation of a different type of malfunction or accident or a reduction in margin of safety from what was reported in the SAR should be considered a USQ. The current defined threshold results in the need for prior staff approval of not only significant changes, but also others that are still well within the envelope that the staff would have found acceptable. Further, there is uncertainty about the USQ definition, in particular regarding "margin of safety as defined in the basis for any technical specification", which leads to differences of opinion on whether certain changes involve USQs.

Thus, the key policy question is whether there is a need to redefine USQ in a manner that more clearly defines those changes for which prior staff approval is needed, or to redefine the threshold, or make it more amenable to a risk-based regulatory regime.

The question of the USQ "threshold" is important because of the different actions required depending on whether a USQ is involved. If a change does not involve a USQ (or involve a TS change), the licensee may proceed to make the change, with the

only reporting requirement being submittal of a report listing the changes with a summary of the evaluation, up to two years after the change was made. On the other hand, for changes involving a USQ, a license amendment must be submitted and approved, before the change can be implemented. These processes are appropriate for changes that may be significant, but could be considered unreasonable for changes that might be found to meet the USQ definition (as presently interpreted), but which have little true significance for the licensing basis.

In considering policy implications with respect to 10 CFR 50.59, the integrated effect of decisions on the above issues needs to be considered. Efforts to broaden the scope (making the rule applicable to licensing basis, or by revising SAR update requirements), coupled with a strict interpretation of when a USQ is involved, will likely result in more changes being submitted as license amendments for staff approval. The additional staff review requirements will have schedular and resource implications to review issues that are (by definition) USQs, but which may not be significant from a licensing or safety perspective. Rulemaking to clarify the definition of USQ could reduce uncertainty about when a USQ is involved and also eliminate the need for review of some changes that have only a minor effect on the "licensing basis" considered by the staff, but which meet the present USQ definition. These options would require rulemaking.

The issues about the threshold are also related to the topics of use of new analysis methods, and of compensating effects, both of which affect the "change" being evaluated to determine if the USQ threshold has been reached.

B.2 Current Industry Position

The industry-developed guidance indicates that they would like to interpret the rule in certain ways that are not consistent with the rule as written. It is not known whether there is interest in rulemaking such that their guidance could be implemented as written and be in accordance with the rule.

B.3 Discussion of NRC Position and Options

Probability of occurrence

As discussed in the guidance section, the existing rule language would require that a change resulting in any increase, or even uncertainty about whether there has been an increase to be deemed to involve a USQ.

The staff recognizes that with respect to probability of occurrence of accidents or of equipment malfunction, SAR assessments were generally qualitative, since licensing of most facilities predated use of probabilistic risk analysis techniques; thus, it could be concluded that negligible increases (i.e. too small to be worth considering) should not result in a USQ. In other words, since the tools for more precise estimates of probabilities did not exist when the rule was written, the potential concern for increase in probability arguably must have been focused on discernable increases that might have affected the staff’s view of acceptability. Thus, a policy option would be to revise this part of the USQ criterion from "may be increased" to "is increased", or "is more than negligibly increased". Such a revision would allow a determination that a USQ is involved as a result of an increase in probability when such an increase is discernable, not when an increase cannot absolutely be ruled out. This option would recognize that the staff’s consideration of probability is largely qualitative. This approach would give more latitude to

a licensee’s judgment on whether a USQ is involved, which may be a potential concern in some specific situations. This approach would require rulemaking.

Increase in consequences

As discussed in the guidance section, changes resulting in an increase in radiological consequences above the value(s) calculated in the SAR involve USQs. Industry guidance documents propose an approach similar to that discussed under margin of safety, that is, that no USQ is involved if the resulting dose remains within the staff’s explicit acceptance guidelines for the plant and accident analyses involved.

However, there are two factors that would suggest that the threshold for determining if a USQ is involved for radiological consequences is any increase from the safety analysis results as documented in the SAR for the accident(s) involved. The first factor is the rule language which states "consequences of an accident previously evaluated in the SAR may be increased"; the second is the way the staff reviews radiological consequences during licensing. Typically, the staff did not review the licensee’s dose analysis for acceptability; rather, the staff evaluated the design by performing its own calculations of consequences using the design performance features, and concluded that the design was acceptable if the staff’s calculated dose consequences met applicable requirements. Therefore, it would be difficult to determine how a change that resulted in an increase in the dose as calculated by the licensee would affect the staff’s conclusions.

There are options for rulemaking that could be explored such that certain changes involving increases in consequences could

be made under 10 CFR 50.59. One option would be to revise the rule such that no USQ would be involved if the results are still within the acceptance guidelines specified by the staff and the licensee's SAR analysis has been specifically reviewed by the staff. Another option that might be considered is that the "previous evaluation" includes the staff's analysis as documented in the SER, and therefore, that a licensee is permitted to consider the acceptance guidelines discussed in the SER as the baseline for determining if an increase in consequences has occurred, provided that they also adopt the staff analysis assumptions as part of its analysis of record; then for purposes of evaluating changes, the "no increase in consequences" could be based on the acceptance value established by the staff.

Another option with respect to consequences would be to delete the "increase in consequences" as a separate part of the definition of USQ, and define margin of safety to encompass all results of analyses, including dose calculations. If as part of this redefinition, the licensee were to be allowed to consider the acceptance values discussed in the staff SER for these analyses (as proposed for margin of safety), the above issues concerning the staff's analysis for radiological consequences would also have to be taken into account. These options would require rulemaking to implement.

Margin of Safety

The proposed staff position on margin of safety would allow consideration of the staff conclusions with respect to when a USQ is involved if the acceptance limit is clearly specified by the staff; otherwise, the value calculated in the SAR must be used as the baseline to gauge whether a reduction in margin has occurred. This position recognizes that for results of safety

analyses other than radiological consequences, the staff does review the licensee's analyses and makes a determination on acceptability. Further, if the analyses were found acceptable because they met specified acceptance criteria, it could be concluded that a calculated result (arising from a change to the facility or procedures) that remains within the criteria explicitly approved by the staff already is not "unreviewed", and changes which result in reductions in margin of safety that still satisfy the explicit acceptance criteria used by the staff should not be USQs.

The staff position also recognizes that the TS BASIS sections do not consistently address margin of safety, so "as defined in the basis for any TS" is being interpreted to include consideration of the SAR information.

A policy option would be to define more specifically in the rule itself that a reduction in margin of safety has occurred if the results of any safety analyses documented in the SAR are no longer bounded by the staff acceptance criteria. Further, a rule change on the language for "margin of safety" could clarify whether "basis" should be read to mean the SAR and other information, or only the BASIS section of the TS.

Other Options

More wide ranging options would include totally revising all the criteria for USQ, including use of the term, by developing an alternative characterization of when prior staff approval of a change is needed. The term "unreviewed safety question" is sometimes confusing with respect to whether it is a test of safety or a test of the extent of review needed by NRC. Use of a different term and a definition more explicitly focused on

the regulatory envelope previously reviewed could clarify the intent of the 10 CFR 50.59 evaluation process.

Other options could introduce a "risk significance" test; changes that meet the USQ definition, but that are not "risk-significant" might be allowed without prior approval subject to a more timely reporting requirement, while more risk-significant changes would continue to require prior staff approval. Similarly, with respect to margin, a change that made only a small reduction in the available margin might be allowed without prior approval, whereas changes which result in being close to the limits would require prior approval. Such options would require rulemaking and would also require development of guidelines for significance. However, these approaches would be more consistent with a performance-based, risk-informed regulatory framework.

The idea of a shorter reporting time was suggested by the review previously conducted by the Regulatory Review Group (August 1993). It was noted in that report that for certain types of plan changes (e.g. for quality assurance, safeguards or emergency preparedness plans) made in accordance with 10 CFR 50.54, reports are to be submitted 30 to 60 days after being implemented. In contrast, Section 50.59 change reporting may be up to 2 years after the change is made.

B.4 Impacts for the NRC

If rulemaking is undertaken regarding the definition of an USQ, there would be significant impacts on the staff. A rulemaking would take at least two years, and require staff resources on the order of 5 FTE.

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LIST OF REFERENCES

1. NUREG-0800, Standard Review Plan for Nuclear Power Reactors, July 1981.

2. Regulatory Guide 1.70 Standard Format and Content for Safety Analysis Report", Revision 3, November 1978.

3. December 15, 1980 Generic Letter 80-110, Periodic Updating of Final Safety Analysis Reports.

4. May 10, 1989 Letter from Rossi (NRC) to Tipton (NUMARC).

5. June 1989 NSAC-125 Guidelines for Performing 10 CFR 50.59 Safety Evaluations.

6. November 7, 1991 Generic Letter 91-18, forwarding Inspection Manual Guidance 9900 on Degraded/Nonconforming Conditions and on Operability.

7. October 21, 1994 Letter from Stolz (NRC) to Kacich, Northeast Nuclear Energy Company, concerning degraded or nonconforming conditions.

8. December 15, 1995 Memo from EDO to Chairman Jackson, Response to Question on Facility Changes Pursuant to 10 CFR 50.59.

9. April 9, 1996, Inspection Manual Guidance Part 9900, Interim Guidance on 10 CFR 50.59.

10. April 15, 1996, Memorandum from Taylor (EDO) to Chairman Jackson (NRC), forwarding Action Plan on 10 CFR 50.59.

11. August 13, 1996 Letter from Tipton (NEI) to Russell (NRC), forwarding NEI 96-07 (draft).

12. September 19, 1996, Memorandum, Taylor (EDO) to Commissioners, forwarding Part 1 of Millstone Lessons-Learned Task Group Report.

13. October 24, 1996 Letter from Pietrangelo (NEI) to Martin (NRC), forwarding "Point Papers."

APPENDIX A - TEXT OF 10 CFR 50.59

10 CFR § 50.59

§ 50.59 Changes, tests and experiments

(a) (1) The holder of a license authorizing operation of a production or utilization facility may (i) make changes in the facility as described in the safety analysis report, (ii) make changes in the procedures as described in the safety analysis report, and (iii) conduct tests or experiments not described in the safety analysis report, without prior Commission approval, unless the proposed change, test or experiment involves a change in the technical specifications incorporated in the license or an unreviewed safety question.

(2) A proposed change, test or experiment shall be deemed to involve an unreviewed safety question (i) if the probability of occurrence or the consequences of an accident or malfunction of equipment important to safety previously evaluated in the safety analysis report may be increased; or (ii) if a possibility for an accident or malfunction of a different type than any evaluated previously in the safety analysis report may be created; or (iii) if the margin of safety as defined in the basis for any technical specification is reduced.

(b) (1) The licensee shall maintain records of changes in the facility and of changes in procedures made pursuant to this section, to the extent that these changes constitute changes in the facility as described in the safety analysis report or to the extent that they constitute changes in procedures as described in the safety analysis report. The licensee shall also maintain records of tests and experiments carried out pursuant to paragraph (a) of this section. These records must include a written safety evaluation which provides the bases for the determination that the change, test or experiment does not involve an unreviewed safety question.

(2) The licensee shall submit, as specified in [10 C.F.R.] § 50.4, a report containing a brief description of any changes, tests, and experiments, including a summary of the safety evaluation of each. The report may be submitted annually or along with the FSAR updates as specified by [10 C.F.R.] § 50.71(e), or at such shorter intervals as may be specified in the license.

(3) The records of changes in the facility shall be maintained until the termination of the license, and records of changes in procedures and records of tests and experiments shall be maintained for a period of five years.

(c) The holder of a license authorizing operation of a production or utilization facility who desires (1) a change in technical specifications or (2) to make a change in the facility or the procedures described in the safety analysis report or to conduct tests or experiments not described in the safety analysis report, which involve an unreviewed safety question or a change in technical specifications, shall submit an application for amendment of his license pursuant to [10 C.F.R.] § 50.90.

APPENDIX B- TEXT OF 10 CFR 50.34

10 CFR 50.34 Contents of applications; technical information

(a) *Preliminary Safety Analysis Report*

...

(4) A preliminary analysis and evaluation of the design and performance of structures, systems and components of the facility with the objective of assessing risk to public health and safety resulting from operation of the facility and including determinations of (i) the margins of safety during normal operations and transient conditions anticipated during the life of the facility, and (ii) the adequacy of structures, systems, and components provided for the prevention of accidents and the mitigation of the consequences of accidents. Analysis and evaluation of ECCS cooling performance following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of § 50.46 of this part for facilities for which construction permits may be issued after December 28, 1974.

...

(b) *Final Safety Analysis Report.* Each application for a license to operate a facility shall include a final safety analysis report. The final safety analysis report shall include information that describes the facility, presents the design bases and the limits on its operation, and presents a safety analysis of the structures, systems, and components and of the facility as a whole, and shall include the following:

(1) All current information, such as the results of environmental and meteorological monitoring programs, which has been developed since issuance of the construction permit, relating to site evaluation factors identified in part 100 of this chapter.

(2) A description and analysis of the structures, systems and components of the facility, with emphasis upon performance requirements, the bases, with technical justification therefor, upon which such requirements have been established, and the evaluations required to show that safety functions will be accomplished. The description shall be sufficient to permit understanding of the system designs and their relationship to safety evaluations.

(i) For nuclear reactors, such items as the reactor core, reactor coolant systems, instrumentation and control systems, electrical systems, containment system, other engineered safety features, auxiliary and emergency systems, power conversion systems, radioactive waste handling systems, and fuel handling systems shall be discussed insofar as they are pertinent.

(ii) For facilities other than nuclear reactors...

(3) The kinds and quantities of radioactive materials expected to be produced in the operation and the means for controlling and limiting radioactive effluents and radiation exposures within the limits set forth in part 20 of this chapter.

(4) A final analysis and evaluation of the design and performance of structures, systems, and components with the objective stated in paragraph (a)(4) of this section and taking into account any pertinent information developed since the submittal of the preliminary safety analysis report. Analysis and evaluation of ECCS cooling performance following postulated loss-of-coolant accidents shall be performed in accordance with the requirements of § 50.46 for facilities for which a license to operate may be issued after December 28, 1974.

(5) A description and evaluation of the results of the applicant's programs, including research and development, if

any, to demonstrate that any safety questions identified at the construction permit stage have been resolved.

(6) The following information concerning facility operation:

(i) The applicant’s organizational structure, allocations or responsibilities and authorities, and personnel qualifications requirements;

(ii) Managerial and administrative controls to be used to assure safe operation. Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," sets forth the requirements for such controls for nuclear power plants and fuel reprocessing plants. The information on the controls to be used for a nuclear power plant or a fuel reprocessing plant shall include a discussion of how the applicable requirements of appendix B will be satisfied;

(iii) Plans for preoperational testing and initial operation;

(iv) Plans for conduct of normal operations, including maintenance, surveillance, and periodic testing of structures, systems, and components.

(v) Plans for coping with emergencies, which shall include the items specified in appendix E.

(vi) Proposed technical specifications prepared in accordance with the requirements of § 50.36.

(vii) On or after February 5, 1979, applicants who apply for operating licenses for nuclear powerplants to be operated on multiunit sites shall include an evaluation of the potential hazards to the structures, systems, and components important to safety of operating units resulting from construction activities, as well as a description of the managerial and administrative controls to be used to provide assurance that the limiting conditions for operation are not exceeded as a result of construction activities at the multiunit sites.

(7) The technical qualifications of the applicant to engage in the proposed activities in accordance with the regulations in this chapter.

(8) A description and plans for implementation of an operator requalification program. The operator requalification program must as a minimum, meet the requirements for those programs contained in § 55.59 of part 55 of this chapter.

(9) A description of the protection provided against pressurized thermal shock events, including projected values of the reference temperature for reactor vessel beltline materials as described in § 50.61(b)(1) and (b)(2).