

May 17, 1999

SECY-99-133

FOR: The Commissioners

FROM: William D. Travers /s/
Executive Director for Operations

SUBJECT: FINAL REVISION TO 10 CFR 50.65 TO REQUIRE LICENSEES TO
PERFORM ASSESSMENTS BEFORE PERFORMING MAINTENANCE

PURPOSE:

To obtain the Commission's approval to publish a final rule in the Federal Register that amends 10 CFR 50.65 to require that, before performing maintenance, licensees assess, and manage the increase in risk that may result from the maintenance activities. The rule will permit licensees to use a risk-informed scope for the assessments.

BACKGROUND:

On December 17, 1997, the Commission issued a staff requirements memorandum (SRM) directing the staff to make certain changes to 10 CFR 50.65, the maintenance rule. Emphasis was on the paragraph (a)(3) recommendation: "In performing monitoring and preventive maintenance activities, an assessment of the total plant equipment that is out of service should be taken into account to determine the overall effect on performance of safety functions." The principal purpose of the amendment is to require licensees to perform the assessments and manage the increase in plant risk that may result from the maintenance activity. On July 2, 1998, the staff presented its proposed revision to the rule in SECY-98-165; and on September 3, 1998, the Commission issued SRM-98-165 approving publication of the proposed rule in the Federal Register for a 75-day comment period (63 FR 52201; September 30, 1998). That comment period ended December 14, 1998.

CONTACT:

Richard Correia, NRR
301-415-1009

Harry Tovmassian, NRR
301-415-3092

DISCUSSION:

The proposed revision to the maintenance rule to require that licensees perform assessments and use the results to manage the increase in risk due to maintenance activities has been modified in response to public comments. Comments were received from 34 sources: 26 utilities with operating units, 3 nuclear industry service companies or consultants, a utility with a single unit in decommissioning status, an individual, a State agency, a law firm representing several utilities, and the Nuclear Energy Institute (NEI), whose comments were supported by 29 respondents. The details of the comments and responses are incorporated in the final Federal Register notice (Attachment 1).

Nearly all respondents were concerned with the wording of paragraph (a)(4) of the proposed rule. The proposed paragraph (a)(4) read:

“Before performing maintenance activities on structures, systems or components within the scope of this section (including but not limited to, surveillance testing, post-maintenance testing, corrective maintenance, performance/condition monitoring, and preventive maintenance), an assessment of the current plant configuration as well as expected changes to plant configuration that will result from the proposed maintenance activities shall be conducted to determine the overall effect on performance of safety functions. The results of this assessment shall be used to ensure that the plant is not placed in risk significant configurations or configurations that would degrade the performance of safety functions to an unacceptable level.”

Paragraph (a)(4) as revised after consideration of public comments now reads:

“Before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee shall assess and manage the increase in risk that may result from the proposed maintenance activities. The scope of the assessment may be limited to structures, systems, and components that a risk-informed evaluation process has shown to be significant to public health and safety.”

In its comments, NEI stated that “this rulemaking represents a significant new requirement,” and provided three specific concerns about the rule. The first concern addressed terminology and stated that terms such as “risk-significant configuration” and “configurations that would degrade the performance of safety functions to an unacceptable level” are new and subjective. The staff’s position is that the language is not new. It was taken from the statement of considerations (SOC) for the original issuance of §50.65 on July 10, 1991 (56 FR 31306-31323). The staff acknowledges it could be argued that because the original paragraph (a)(3) was silent on the use of the assessment, an explicit requirement to use the assessment constitutes a new requirement. However, the staff believes requiring that the assessment results be used codifies the Commission’s original intent as reflected in the original rule’s SOC. In any case, because paragraph (a)(4) of the proposed rule could be interpreted as meaning that a risk-significant configuration would not be permitted under any circumstances, regardless of degree of risk and duration of that risk, the term “manage” has been introduced to maintain the Commission’s original intent and also to be consistent with the flexibility that §50.65 gives licensees.

The staff's expectations for licensee assessment activities have not changed. Licensees will be expected to review the current plant configuration and the anticipated changes caused by the proposed maintenance activities, although licensees may limit the scope of their assessments through use of an appropriate risk-informed evaluation process. Licensees are expected to consider potential failures and emergent maintenance requirements. The sophistication of the assessments, ranging from deterministic judgments to in-depth analyses, is expected to be commensurate with the complexity of the involved configurations. (More detail on staff expectations is provided in the discussion under Item 4 of Section III, "The Final Rule," in the Federal Register notice, Attachment 1.)

The second NEI concern addressed the apparent overlapping regulatory requirements of technical specifications (TS) and the proposed maintenance rule. Under certain conditions, a plant's TS may allow a structure, system, or component (SSC) to be out of service, while a pre-maintenance assessment proposing the removal of that same SSC from service may preclude that configuration. Also, it is possible that allowed outage times of TS may not be in complete agreement with out-of-service times resulting from the assessments. The staff recognizes that TS limiting conditions for operation were, in part, developed to address random failures of plant SSCs but have been used by licensees as rationale for the deliberate removal of those SSCs from service to perform on-line maintenance. The maintenance rule is intended to apply to proposed maintenance activities that will directly, or may inadvertently, result in equipment being taken out of service. Normally, TS may serve as the pre-analyzed assessment, used with sound judgement, when the licensee proposes that a single SSC be removed from service for maintenance when no other SSC is out of service. However, as the licensee proposes that additional SSCs undergo concurrent maintenance, the configuration becomes more complex, and more sophisticated assessment processes are necessary and appropriate.

The staff believes that, in general, TS allowed outage times were not developed for and are inappropriate for controlling concurrent removals of SSCs from service during plant operation. In an October 6, 1994, letter to Mr. Zach T. Pate, President of the Institute of Nuclear Power Operations (INPO), NRC's Executive Director for Operations, James M. Taylor, stated: "Doing preventive maintenance on more than one train or system at a time can result in plant configurations that, although not prohibited by technical specifications, are detrimental to plant safety." Mr. Taylor also said: "When performing on-line maintenance, confidence in the operability of the independent equipment that is redundant or diverse to the affected equipment should be high." On the same date, in a letter to Mr. Joe F. Colvin, Executive Vice President of NEI, William T. Russell, Director of NRC's Office of Nuclear Reactor Regulation (NRR), wrote: "It is important for licensees to understand that the allowable outage times specified in plant technical specifications are based upon a random single failure in a system and a judgement of a reasonable time to effect repairs before plant shutdown is required. The technical specifications do not address allowable outage times for multiple equipment being taken out of service at the same time." The staff expects that, while performing on-line or shutdown maintenance, the licensee will remain in conformance with its TS. In addition, the licensee's pre-maintenance planning is expected to include, to the depth necessary for the complexity of the maintenance activities, (1) identification of the equipment to be protected during the maintenance activity and (2) contingency plans that identify equipment to be restored first, if necessary, should a random equipment failure occur, and compensatory actions to be taken should the proposed outage duration be exceeded. The revised wording requiring licensees to assess and manage the increase in risk is intended to cause the licensee to determine its

options and follow a prudent course of action, consistent with the staff's expectations outlined above.

The third NEI concern was that the scope of SSCs subject to the proposed assessment requirement was impractical. Paragraph 50.65(b) defines the scope of SSCs that are covered by the rule (with the exception of SSCs for decommissioning plants). Chapter 11.0 of NUMARC 93-01, "Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," Revision 2, dated April 1996 (which has been endorsed by Regulatory Guide 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," Revision 2, dated March 1997), is entitled "Evaluation of Systems to be Removed from Service." Chapter 11.0 guidance describes the assessment as a three-step process: (1) Identify key plant safety functions to be maintained, (2) identify SSCs that support key plant safety functions, and (3) consider the overall effect of removing SSCs from service on key plant safety functions. Requiring, instead of recommending, those assessments does not change the expectation that the assessments need only involve SSCs associated with initiating or mitigating impacts on key plant safety functions. This expectation will be emphasized in Revision 3 to Regulatory Guide 1.160. Further, licensees may limit the scope of their assessments to SSCs that a risk-informed evaluation process has shown to be significant to public health and safety.

The staff recognizes that the coordination between the effective date of the revised rule and the issuance of the revised regulatory guidance is an important consideration. In SRM-97-173, dated December 17, 1997, the Commission indicated that development of the regulatory guidance should not delay issuance of the final maintenance rule. Later, in SRM-98-165, dated September 3, 1998, the Commission requested the staff to strive to present the regulatory guidance no later than the final rule package. The staff has prepared draft guidance, which will be provided to the public for comment. The staff agrees with the public comments that the rule should not be made effective until a reasonable period subsequent to the issuance of the final regulatory guidance. In SECY-98-165, dated July 2, 1998, the staff committed to providing guidance 120 days after the rule is issued. The staff now requests that the effective date of the revised rule be 120 days after issuance of Regulatory Guide 1.160, Revision 3.

CONCLUSION:

The staff believes that the revised wording, when supported by appropriate guidance that will be issued 120 days before the effective date of the rule, will accomplish the Commission's intent for modification of the maintenance rule.

This paper provides the Commission with the rulemaking package for the final rule that amends 10 CFR 50.65 as directed. The regulatory analysis supporting this final rule is included as Attachment 2.

COORDINATION

The Office of the General Counsel has reviewed this final rule and has no legal objection to its content. The Office of the Chief Financial Officer has reviewed this final rule for resource

implications and has no objection to its content. The Office of the Chief Information Officer has reviewed this final rule for information technology impacts and has no objections. The Advisory Committee on Reactor Safeguards (ACRS) reviewed the final rule and draft guidance on April 8, 1999, and the modified final rule on May 5, 1999. In their letter to the Chairman dated April 14, 1999, ACRS supported the version of the rule and the draft regulatory guidance. In their letter to the Chairman dated May 11, 1999, the Committee recommended the addition of "for the proposed configuration" to the end of the second sentence in paragraph (a)(4). The staff will address the May 11, 1999, letter by separate correspondence.

The staff met with the Committee to Review Generic Requirements (CRGR) on April 27, 1999, to discuss this final rule. Pending issuance of the final meeting minutes, the CRGR Chairman informed the NRC Executive Director for Operations (EDO) of the issues raised by the Committee in a memorandum dated April 29, 1999. The staff addressed those issues and responded to the CRGR Chairman by memorandum from NRR's Director, Division of Inspection Program Management (DIPM), dated May 5, 1999. The latter memo, which includes staff response on a comment-by-comment basis, was forwarded to the Commission by the Assistant for Operations, OEDO, on May 10, 1999.

Finally, from an enforcement perspective, the severity of violations of this rule will be based on the risk significance of the maintenance configuration that was either not evaluated or for which the evaluation was inadequate. Risk significant violations will be considered for escalated action. Failure to evaluate the maintenance configuration which did not result in risk significant configurations will be normally considered as a Severity Level IV violation and, in accordance with Appendix C of the Enforcement Policy, be processed as a non-cited violation. Under the proposed integrated reactor oversight process in SECY 99-007A, violations of the maintenance rule will be evaluated by the Significance Determination Process and not treated under the traditional enforcement process.

RESOURCES:

Resources for possible Maintenance Rule Baseline Inspection follow-up activities are budgeted at a total of 1.0 full-time-equivalent position.

RECOMMENDATIONS:

That the Commission:

1. Approve the notice of final rulemaking (Attachment 1) for publication in the Federal Register. Note that the rule will become effective 120 days following the issuance of Revision 3 to Regulatory Guide 1.160.
2. Certify that this rule, if issued, would not have a significant economic impact on a substantial number of small entities to satisfy the requirements of the Regulatory Flexibility Act, 5 U.S.C. 605(b).

3. Note that:

- a. This final rule will be published in the Federal Register (Attachment 1);
- b. The appropriate congressional committees will be informed (Attachment 3);
- c. A public announcement (Attachment 4) will be issued when this final rule is filed with the Office of the Federal Register;
- d. This final rule contains no new or amended information collection requirements;
- e. Forms to be submitted for federal rules under the Congressional Review Act are included as Attachment 5; and
- f. Copies of the Federal Register notice of final rulemaking will be distributed to all affected Commission licensees. The notice will be sent to other interested parties upon request.

William D. Travers
Executive Director
for Operations

- Attachments: 1. Federal Register Notice
2. Regulatory Analysis
3. Congressional Letters
4. Public Announcement
5. Congressional Review Act Forms

ATTACHMENT 1
FEDERAL REGISTER NOTICE

NUCLEAR REGULATORY COMMISSION

10 CFR Part 50

RIN 3150-AF95

Monitoring the Effectiveness of Maintenance at Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its power reactor safety regulations to require that licensees assess the effect of equipment maintenance on the plant's capability to perform safety functions before beginning maintenance activities on structures, systems, and components (SSCs) within the scope of the maintenance rule. The amendments clarify that these requirements apply under all conditions of operation, including shutdown, and that the assessments are to be used so that the increase in risk that may result from the maintenance activity will be managed to ensure that the plant is not inadvertently placed in a condition of significant risk or a condition that would degrade the performance of safety functions to an unacceptable level. These amendments permit licensees to limit the scope of the assessments to SSCs that a risk-informed evaluation process has shown to be significant to public health and safety.

EFFECTIVE DATE: The final rule becomes effective 120 days after issuance of Revision 3 to Regulatory Guide 1.160, "Monitoring the Effectiveness of Nuclear Power Plants." The NRC will

publish a document in the Federal Register that announces the issuance of Revision 3 to the regulatory guide and specifies that the final rule becomes effective in 120 days.

FOR FURTHER INFORMATION CONTACT: Richard P. Correia, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, 301-415-1009,
e-mail rpc@nrc.gov.

SUPPLEMENTARY INFORMATION:

I. Background

The NRC's maintenance team inspections of all nuclear power plant licensees in the late 1980s found the lack of consideration of plant risk in prioritizing, planning, and scheduling maintenance activities to be a common weakness. To address that weakness, paragraph (a)(3) of 10 CFR 50.65, the maintenance rule, currently includes the provision that "(I)n performing monitoring and preventive maintenance activities, an assessment of the total plant equipment that is out of service should be taken into account to determine the overall effect on performance of safety functions." The maintenance rule was issued on July 10, 1991 (56 FR 31306).

During plant visits in mid-1994, several NRC senior managers expressed concerns that licensees were increasing both the amount and frequency of maintenance performed during power operation without adequately evaluating safety when planning and scheduling these maintenance activities. The NRC Executive Director for Operations (EDO) addressed these concerns regarding the safety implications of performing maintenance while at power to the President of the Institute of Nuclear Power Operations (INPO) in a letter dated October 6, 1994. In this letter, the EDO noted that it appeared that some licensees were either not following

INPO guidelines for the conduct of maintenance and management of outages or had adopted only portions of the guidance. The EDO also recommended that INPO support the Nuclear Energy Institute (NEI) and appropriate utility managers during meetings with NRC senior managers to discuss the concerns they raised during the site visits.

The growing amount of on-line maintenance (i.e., maintenance during power operations) being performed by licensees and the quality of pre-maintenance assessments have merited the Commission's concern. To address this concern, to clarify the plant operating conditions under which the maintenance rule is applicable, and to make the requirements fully enforceable, the Commission published proposed revisions to 10 CFR 50.65 in the Federal Register on September 30, 1998 (63 FR 52201-52206). The 75-day comment period closed December 14, 1998.

II. Comments on the Proposed Rule

Twenty-nine comments were submitted during the comment period, and five were submitted after the comment period closed. Copies of the letters are available for public inspection and copying for a fee at the Commission's Public Document Room, located at 2120 L Street, NW (Lower Level), Washington, D.C. The last public comment was received on December 29, 1998. All comments were considered in formulating the final rule. The 34 comments were submitted by 26 utilities with operating power reactors, one utility with a decommissioning status facility, three nuclear industry service companies or consultants, one individual, one State agency, NEI, an industry group, and one law firm representing several utilities. Twenty-nine commentors endorsed the NEI comments. NEI stated in its comment letter that the industry generally supports the Commission's intent in the proposed rule but has a number of significant concerns that should be addressed before rulemaking proceeds. Of the commentors who did not endorse the NEI comments, one (combined State agencies) supported the concept of the proposed rule and provided comments to enhance it, and two

others (an individual and a utility) provided recommendations in specific areas to enhance the proposed rule. Two of the commentors (a consultant and a consulting firm) stated that the rule was unnecessary and presented supporting reasons.

The comments have been grouped under the following general topics:

1. Rule issuance
2. New, vague, ambiguous, undefined terminology in the proposed rule
3. Scope issues
4. Suggestions for wording modifications
5. Regulatory controls overlapping technical specifications
6. Performing assessments
7. Assessing and managing risk
8. Emergent maintenance requirements
9. Documentation of the assessment
10. Definition of availability
11. Backfit and regulatory analyses
12. Regulatory analysis cost estimates
13. Application to decommissioning plants.

Summaries of the grouped comments and discussions of the NRC responses follow.

1. Rule issuance.

Comment. One commentor, a utility, stated that they consider the proposed rule unnecessary, and NEI and other utilities stated that the proposed rule, as written, should be withdrawn. However, they also stated that if the rule is approved, Regulatory Guide 1.160 should be revised and issued before finalizing the changes to the rule.

Response. The NRC has determined that the rule is necessary and believes that the performance of this type of assessment is prudent because of changes in industry maintenance practices and findings during NRC inspections of maintenance rule programs. When the maintenance rule was first promulgated in 1991, the NRC had not foreseen the significant changes licensees would be making in maintenance practices. To enhance operational efficiency, made increasingly necessary by the rate deregulation of the electric utility industry, licensees are shortening their refueling outages by performing more maintenance while the plant is at power. At-power maintenance practices have evolved to the point that not only are major systems, subsystems, and components taken off line, but also multiple systems, subsystems, and components are taken off line simultaneously. Taking systems and components off line for maintenance could result in an increase in risk because of the reduced capability to mitigate the consequences of an accident or a transient, compared to risk that occurs from expected random equipment failures. In addition, although the maintenance rule baseline inspections of all operating nuclear power plant sites found that all licensees have implemented programs to perform the assessments, about half of the sites had programs with discernable weaknesses in this area, including instances in which, in accordance with the licensees' own programs, assessments should have been made but were not.

The NRC agrees that it is appropriate to revise Regulatory Guide 1.160 to incorporate clarifying guidance before the final rule's effective date. Accordingly, Revision 3 to Regulatory Guide 1.160 will be prepared for public comment and will be published in final form 120 days before the effective date of the rule.

2. New, vague, ambiguous, undefined terminology in the proposed rule.

Comment. Most commentors identified concerns related to the proposed rule's introduction of new, vague, ambiguous, or undefined terminology and recommended that the rule be withdrawn and reissued for public comment after substantial modification. NEI and

utilities indicated that terms such as “risk-significant condition” and “unacceptable level” should be explicitly defined.

Response. Paragraph (a)(4) has been reworded. Guidance for the revised terminology appears below in Item 4 of Section III, “The Final Rule.”

3. Scope issues.

Comment. Many commentors stated that assessments required by the proposed rule should apply only to high safety-significant SSCs. NEI and utilities expressed concerns that the scope of SSCs subject to assessments was impractical. Such broad scope would dilute attention from high safety-significant SSCs by requiring too many detailed assessments.

Response. Paragraph 50.65(b) defines the scope of SSCs that are covered by the rule (with the exception of SSCs for decommissioning plants). Chapter 11.0 of NUMARC 93-01, “Industry Guidelines for Monitoring the Effectiveness of Maintenance,” Revision 2, dated April 1996 (which has been endorsed by Regulatory Guide 1.160, Revision 2, dated March 1997), is entitled “Evaluation of Systems to be Removed from Service.” Chapter 11.0 guidance makes the evaluation, or assessment, a three-step process: (1) Identify key plant safety functions to be maintained, (2) identify SSCs that support key plant safety functions, and (3) consider the overall effect of removing SSCs from service on key plant safety functions. Requiring, instead of recommending, those assessments does not change the expectation that the assessments need only involve SSCs associated with initiating and mitigating impacts on key plant safety functions. To codify this expectation, paragraph (a)(4) of the final rule contains a second sentence as follows: “The scope of the assessment may be limited to structures, systems, and components that a risk-informed evaluation process has shown to be significant to public health and safety.”

4. Suggestions for wording modifications.

Comment. Five commentors provided suggestions clarifying regulatory text. Two of these commentors stated that the plant configuration should be defined as “SSCs within the scope of the rule,” and three commentors suggested limiting the scope of maintenance activities to those that result in removing equipment from service.

Response. The NRC disagrees with these suggested language changes. The rule currently applies only to SSCs within the scope of the rule. A revision to specify that fact is not needed, although this rule is being revised to permit licensees to limit the scope of their assessments to SSCs that a risk-informed evaluation process has shown to be significant to public health and safety. Additionally, certain maintenance activities are performed that do not remove equipment from service but have the potential for challenging safety systems. One example is valve testing on certain balance-of-plant systems during which open valves are cycled shut and reopened. If such a valve was to inadvertently stick shut, a transient could ensue. Those scenarios must be assessed and managed to ensure that the risks associated with these activities are properly identified and controlled.

5. Regulatory controls overlapping technical specifications.

Comment. Several commentors stated that there is a need to reconcile the overlapping regulatory regimes of the maintenance rule, technical specifications (TS), and the configuration risk management program (CRMP) (described in Regulatory Guide 1.177, “An Approach for Plant-Specific, Risk-Informed Decisionmaking: Technical Specifications”). NEI and the utilities were mainly concerned with the overlap of regulatory controls in the revised rule and TS.

Response. The NRC agrees that some overlap exists among these regulatory controls. Under certain conditions, a plant’s TS may allow an SSC to be out of service, while a pre-maintenance assessment proposing the removal of that same SSC from service may indicate a need to take other actions to preclude that configuration. It is possible that allowed outage times of TS may not be in complete agreement with reasonable out-of-service times resulting

from the required assessments. However, TS limiting conditions for operation were, in part, developed to address random single failures of plant SSCs; they were not intended to be used by licensees as rationale for removing multiple SSCs from service to perform on-line maintenance. In general, TS may serve as a pre-analyzed assessment, when used with sound judgement, when a licensee proposes to remove a single, simple SSC (an SSC with no interactions or dependencies with other key plant safety functions) from service for maintenance. Paragraph (a)(4) is intended to cause the licensee to determine its options and follow a prudent course of action. Nevertheless, while performing on-line or shutdown maintenance, the licensee will remain in conformance with its TS.

In NRC staff requirements memorandum dated June 29, 1998, for SECY-98-067, the Commission directed the NRC staff to take actions to ensure that CRMP regulatory guidance conforms to the provisions of the final maintenance rule. After revisions to the maintenance rule are completed, the NRC will expeditiously support licensee requests to remove the CRMP requirements from plant TS.

6. Performing assessments.

Comment. NEI and the utilities expressed the need for clarification of when an assessment would be required, the level of complexity necessary in the assessment, and the criteria to be used to evaluate the adequacy of the assessment process.

Response. Please refer to the discussion in Item 4 of Section III, "The Final Rule," below.

7. Assessing and managing risk.

Comment. Three commentors expressed similar views related to high-risk activities. One noted that, under suitable controls, a shorter time in a more risk-significant configuration may be safer than a longer time in a less risk-significant configuration. Another noted that high risk-significant activities should be recognized and avoided, where practical, and limited in

duration when they are necessary. The third noted that the proposed rule does not address situations in which failure to perform a maintenance activity may have a greater impact on risk than performing the high safety-significant activity.

Response. The NRC agrees that the proposed rule precluded entering risk-significant configurations, no matter the duration, when, in fact, situations may exist that would yield a net safety benefit by performing maintenance in a risk-significant configuration for a short time. The rule has been revised to require licensees to understand their options with respect to risk and to manage their maintenance activities according to their best judgment, considering insights from operating experience and deterministic and probabilistic analyses.

8. Emergent maintenance requirements.

Comment. Two commentors stated that the proposed rule does not address expectations for revising assessments upon the discovery of a previously unknown condition requiring maintenance (emergent maintenance). They also expressed concerns that if certain emergent maintenance activities are not completed immediately, the plant could be at greater risk.

Response. Under the revised rule, an assessment is required to be initiated following the discovery of emergent failures or changes in plant conditions to determine the safety impact of the failure or the change in plant conditions. For additional information on this subject, please see the discussion in Item 4 of Section III, "The Final Rule," below.

9. Documentation of the assessment.

Comment. Three utility commentors stated that the proposed rule is not explicit enough regarding assessment documentation expectations.

Response. The rule has no explicit documentation requirements. Instead, the rule emphasizes performance. A licensee's assessment process is expected to identify the impact on safety that is caused by the performance of maintenance. Licensees should use

documentation to the extent necessary to assure themselves that the requirement for an assessment has been acknowledged and performed adequately. NRC expectations are that a licensee will have a requirement for the assessments and an explanation of the process to be followed in its maintenance rule program, along with a description of assessment tool(s) to be used and their limitations, implementing procedures, and explicit direction covering instances when the plant configuration is or is proposed to be outside the span of the assessment tool. Further, the assessment process is expected to be incorporated into the maintenance planning and scheduling process and into work package requirements. Moreover, control room operators, who are expected to understand, use, and know the limitations of the assessment tools, generally use and maintain a variety of documents, such as logs and checklists, that contain information relating to out-of-service SSCs.

10. Definition of availability.

Comment. Three commentors stated that the definition of availability will be key to this rulemaking. They also stated that the availability definition should take into account the time required to restore the functionality of an SSC and should also be risk informed.

Response. A definition of availability for licensee maintenance rule programs is set forth in NUMARC 93-01, Revision 2, which was endorsed by the NRC in Regulatory Guide 1.160, Revision 2, of March 1997. According to that document, availability is “(t)he time that a(n) SSC is capable of performing its intended function (expressed) as a fraction (usually as percent) of the total time that the function may be demanded.” Also according to that document, under the definition of “unavailability,” is the following statement: “An SSC that is required to be available for automatic operation must be available and respond without human action.” Additionally, in the instance where an SSC is taken out of service for testing but could be manually activated, the NRC has accepted that, as long as the dedicated operator’s written procedure specifies a single action that would permit an automatic initiation of the out-of-service SSC in the event of

an accident or transient during the test, the SSC could be considered available. (Meeting Summary -- November 19, 1991 NRC/NUMARC Public Meeting on the Development of Guidance Documents for the Implementation of the Maintenance Rule (10 CFR 50.65), R.P. Correia, Office of Nuclear Reactor Regulation, memorandum to E.W. Brach, Office of Nuclear Reactor regulation, dated November 23, 1991.) The NRC's expectation is that, by procedure, the dedicated operator is stationed at the equipment and is ready and qualified to perform that single action in a moment. An acceptable single action could be the rapid repositioning of a switch or a lever; an unacceptable action would be racking in a breaker or, in some instances, opening a manual gate valve.

With respect to risk-informing the maintenance rule definition of availability, the reliance of initial availability performance measures on probabilistic risk assessment (PRA) data provided such a basis. However, in quality maintenance programs, availability is monitored to identify and trend the performance of equipment, thereby permitting certain conclusions to be drawn about the effectiveness of the equipment's maintenance program. Paragraph (a)(3) of the rule requires that the prevention of SSC failures (reliability) through maintenance is appropriately balanced against the objective of minimizing unavailability. Omitting unavailability time from the maintenance effectiveness determination analysis is flawed logic. Omitting unavailability time because, in an accident scenario, the equipment may not be needed for the time it may take to restore its safety function recognizes the role of the equipment but masks the actual requirement for maintenance. The maintenance rule requires licensees to monitor the effectiveness of their maintenance programs. Omitting significant details, such as how much maintenance time an SSC requires in order to attain the objective of preventing failures, is contrary to the purpose of the rule.

Note also that maintenance rule "availability" is not technical specification "operability."

11. Backfit and regulatory analyses.

Comment. One commentator stated that the regulatory analysis does not justify the expansion of the maintenance rule to "normal shutdown operations" and that a revision of the analysis to better consider such expansion would show through backfit considerations that the expansion is not justified. Another commentator also presented a concern that the overall implications of the rule were not supported by the backfit analysis.

Response. The new preamble to the rule is an introductory sentence clarifying that the rule applies under all operating conditions, including normal shutdown. The Commission intended the rule to apply to all operating conditions, and it has been implemented by the NRC staff consistent with such an interpretation. Moreover, Section 11.2.3 of NUMARC 93-01 specifically states that "assessment applies during all modes of plant operation." The overall implications of the rule were assessed in the backfit analysis for the original maintenance rule, which was issued July 10, 1991.

12. Regulatory analysis cost estimates.

Comment. One commentator raised the concern that if facilities are required to develop numerical models for every combination of low safety-significant SSCs, the cost of implementing the program would be significantly higher than estimated in the regulatory analysis.

Response. The NRC does not expect licensees to develop numerical models for assessing all possible combinations of low-risk-significant SSCs. The regulatory analysis states that the complexity of assessments to be performed can vary, depending upon the configuration of SSCs to be maintained on line or out of service. It was presumed that assessments involving SSCs having little bearing on safety could be performed in an uncomplicated, deterministic manner and that the cost of the overall program would be dominated by the need for assessment of combinations of SSCs, which, when taken out of service simultaneously, could have an adverse effect on the safe operation of the facility.

Additionally, the licensee controls the degree of complexity of the proposed configuration and thereby controls the level of sophistication required for the assessment. Consequently, the licensee should not propose to enter a plant configuration the complexity of which exceeds the licensee's ability to assess.

13. Application to decommissioning plants.

Comment. One commentor presented concerns regarding the application of the rule to plants in a decommissioning status. The commentor requested that, as part of this rulemaking, the NRC remove the applicability of the rule to decommissioning status plants following some modest level of fission product decay.

Response. This rulemaking is focused on requiring pre-maintenance assessments of plant risk. However, the NRC is considering the issue in a separate rulemaking activity.

III. The Final Rule

The final rule amends 10 CFR 50.65 as follows:

1. An introductory paragraph has been added to 10 CFR 50.65 clarifying that the rule applies under all conditions of operation, including normal shutdown. This introductory language reads as follows: "The requirements of this section are applicable during all conditions of plant operation, including normal shutdown operations." The intent of this paragraph is to ensure that assessments are performed before maintenance activities when the plants are shut down as well as when the plants are at power. (Note that the word "section," as used in this rulemaking, means all of §50.65.)

2. The second sentence in paragraph (a)(3) has been revised as follows: "The evaluations shall take into account, where practical, industry-wide operating experience." The change was made only to simplify the language and is purely editorial.

3. The last sentence of paragraph (a)(3), containing the current, non-mandatory provision for performing safety assessments, is deleted. The revised paragraph (a)(3) now contains only the requirement for periodic, programmatic, long-term review.

4. A new paragraph, (a)(4), has been added requiring the performance of assessments. The first sentence of the new (a)(4) paragraph states: "Before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee shall assess and manage the increase in risk that may result from the proposed maintenance activities." Separating the assessment requirement from the long-term review requirement in paragraph (a)(3) will more clearly distinguish between the two types of activity.

The intent of this requirement is to have licensees appropriately assess the risks related to proposed maintenance activities that will directly, or may inadvertently, result in equipment being taken out of service and then, using insights from the assessment, suitably minimize the out-of-service time resulting from the proposed maintenance activities while also controlling the configuration of the total plant to maintain and support the key plant safety functions.

Risk is the result of the likelihood of an event with due consideration of the consequences of that same event. The term "risk" is used to address what can go wrong, its likelihood, and its consequences. The risk perspective can be assessed deterministically or probabilistically.

In general, a risk assessment is necessary before all planned maintenance activities. Assessments should also be performed when an unexpected SSC failure initiates required maintenance activities or when changes to plant conditions affect a previously performed assessment. However, the reevaluation of a previous assessment should not interfere with, or delay, the plant staff's taking timely actions to restore the appropriate SSC to service or taking

compensatory actions necessary to ensure that plant safety is maintained. If the SSC is restored to service before performing the assessment, the assessment need not be conducted.

Assessments may vary from simple and straightforward to highly complex. However, the degree of sophistication required for the assessment notwithstanding, the NRC intends that the assessment process will examine the plant condition existing before the commencement of the maintenance activity, examine the changes expected by the proposed maintenance activity, and identify the increase in risk that may result from the maintenance activity. The assessments are expected to provide insights for identifying and limiting risk-significant maintenance activities and their durations.

The level of complexity necessary in the assessment would be expected to differ from configuration to configuration. When a licensee proposes to remove a single SSC from service for maintenance while no other SSC is out of service, a simple deterministic assessment may suffice. If the SSC is covered by TS, then the assessment could be as simple as an expert judgement, along with confirming the relevant requirements of TS. When one SSC is out of service and the licensee proposes to remove a second SSC from service for maintenance, the assessment could be simplified through the use of a table of results for pre-analyzed combinations, typically high-safety-significant SSCs paired against each other. However, more detailed assessments are required if a licensee proposes to remove multiple SSCs from service during power operations or to remove from service systems necessary to maintain safe shutdown during shutdown or startup operations. These more detailed assessments are expected to involve probabilistic analyses where possible, and to also include considerations of key plant safety functions to be maintained and defense in depth.

The NRC believes that an appropriate assessment and management process should include the following considerations:

5. The likelihood that the maintenance activity will increase the frequency of an initiating event;

6. The probability that the activity will affect the ability to mitigate the initiating event;
7. The probability that the activity will affect the ability to maintain containment integrity;
8. Whether multiple trains are affected;
9. How probabilistic insights are used;
10. How non-probabilistic insights are used;
11. Component and system dependencies;
12. Measures to prevent concurrent unavailabilities of equipment necessary for accident mitigation;
 - i. Methods to determine the duration of the activity and account for the projected duration;
 - j. The analytical basis for allowed configurations (quantitative or qualitative consideration);
 - k. Provisions for accommodating configurations not encompassed by preanalyzed, acceptable configurations; and
 - l. Scope and quality of analysis for quantified assessments.

In general, it is the NRC's expectation that the processes for managing the risk are scrutable and limit the risk increase of the proposed maintenance activities. This process should include an understanding of the nature (i.e., affecting the core damage, or large early release frequency) and significance of the risk implications of a maintenance configuration on the overall plant baseline risk level. For example, risk-significant plant configurations should generally be avoided, as should conditions where a key plant safety function would be significantly degraded while conducting maintenance activities. The effective control of potentially significant risk increase due to an unexpected failure of another risk-important SSC can be reasonably assured by planning for contingencies, or coordinating, scheduling, monitoring, and modifying the duration of planned maintenance activities.

5. The second sentence in the new (a)(4) paragraph states: "The scope of the assessments may be limited to structures, systems, and components that a risk-informed

evaluation process has shown to be significant to public health and safety.” In response to public comments on the proposed rule, this second sentence has been added so that licensees may reduce the scope of SSCs subject to the pre-maintenance assessment to those SSCs which, singularly or in combination, can be shown to have a significant effect on the performance of key plant safety functions. The focus of the assessments should be on the SSCs modeled in the licensee’s PRA, in addition to all SSCs evaluated as risk significant (high safety-significant) by the licensee’s maintenance rule expert panel. Typically, these SSCs have been analyzed as causing potential initiating events, if failed, and as accident mitigators, or as high safety-significant SSCs with their support systems. Such SSCs may be identified by operating experience or by deterministic or probabilistic analyses.

Finding of No Significant Environmental Impact: Environmental Assessment

The Commission has determined under the National Environmental Policy Act of 1969, as amended, and the Commission's regulations in Subpart A of 10 CFR Part 51 that this final rule is not a major Federal action significantly affecting the quality of the human environment and, therefore, an environmental impact statement is not required. The environmental assessment that forms the basis for this determination reads as follows:

Identification of the Proposed Action

The Commission is amending its regulations to require commercial nuclear power plant licensees to perform assessments of changes to the plant’s status that would result from maintenance activities before performing the maintenance activities on structures, systems, and components (SSCs) within the scope of 10 CFR 50.65, the maintenance rule. Thus, the maintenance rule has been modified by adding an introductory sentence to clarify that the rule applies under all conditions of operation,

including normal shutdown; by making editorial revision to the second sentence of paragraph (a)(3); by deleting the last sentence of paragraph (a)(3); and by creating a new paragraph, (a)(4), that requires licensees to assess and manage the risk that may result from proposed maintenance activities.

The Need for the Proposed Action

Formerly, paragraph (a)(3) of the maintenance rule was in the form of a recommendation because it read as follows: "(I)n performing monitoring and preventive maintenance activities, an assessment of the total plant equipment that is out of service should be taken into account to determine the overall effect on performance of safety functions." The Commission believes that the performance of this type of assessment is prudent. The maintenance rule baseline inspections, performed at each operating nuclear power plant site, found that all licensees have implemented programs to perform the assessments. However, about half of the sites had programs with discernable weaknesses in this area, including instances in which, in accordance with the licensee's own programs, assessments should have been made but were not. Because of the hortatory nature of the assessment provision in §50.65(a)(3), the Commission cannot ensure that licensees perform the assessments. Moreover, licensees are free to remove the performance of the assessments from their programs as they so desire. This final rule permits the Commission to ensure that licensees perform the assessments, as appropriate.

Removing the provision regarding safety assessments from paragraph (a)(3) and creating for it a new, separate paragraph, (a)(4), disassociates the new requirement from the more time-dependent requirement for evaluating the program and the program's effectiveness at maintaining an appropriate balance between reliability and

availability for each SSC. In the new paragraph, the requirement for assessment performance is stipulated to ensure that licensees will perform those assessments. There were questions regarding when the assessments are to be performed, which plant conditions are to be evaluated, how the assessments are to be used, and which SSCs are subject to the assessments. The new paragraph (a)(4) was revised to describe that the assessments are to be performed before proposed maintenance activities and are to examine pre-maintenance plant conditions and expected changes as a result of the proposed maintenance activities. The assessments may be limited to SSCs that a risk-informed evaluation process has shown to be significant to public health and safety. Also, the assessments are to be used to manage the increase in risk that may result from the maintenance activity.

Environmental Impacts of the Proposed Action

This final rule requires that commercial nuclear power plant licensees perform certain assessments of the status of plant equipment before performing proposed maintenance activities. The purpose of this change is to increase the effectiveness of the maintenance rule by requiring licensees to --

- (1) Perform an assessment of the plant conditions before the proposed maintenance and the changes expected to result from the proposed maintenance activity;
- (2) Ensure that the assessments are performed when the plant is shut down as well as at power; and
- (3) Manage the increase in risk that may result from the proposed maintenance activity.

The Commission believes that proper implementation of the rule will reduce the likelihood and consequences of an accidental release of radioactive material caused by imprudently prioritized, planned, or scheduled maintenance.

The determination of this environmental assessment is that there will be no significant offsite impact to the public from this action. The NRC has also committed to complying with Executive Order (EO) 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," dated February 11, 1994, in all its actions. The NRC has determined that there are no disproportionate, high, or adverse impacts on minority or low-income populations. In the letter and spirit of EO 12898, the NRC requested public comment on any environmental justice considerations or questions that the public thinks may be related to this rule but somehow were not addressed. No public comments on this issue were received.

States Consulted and Sources Used

The NRC sent a copy of the proposed rule to every State Liaison Officer and requested his or her comments on the environmental assessment. No comments were received on this issue.

Paperwork Reduction Act Statement

This final rule does not contain a new or an amended information collection requirement subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Existing requirements were approved by the Office of Management and Budget (OMB), approval number 3150-0011.

Public Protection Notification

If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

Regulatory Analysis

The Commission has prepared a final regulatory analysis for this rule. The analysis examined the costs and benefits of the alternatives considered by the Commission for revising 10 CFR 50.65, the maintenance rule. Those alternatives were to (1) make no change to the rule, (2) require the safety assessments currently recommended in paragraph (a)(3) of the rule, and (3) make comprehensive revisions to paragraph (a)(3) of the rule. The analysis supported the selection of Alternative 2 as the preferred course of action. Details of the alternative selection are contained in the regulatory analysis, which is available for inspection in the NRC Public Document Room, 2120 L Street NW (Lower Level), Washington, D.C. Single copies of the analysis may be obtained from Richard P. Correia, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, 301-415-1009, e-mail rpc@nrc.gov.

Regulatory Flexibility Certification

In accordance with the Regulatory Flexibility Act of 1980 (5 U.S.C. 605(b)), the Commission certifies that this final rule will not have a significant economic impact on a substantial number of small entities. This rule affects only the operation of nuclear power plants. The companies that own these plants do not fall within the scope of the definition of small entities set forth in the Regulatory Flexibility Act or the size standards adopted by the NRC (10 CFR 2.810).

Backfit Analysis

As required by 10 CFR 50.109, the Commission has completed a backfit analysis for this final rule. The Commission has determined, on the basis of this analysis, that backfitting to comply with the requirements of this rule provides a substantial increase in protection to the public health and safety or the common defense and security at a cost that is justified by the increased protection.

When the maintenance rule was issued, the NRC had not foreseen the rate deregulation of the electric utility industry and the changes to maintenance practices that licensees would make to enhance operational efficiency. Specifically of concern is the significant increase in maintenance while the plant is at power, permitting shortened refueling outages. At-power maintenance practices have evolved to the point that multiple systems, trains, and components are simultaneously out of service. Compared to the risk that occurs from expected random equipment failures, the risk of an accident or transient caused by taking systems, trains, and components off line for maintenance or from performing maintenance on systems, trains, or components while they remain on line could be increased.

The objective of this rule is to require that --

(1) Licensees assess the impact of equipment maintenance on the capability of the plant to perform key plant safety functions; and

(2) Licensees use the results of the assessment before undertaking maintenance activities at operating nuclear power plants to manage the increase in risk caused by those activities.

Thus, the rule adds a new paragraph, (a)(4), that requires the performance of assessments, specifies that the scope of the requirement for performing those assessments covers proposed maintenance activities, specifies that the scope of SSCs to be assessed may be limited to those that a risk-informed evaluation process has shown to be significant to public

health and safety, and specifies that the increase in risk that may occur from the maintenance activity must be managed.

This final rule also adds an introductory sentence to 10 CFR 50.65 clarifying that the rule applies under all conditions of operation, including normal shutdown; revises the second sentence of paragraph (a)(3) to simplify the language; and deletes the last sentence of paragraph (a)(3) of the rule.

The details of this backfit analysis have been incorporated in the regulatory analysis. For the reasons elaborated in the regulatory analysis, which also contains cost information, the Commission concludes that this modification to the maintenance rule will result in a substantial increase in the overall protection to the public health and safety, and that the net costs of the rule are justified in view of this increased level of safety.

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Fairness Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of OMB.

National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act of 1995, Pub. L. 104-113, requires that Federal agencies use technical standards developed or adopted by voluntary consensus standards bodies unless the use of such a standard is inconsistent with applicable law or is otherwise impractical. There are no industry consensus standards that apply to the area of maintenance. Thus, the provisions of the Act do not apply to this rulemaking.

Antitrust, Classified information, Criminal penalties, Fire protection, Intergovernmental relations, Nuclear power plants and reactors, Radiation protection, Reactor siting criteria, Reporting and recordkeeping requirements.

For the reasons set out in the preamble and under the authority of the Atomic Energy Act of 1954, as amended; the Energy Reorganization Act of 1974, as amended; and 5 U.S.C. 552 and 553, the NRC is adopting the following amendments to 10 CFR Part 50.

PART 50 -- DOMESTIC LICENSING OF PRODUCTION AND UTILIZATION FACILITIES

1. The authority citation for Part 50 continues to read as follows:

AUTHORITY: Secs. 102, 103, 104, 105, 161, 182, 183, 186, 189, 68 Stat. 936, 937, 938, 948, 953, 954, 955, 956, as amended, sec. 234, 83 Stat. 444, as amended (42 U.S.C. 2132, 2133, 2134, 2135, 2201, 2232, 2233, 2236, 2239, 2282); secs. 201, as amended, 202, 206, 88 Stat. 1242, as amended, 1244, 1246 (42 U.S.C. 5841, 5842, 5846).

Section 50.7 also issued under Pub. L. 95-601, sec. 10, 92 Stat. 2951 (42 U.S.C. 5851). Section 50.10 also issued under secs. 101, 185, 68 Stat. 955, as amended (42 U.S.C. 2131, 2235), sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.13, 50.54(dd), and 50.103 also issued under sec. 108, 68 Stat. 939, as amended (42 U.S.C. 2138). Sections 50.23, 50.35, 50.55, and 50.56 also issued under sec. 185, 68 Stat. 955 (42 U.S.C. 2235). Sections 50.33a, 50.55a and Appendix Q also issued under sec. 102, Pub. L. 91-190, 83 Stat. 853 (42 U.S.C. 4332). Sections 50.34 and 50.54 also issued under sec. 204, 88 Stat. 1245 (42 U.S.C. 5844). Sections 50.58, 50.91, and 50.92 also issued under Pub. L. 97-415, 96 Stat. 2073 (42 U.S.C. 2239). Section 50.78 also issued under sec. 122, 68 Stat. 939 (42 U.S.C.

2152). Sections 50.80-50.81 also issued under sec. 184, 68 Stat. 954, as amended (42 U.S.C. 2234). Appendix F also issued under sec. 187, 68 Stat. 955 (42 U.S.C. 2237).

2. In §50.65, an introductory paragraph is added, paragraph (a)(3) is revised, and a new paragraph (a)(4) is added, to read as follows:

§50.65 Requirements for monitoring the effectiveness of maintenance at nuclear power plants.

The requirements of this section are applicable during all conditions of plant operation, including normal shutdown operations.

(a) * * *

(3) Performance and condition monitoring activities and associated goals and preventive maintenance activities shall be evaluated at least every refueling cycle provided the interval between evaluations does not exceed 24 months. The evaluations shall take into account, where practical, industry-wide operating experience. Adjustments shall be made where necessary to ensure that the objective of preventing failures of structures, systems, and components through maintenance is appropriately balanced against the objective of minimizing unavailability of structures, systems, and components due to monitoring or preventive maintenance.

(4) Before performing maintenance activities (including but not limited to surveillance, post-maintenance testing, and corrective and preventive maintenance), the licensee shall assess and manage the increase in risk that may result from the proposed maintenance activities. The scope of the assessment may be limited to structures, systems, and components that a risk-informed evaluation process has shown to be significant to public health and safety.

* * * * *

Dated at Rockville, Maryland, this ____ day of _____, 1999.

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For the Nuclear Regulatory Commission.

Annette Vietti-Cook,

Secretary of the Commission.

ATTACHMENT 2

REGULATORY ANALYSIS

Regulatory Analysis

Amendments to 10 CFR 50.65

Monitoring the Effectiveness of Maintenance

at Nuclear Power Plants

Introduction

This regulatory analysis will examine three options for implementing a requirement that licensees perform assessments of the increases in risk before performing maintenance activities. The assessments are now in the rule as a recommendation; this rulemaking makes the assessments a requirement. The first alternative would maintain the status quo. For that alternative, the basic assumption is that no licensee is performing pre-maintenance assessments. The second alternative would promulgate this rule, which requires some form of pre-maintenance assessment before taking equipment off line for maintenance purposes. The final alternative is to examine the use of a full probabilistic analysis approach to be used anytime equipment is proposed to be taken off line for maintenance. This regulatory analysis will conclude that Alternatives 1 and 3 are unacceptable. Alternative 1 would fail to satisfy the NRC's need to make the pre-maintenance assessments a requirement and thereby make them enforceable. Alternative 3 would require very rigorous and costly analyses. Therefore, this regulatory analysis supports the adoption of Alternative 2, which makes pre-maintenance assessments a requirement but allows licensees some level of flexibility in determining the complexity of the assessments to be performed.

Additionally, this regulatory analysis assumes that all structures, systems, and components within the scope of the rule (per paragraph (b)) would be subject to the pre-maintenance assessments. Based on public comments on the proposed rule, the staff has further modified the rule, allowing licensees the option of limiting the scope of the assessments to structures, systems, and components (SSCs) that a risk-informed evaluation process has shown to be significant to public health and safety. This further modification is a reduction in the burden described in this regulatory analysis and, therefore, is bounded by the regulatory and backfit analyses.

This regulatory analysis conforms to the guidance as specified in NUREG\BR-0058, "Regulatory Analysis Guidelines of the U. S. Nuclear Regulatory Commission," and contains the information and analyses that meet the requirements of both 10 CFR 50.109, the backfit rule, and provisions of the Charter for the Committee To Review Generic Requirements (CRGR), Revision 6, dated April 1996. Passages that address the items that must be considered in the backfit analysis have been cross-referenced to the appropriate 10 CFR 50.109 citation. The included backfit analysis demonstrates that the requirements provide a substantial increase in protection to the public health and safety or the common defense and security at a cost that is justified by the substantial increase.

1.0 Statement of the Problem

On July 10, 1991 (61 FR 31306), the U.S. Nuclear Regulatory Commission (NRC) published 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants." The Commission took this action because proper maintenance is essential to plant safety and there is a clear link between effective maintenance and safety as it relates to such factors as the number of transients and challenges to safety systems and the associated need for operability, availability, and reliability of safety equipment. Good maintenance is also important in providing assurance that failures of other than safety-related SSCs that could initiate, adversely affect, or mitigate a transient or an accident are minimized. Minimizing challenges to safety systems is consistent with the Commission's defense-in-depth philosophy. Maintenance is also important in ensuring that design assumptions and margins in the original design basis are maintained and are not degraded. Therefore, nuclear power plant maintenance is clearly important in protecting public health and safety.

In the late 1980s, the NRC's maintenance team inspections found that although licensees had adequate maintenance programs in place and had shown an improving trend in implementing those programs, a common weakness in those programs was a lack of consideration of plant risk in the prioritization, planning, and scheduling of maintenance activities. This weakness was one of the major reasons for the pre-maintenance assessment provision in 10 CFR 50.65(a)(3), which states: "In performing monitoring and preventive maintenance activities, an assessment of the total plant equipment that is out of service should be taken into account to determine the overall effect on performance of safety functions." Because this provision uses

the word “should” instead of “shall,” the legal effect is that the provision serves as a recommendation rather than as a requirement.

During plant visits in mid-1994, several NRC senior managers had concerns with the fact that licensees were increasing both the amount and the frequency of maintenance performed during power operations. Some licensees were limiting maintenance activities to a single train of a system, while others would allow multiple equipment in other systems within a single train to be out of service as long as it did not violate the plant’s technical specifications. However, allowable outage times specified in technical specifications are based upon a random single failure in a system and a judgment as to a reasonable time to effect repairs before plant shutdown is required. In general, technical specifications were not intended to address allowable outage times for multiple equipment being out of service concurrently. Further, it cannot be implied that it is acceptable to voluntarily remove equipment from service to perform on-line maintenance on the assumption that such actions are bounded by a worst-case single failure, which is a plant-specific design requirement that is contained in a number of the general design criteria in 10 CFR Part 50, Appendix A. The NRC senior managers also had concerns with the fact that on-shift personnel, planning and scheduling personnel, and licensee management lacked an understanding of the importance of safety systems or combinations of equipment that would have risk significance if taken out of service. It appeared that risk insights from plant-specific individual plant examinations, which were performed to improve licensee understanding of the plant’s safety and to address potential vulnerabilities, were not fully used in the plant’s operations and maintenance decision processes. These concerns were addressed in a letter dated October 6, 1994, from the Director of the Office of Nuclear Reactor Regulation to the Executive Vice President of the Nuclear Energy Institute. The growing

amount of maintenance performed during power operations and the underutilization of risk insights in plant operations and maintenance activities are safety concerns.

In SECY-97-055, "Maintenance Rule Status, Results, and Lessons Learned," dated March 4, 1997, the NRC staff described the challenge of inspecting and the NRC staff's inability to enforce the pre-maintenance assessment provision of §50.65(a)(3). The staff notes that, in general, licensees have followed the guidance contained in Regulatory Guide 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," and NUMARC 93-01, "Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," and, thus, have voluntarily complied with this provision of §50.65(a)(3) because it is obvious that there is a nexus between safety and having equipment out of service. When the maintenance rule was first promulgated in 1991, the NRC staff did not foresee the significant changes licensees would be making in maintenance practices. Typically, licensees performed significant amounts of maintenance during refueling outages. To enhance operational efficiency in reaction to rate deregulation of the electric utility industry, licensees are shortening their refueling and maintenance outages by performing more maintenance while the plant is at power. At-power maintenance practices have evolved to the point that not only are major systems and components taken off line, but also multiple systems and components are taken off line concurrently.

However, in the few cases in which the NRC staff has observed weak implementation or plant configurations for which the licensee did not adequately assess the configuration's safety impact, the NRC staff was unable to take actions to ensure that licensees perform appropriate assessments. Under current enforcement guidance, the NRC staff can invoke this provision of

paragraph (a)(3) in enforcement actions if the failure to perform an adequate pre-maintenance assessment causes, contributes to the severity of, or complicates recovery from an event. However, such a failure to perform an assessment can only be used as an escalating factor in enforcement actions otherwise taken as a result of the event, and it cannot be used as a separate violation.

For these reasons, the NRC staff is amending 10 CFR 50.65(a)(3) to ensure that licensees effectively assess and manage the increase in plant risk that may result from maintenance on SSCs within the scope of the rule. The objective of the rule is to require that licensees use the assessment of the impact of risk resulting from maintenance activities on equipment to ensure that the increase in risk that may result from maintenance activities does not inadvertently place the plant in a risk-significant configuration, that is, a configuration for which the contribution to the incremental annual risk is not insignificant, or in a configuration that would degrade key plant safety functions to an unacceptable level. **[\$50.109(c)(1)]** Additionally, in Staff Requirements Memorandum 97-173, dated December 17, 1997, the Commission approved the staff's recommendation to develop this rulemaking, provided text for revisions to 10 CFR 50.65, stated that "extended or protracted regulatory analysis of Alternative 1 (no rule change) is unnecessary," and directed that the regulatory analysis discussion of Alternative 3 (comprehensive rule change) be limited.

2.0 Identification and Preliminary Analysis of Alternative Approaches

2.1 Alternative 1--Make No Change to Paragraph (a)(3) in the Rule

The first alternative considered is to maintain the status quo and not revise paragraph (a)(3). As noted in SECY 97-055, licensees have, for the most part, voluntarily incorporated the paragraph (a)(3) pre-maintenance assessment provision in their maintenance rule implementation programs using Regulatory Guide 1.160 and NUMARC 93-01 because of the obvious connection between safety and maintenance on equipment. Additionally, some licensees have indicated a willingness to improve their programs to address weaknesses identified during inspections. Thus, the existing codified text could be considered sufficient. When inspections identify deficiencies in the programs of individual licensees, the staff could continue to encourage those licensees to improve their performance.

The obvious advantage of this alternative is that no additional burden would be placed on licensees or on the NRC staff to conduct such a rulemaking.

The disadvantages of Alternative 1 are that (1) licensees could remove the paragraph (a)(3) assessment provision in their maintenance rule implementation programs at their own discretion; (2) since the performance of an assessment is discretionary and not mandatory, licensees cannot take credit for their assessment programs under other risk-informed initiatives (unless they make the assessments a requirement through the other initiative); (3) because the assessments are not required, some licensees could view any efforts to encourage the

assessments as a potential backfit; and (4) the NRC staff cannot enforce this provision of the rule.

2.2 Alternative 2--Change Paragraph (a)(3) of the Rule to Require Assessments

Under §50.65(a)(4) of the final rule, before performing maintenance activities on SSCs within the scope of the rule, licensees would be required to conduct an assessment of the current plant configuration, as well as of expected changes to the plant configuration that will result from the proposed maintenance activities, to determine the overall effect on performance of key plant safety functions. Licensees would also be required to use the results of the assessment to manage the risk to ensure that the increase in risk that may result from maintenance activities does not inadvertently place the plant in a risk-significant configuration or a configuration that would degrade key plant safety functions to an unacceptable level. The SSCs that are subject to the requirements of the rule are those that are safety related, and certain non-safety-related SSCs as defined in §50.65(b) and (a)(1). Licensees have programs in place for implementing Regulatory Guide 1.160 and the industry guidance document it endorses, NUMARC 93-01, which accepts the existing paragraph (a)(3) recommendation as part of its program. To comply with this final rule and complete this backfit, licensees would need to incorporate the rule changes into their existing programs.

The final rule will add an introductory sentence to 10 CFR 50.65 clarifying that the rule applies under all conditions of operation, including normal shutdown; will revise the second sentence of paragraph (a)(3) for clarity; will delete the last sentence of paragraph (a)(3) of the rule; will create a new paragraph, (a)(4), that requires the performance of assessments; will specify that

the assessments are to be performed for all proposed maintenance activities; and will specify that the increase in risk that may occur from the maintenance activity must be managed.

Additionally, the rule will permit licensees to limit the scope of the assessment to SSCs that a risk-informed evaluation process has shown to be significant to public health and safety.

[\$50.109(c)(2)]

The advantages of Alternative 2 are that (1) licensees would retain maximum flexibility to operate within configurations allowed by their current license as envisioned when the rule was originally issued; (2) there would be little or no burden on most licensees because licensees already have voluntary programs in place in accordance with NUMARC 93-01, which the NRC endorsed by Regulatory Guide 1.160, and the weaknesses in those programs that led to the failures to perform assessments found during the baseline inspections could be corrected relatively easily; (3) if licensees fail to perform an assessment (as was found by 7 of the maintenance rule baseline inspections at the 68 operating reactor sites), the NRC staff could use enforcement to require corrective actions that ensure licensees perform the assessments in the future; and (4), when appropriate, licensees may be able to take credit for their paragraph (a)(4) assessment program in other regulatory initiatives.

The disadvantages of Alternative 2 are that (1) licensees are, in general, exercising their discretion to perform the assessments, and thus, the NRC may be unnecessarily expending resources on a rule change mandating the performance of an assessment already being performed voluntarily and (2) it would not address the weaknesses identified during 35 of the 68 baseline inspections pertaining to the quality and technical adequacy of licensees' methods for performing the assessments.

2.3 Alternative 3--Make Comprehensive Revisions to Paragraph (a)(3) of the Rule

The Statement of Considerations (SOC) for the maintenance rule noted that the assessments would be refined on the basis of technological improvement and experience. Therefore, as the third alternative, the staff considered a comprehensive revision of the paragraph (a)(3) assessment provision to incorporate the use of more modern technology and the experience with sophisticated techniques used by some utilities. To remain performance based, the rule would not prescribe a specific approach. Rather, it would provide considerations that assessment methodologies would have to address, while continuing to give licensees the flexibility to develop specific approaches that best suit the needs of each.

The advantages of Alternative 3 are that it would (1) require licensees to evaluate and control maintenance activities through technically advanced methods, (2) provide specific limits to the risk associated with maintenance activities, and (3) establish a foundation upon which other risk-informed regulation could build. Thus, Alternative 3 would address the weaknesses pertaining to the quality and technical adequacy of licensees' methods for performing the assessments identified during the baseline inspections and allow the use of the enforcement policy to require corrective actions for any of the weaknesses.

The disadvantages of Alternative 3 are that (1) such a rule would have a broad impact on other current and future rules and, instead, should be separated from this maintenance rule and developed as a rule that would be used generically for other risk-informed regulation; (2) since it would likely result in the use of probabilistic methods, Alternative 3 would impose a substantial

burden on both licensees and the staff; and (3) because of the greater burden on licensees, Alternative 3 may be less likely to have industry support relative to Alternative 2.

3.0 Estimation and Evaluation of Values and Impacts

3.1 Alternative 1--Make No Change to Paragraph (a)(3) of the Rule

This alternative is the base case for this regulatory analysis. Therefore, the assumption is made that no licensee performs the pre-maintenance assessments that are recommended in §50.65(a)(3). Thus, there would be no impact upon licensees if this alternative is adopted, and there would be no additional resource burden on the NRC. Likewise, there would be no safety benefit to the public.

3.2 Alternative 2--Change Paragraph (a)(3) of the Rule To Require Assessments

3.2.1 Impact of Alternative 2

If this alternative is adopted, all licensees would be required to assess and manage the effect that the resulting plant configuration would have on the safe operation of the facility. The degree of complexity of the assessments would be expected to differ from configuration to configuration within a given plant. The characterization of the manpower cost to the licensees is complicated by the fact that the complexity of the assessment will depend upon a number of factors. For example, if a licensee is to take only one or two SSCs off line, the assessment

required may involve checking to see that the resulting configuration is not in violation of technical specifications and possesses the capability of adequately performing all required safety functions. Conversely, if the licensee plans to perform maintenance on several SSCs at the same time, a more complex assessment may be required. The complexity of the assessments to be performed will also be governed by other factors, such as plant type. It is envisioned that licensees will develop strategies to minimize the burden resulting from these assessments. One such strategy might be to develop sets of pre-analyzed configurations. Once an analysis has been made of a configuration in which a number of SSCs are to be taken off line and it is shown that this configuration does not unacceptably increase the overall risk, this same set of SSCs may be taken off line in future maintenance outages if it can be shown that the resulting and the previously analyzed configurations are the same.

In Section 2.2 of this regulatory analysis, seven modifications to the existing requirements in §50.65 are identified. Because of the nature of these existing requirements and the proposed modifications, the costs and impacts of these amendments are being treated together. For example, item (1), which adds a preamble to the rule, clarifies that the requirements apply to all conditions of operation, including normal shutdown. Since the existing language of the rule was already applicable to power reactors in all modes, the amendatory language has no effect. Item (2) revises the second sentence in paragraph (a)(3) for clarity only and has no regulatory impact. Item (3) deletes the last sentence in paragraph (a)(3). Because the last sentence of paragraph (a)(3) does not specify a requirement, its deletion has no effect. Item (4) creates a new paragraph, (a)(4), that requires the pre-maintenance performance of assessments. Items (4), (5), (6), and (7) provide definition of the scope and timing of the requirements, and their costs and benefits are included in the analysis to follow. Using the results of the pre-

maintenance assessments to manage the risk that may result from the proposed maintenance activities, as required in item (6), will have an impact on plant operations. There will be times that the assessments will reveal that certain maintenance activities should not be performed simultaneously and, thus, maintenance schedules will need to be modified accordingly. It is difficult, if not impossible, to quantify the effects, if any, of these modified maintenance activities without information concerning the equipment involved. However, the benefit of operating the facility in a risk-managed environment is seen to outweigh any apparent inefficiencies that may result from the occasional need to perform maintenance at a less than optimal schedule in order to lessen overall plant risk.

To estimate the burden of this alternative to the industry, two types of costs have been considered: the costs associated with developing the assessment methodologies and the cost of using and maintaining them. This analysis assumes three levels of sophistication for the assessment methodologies. The first would be a basic deterministic type of analysis performed by plant operations, maintenance, or engineering, or one that might involve cross-checking predetermined non-complex matrices of SSCs to ascertain whether the proposed maintenance would be detrimental to safety. The second would consider an intermediate level of analysis that would involve small groups of SSCs or equipment. It is possible that these intermediate-level assessments may also be performed in a deterministic fashion but would require far more analysis of the interrelationships between SSCs and the role they play in safety. In the event that larger numbers of SSCs are to be taken off line for maintenance, a higher level of assessment, which takes into account the increase, if any, in risk, may be required. This level of assessment may require quantification of risk using probabilistic risk assessment (PRA)

techniques. Thus, this regulatory analysis considers the costs associated with three levels of complexity related to the assessment.

The first cost considered is the one-time¹ cost of developing the methodologies and the procedures for carrying out the various assessments. Estimates received from industry indicate that the cost of developing the basic assessment tools is approximately \$20,000, and the cost of implementing the high-complexity, PRA-type approach is approximately \$300,000.² It should be noted that this cost estimate is for the installation of risk monitors which use the existing plant-specific PRA models for risk analyses. Some plants do not have such PRA models for risk analyses of the shutdown mode of operation. Accordingly, this cost analysis did not include the cost of performing probabilistic risk assessments using a shutdown PRA model. For the purpose of this analysis, it is assumed that the costs for the intermediate assessment development are approximately the same as the basic assessment. Another assumption is that each facility initially developed either a basic or an intermediate methodology. Although many facilities appear to be finding a benefit from moving to the high-complexity methodology, an estimate of the number that will move to the high level is difficult to acquire. Therefore, this analysis will develop the upper bound of costs, assuming all licensees will upgrade. Thus, assuming a total of 68 maintenance assessment programs³ will be developed industry-wide at \$320,000 per facility, this activity would incur a one-time cost of \$22 million across the industry.

¹The recurrent costs of updating the methodologies to account for new information and improved technologies will be accounted for separately.

²Unless otherwise noted or assumed, cost estimates are based upon direct NRC staff communications with licensee management.

³There are approximately 100 operating reactors in the United States. However, many of these units will share maintenance assessment programs because they reside in multiple-reactor sites. The assumption is that only 68 programs will need to be developed.

It is anticipated that the aforementioned methodologies will require some modifications over time because of the possibility of changes in plant equipment and the availability of improved technologies and up-to-date PRA data. Industry estimates to both use and maintain the methodologies are \$50,000 and \$25,000 for the basic and high-complexity assessments, respectively. The higher cost for the basic assessments reflects the need to follow up with PRA-type assessments in the event that a more basic matrix approach is not sufficient. Again, it is assumed that the cost for basic and intermediate assessments is the same. The NRC staff estimates that currently one-third of its licensees use and maintain a high-complexity assessment methodology and two-thirds use a basic or intermediate-level technique. However, to bound the impacts on the conservative side, this analysis assumes that all 68 facilities will utilize either a basic or intermediate-level assessment methodology augmented by a high-complexity methodology. Therefore, the use and maintenance cost for each facility would be \$75,000 per program, or \$5.1 million across the industry, annually. If we assume that the average life expectancy of existing nuclear power plants is 20 additional years per facility, the discounted flow of funds at a 7-percent real discount rate is \$54 million. As an alternative analysis, using a 3-percent discounted rate, the value would be \$75.6 million.

Another impact considered was differences in facility type, design, and age. Facility type and design will have an impact on the amount of maintenance needed and, thus, the number of pre-maintenance assessments that a facility would be required to perform. The larger or more complex facility designs will have more SSCs and, thus, require more maintenance. However, these designs also have larger electrical outputs and, thus, the impact of the differences in plant design and complexity would have a negligible effect when considered across the rate-paying population. **[\$50.109(c)(8)]**

For the most part, however, the aforementioned costs are sunk costs already expended in voluntary compliance with the original version of 10 CFR 50.65 as issued in 1991. The principal cost associated with implementation of this rulemaking will be administrative in nature, dealing with changes to procedures and other documents to indicate the shift to and changes in paragraph (a)(4) and the modest retraining necessary for the appropriate personnel.

[\$50.109(c)(5)]

3.2.2 Value of Alternative 2

Maintenance of plant SSCs is necessary even if a pre-maintenance assessment of the resulting configuration is not required. Thus, the value of such a requirement is found in improvement in safety that results from performing the assessments. If a plant is put in an unsafe configuration because equipment is off line for maintenance, demands may be made on safety and recovery systems that cannot be met. This circumstance may result in damage to the plant and possibly offsite releases of radioactive material to the public, or it could cause excessive actuation of safety system SSCs that are rarely called upon.

The final rule does not require any change in the design or construction of any nuclear power plant. Neither does the final rule apply to activities associated with the planning, design, or installation of plant modifications. Therefore, there would be no plant installation, downtime, or construction costs associated with the final rule to be borne by licensees. **[\$50.109(c)(5)]**

When the maintenance rule was first promulgated in 1991, the NRC staff did not foresee the significant changes licensees would be making in maintenance practices. To enhance operational efficiency in reaction to the rate deregulation of the electric utility industry, licensees are shortening their refueling and maintenance outages by performing more maintenance while the plant is at power. At-power maintenance practices have evolved to the point that not only are major systems and components taken off line, but also multiple systems and components are taken off line simultaneously. This maintenance practice could result in a reduced capability to mitigate an accident or transient while the equipment is rendered unavailable, compared to risk that occurs from expected random equipment failures. The pre-maintenance

assessments, along with the specifications regarding their scope and their use, are intended to cause licensees to manage the risk associated with removing SSCs from service to perform maintenance by ensuring their plants are not inadvertently placed in risk-significant conditions or conditions in which the performance of key plant safety functions are degraded to unacceptable levels. It is this risk aversion feature of this alternative that provides a significant safety benefit over Alternative 1. **[\$50.109(c)(6)]**

Maintenance of plant equipment while the plant is operating at power (i.e., on-line maintenance) has become a common practice in the nuclear power industry. This practice has been caused, in large part, by the licensees' desire to maximize plant availability by minimizing plant refueling and maintenance outage durations. During on-line maintenance activities, the plant risk associated with an accident that would result in damage to the reactor fuel or the release of fission products to the environment would increase because of the unavailability of the equipment taken out of service. Pilot studies by the NRC as well as the industry's maintenance rule implementation assessments have shown that the risk impact of maintenance activities can vary substantially, depending on the duration of the activities and the combinations of equipment allowed to be out of service concurrently. Since imprudently planned and managed maintenance activities have the potential for subjecting a plant to an unacceptable incremental contribution to the annual risk, it is important that the provisions of this final rule be implemented to ensure that on-line maintenance is carefully managed to achieve a balance between the benefits of the maintenance and the potential impacts on safety. Hence, the final rule requires that the on-line maintenance process be carefully managed to avoid unintentional entry into risk-significant configurations, or configurations that would degrade key plant safety functions to an unacceptable level, and thereby ensure an acceptable margin of safety.

Furthermore, the final rule focuses attention on methods to evaluate, both prospectively and in real time, the risk impacts of plant configurations so that undesirable risk impacts from maintenance are avoided. Because this is a performance-based rule, licensees would have flexibility in their selection of evaluation methods and decision criteria as long as they meet the requirement to manage the increase in risk that may arise from maintenance activities. However, the staff would provide guidance in Regulatory Guide 1.160, Revision 3, that would describe methods acceptable to the staff for meeting the requirements of this final rule.

[\$50.109(c)(3)]

Similarly, because there is a potential risk to the public from an accidental offsite release of radioactive material during shutdown operations, maintenance performed during those operations must also be carefully managed. Even though the power level in the reactor is essentially zero, irradiated fuel and contaminated materials present a potential hazard.

The maintenance rule does not prescribe the type, frequency, or duration of maintenance activities but rather requires assessments and management of risk before the performance of maintenance. However, the assessment requirement is expected to greatly reduce the possibility of the plant's being operated in an unsafe configuration. This is likely to result in an overall reduction in occupational exposures. **[\$50.109(c)(4)]**

In addition to the benefit to public health and safety, other effects such as potential damage to plant SSCs and the possible need for the purchase of replacement energy would be avoided. This step would result in a cost savings to the industry that in some measure would offset the increase in costs discussed in Section 3.2.1. While it is impractical to calculate the potential

risk benefits of the final rule revision because of the variability, frequency, and repetitiveness of maintenance tasks associated with each plant configuration, the staff's qualitative assessment supports the beneficial impacts of the final rule change because of risk-aversion strategies resulting from the final change. This qualitative assessment is based on the fact that several conditions inimical to safety would be expected to occur if equipment is taken off line without pre-maintenance assessments. The number of challenges to safety systems would be expected to increase and the number of plant transients and emergency shutdowns would be expected to escalate. In addition, Alternative 2 meets the "substantial increase in safety" standard of 10 CFR 50.109 in that it corrects a significant flaw in the current requirements, i.e., that 10 CFR 50.65 does not require pre-maintenance assessments because, to be legally binding, the regulations must use the word "shall."

3.2.3 Impact of Alternative 2 on the NRC

The impact of Alternative 2 on the NRC would be twofold. The first impact would be the cost of implementing a rule change. On average, the NRC estimates that a rule change requires 1 person-year per year for 2 years. Although Alternative 2 appears to be a relatively straightforward amendment, it nonetheless would require about 2 NRC staff-years to complete. The deterministic analyses required by the basic and intermediate-complexity assessments should require little additional guidance to the licensees. However, additional guidance in the form of a regulatory guide is planned to provide licensees with insights on NRC's expectations for the high-complexity assessments that may require PRA techniques. There is currently a large body of PRA literature available to the public, and the development of NRC-approved guidance from this body of literature should not require more than 0.25 staff-year of effort.

The second impact would be the inspection and oversight of the assessments, both of which should be straightforward and require minimum extra resources. In actuality, the inspection of licensees' implementation of the paragraph (a)(3) assessments is already part of the NRC resident inspector core inspection program. Therefore, similar to the actual impact on the industry, the principal impact on the NRC would be administrative in nature and would deal with changes to inspection procedures and guidance documents to indicate the shift to, and changes in, paragraph (a)(4) and the modest retraining necessary for the appropriate personnel. Nevertheless, the NRC staff is considering the inspection of the implementation of the final rulemaking at about 20 licensee sites selected from those licensees that had assessment weaknesses during initial inspections of maintenance rule implementation. These approximately 20 proposed inspections would cost 1 staff-year and \$400,000 in contractual support.

Thus, the impacts on the NRC are estimated to be a one-time cost for rule and guidance development of 2.25 staff-years plus 1 staff-year and \$400,000 for implementation inspection. These resources have been accounted for in the regional and headquarters budget estimates.

[§50.109(c)(7)]

3.3 Alternative 3--Make Comprehensive Revisions to Paragraph (a)(3) of the Rule

3.3.1 Impact of Alternative 3

Alternative 3 is derived as a consequence of the original intent of the maintenance rule. The SOC for 10 CFR 50.65 stated that the expectation was that the assessments required by

paragraph (a)(3) would be refined on the basis of improvements in technology and experience. Because an approach like this requires the broad use of probabilistic techniques, it is envisioned that the approach would take on a performance-based character. This approach would mandate specific limits on the risk associated with maintenance activities, such as limits on total risk, incremental risk per maintenance outage, or limits on cumulative risk per time period. Because this would be a non-prescriptive approach, it is not feasible to estimate the cost to the industry or to the NRC with any degree of certainty. Licensees will likely take varying approaches to implement such technologies, each requiring sophisticated methodologies and highly trained individuals to perform the assessments.

Although the specific impacts of Alternative 3 have not been quantified, the burden to the licensee is believed to be much greater than Alternative 2. The NRC would promulgate the limits within which the risk of resultant plant configurations could be increased for maintenance activities instead of specifying the probabilistic techniques to be used. The licensee would need to research and evaluate various alternatives and determine which is suitable for its facility. A fair amount of trial and error is expected as various configurations are evaluated and certain maintenance activities are found to exceed NRC-specified limits. This trial and error, in turn, may cause delays in maintenance activities and increase the likelihood of component failures.

3.3.2 Value of Alternative 3

Although it is impractical to calculate the potential risk benefits of this alternative, several qualitative values have been considered. Alternative 3 would limit maintenance activities through the use of mostly risk-based criteria and would require licensees to evaluate and control maintenance activities through much more rigorous, technically advanced methods. Also, it would establish a regulatory precedent for other risk-based requirements.

3.3.3 Impact of Alternative 3 on the NRC

The resource burden to the NRC of Alternative 3 is expected to be significantly greater than for the two lower options of Alternative 2. The NRC would need to develop the risk parameters to be used for setting the limits that risk may be increased while continuing to operate the facility safely. The specific limits must be developed, evaluated, and approved. Assessment methodologies used to estimate the change in risk parameters must be evaluated and approved by the NRC staff to assure their accuracy and reliability. Implementation of such a rule is expected to require extensive interactions between the staffs of the licensee and the NRC to fully understand and evaluate each methodology. Further, the burden of inspecting implementation and compliance with the regulation would be likewise complicated. For example, in a time of shrinking resources, Alternative 3 would necessitate extensive PRA training for region-based inspectors. Because the NRC continues to be a fully fee-recoverable agency, the increased burden would be transferred to the licensee.

Because of the burden that such an approach would place upon licensees, it is unlikely that the industry would support such an approach. Thus, the rulemaking process would be greatly affected, which would result in many industry-NRC interactions and many counter proposals by the industry requiring staff evaluation and Commission action. The resources required for such a rulemaking should be balanced against the incremental benefits. The NRC inspection program has demonstrated that, by and large, licensees are complying with an Alternative 2 type of approach even though it is recommended and not required.

4.0 Discussion of Voluntary Compliance With the Assessment Provision of 10 CFR 50.65(a)(3)

NRC's Regulatory Analysis Guidelines direct the NRC staff to not consider the cost of voluntary licensee actions as the cost basis for decisions concerning contemplated regulatory actions. In accordance with the Guidelines, the costs of this rule as analyzed above in this regulatory analysis do not consider any expenditures by licensees for voluntary compliance with the non-mandatory provision in paragraph (a)(3) of the current maintenance rule.

The guidance also indicates that a sensitivity analysis should be performed to estimate the actual incremental burden that would result from the action. For Alternative 1, there would be no actual burden change because there would be no requirement. For Alternative 3, the actual burden increment to both the NRC and the industry is expected to be significantly greater than for the two lower options of Alternative 2. However, it appears that the actual burden of Alternative 3 is decreasing with time because more licensees are improving their PRAs and

several licensees have already installed so-called on-line risk meters, which not only approaches the objective of Alternative 3 but also is driving down the cost of the tool for subsequent purchasers.

The following discussion represents the sensitivity analysis for the proposed approach (Alternative 2). All licensees have some form of pre-maintenance assessment program as recommended in 10 CFR 50.65(a)(3) and as addressed in NUMARC 93-01, which is endorsed by Regulatory Guide 1.160. The NRC maintenance rule baseline inspections, conducted in 1996 through 1998 at every operating power plant, found that all licensees have programs in place with methodologies for performing the assessments. At about half of the power plants, the inspectors found either programs with minor weaknesses or instances of failure to perform the recommended assessments as specified in the programs. Since all licensees have developed methodologies for performing the assessments to be required under Alternative 2, and at approximately half the licensees' methodologies have been found acceptable, the NRC's assumption that every facility would be required to incur the one-time \$320,000 cost per facility for methodology development and the annual \$75,000 per facility for use and maintenance would seem to overstate the actual increase in cost to individual licensees and the nuclear power industry as a whole attributable to this rulemaking.

5.0 Decision Rationale

Alternative 2 is judged to present a substantial increase in safety as opposed to Alternative 1. The NRC's qualitative assessment supports the beneficial impacts of the final rule change

because of its risk-aversion strategies. This qualitative assessment is based on the fact that several conditions inimical to safety would be expected to occur if equipment is taken offline without pre-maintenance assessments. The number of challenges to safety systems would be expected to increase and the number of plant transients and emergency shutdowns would be expected to escalate. In addition, Alternative 2 meets the "substantial increase in safety" standard of 10 CFR 50.109 in that it corrects a significant flaw in the current requirements (i.e., that 10 CFR 50.65 does not require pre-maintenance assessments because, to be legally binding, the regulations must use the word "shall"). Although Alternative 2 has a non-trivial burden if voluntary compliance is disregarded, its burden is not nearly as great as that of Alternative 3, and the program to be implemented is, in large measure, already in place. Also, full implementation of Alternative 2 should be straightforward. Alternative 1, clearly the least burdensome of the choices considered, will not correct the NRC's principal concern, which is that licensees would not perform pre-maintenance assessments and could remove the paragraph (a)(3) assessment provision in their maintenance rule implementation programs at their own discretion. Alternative 3 is the most comprehensive of the alternatives, but it would create a serious increase in the burden to the licensees and the NRC (which would likewise be borne by the industry). Thus, the NRC is publishing Alternative 2 as a final rule. **[§50.109(c)(9)]**

6.0 Implementation

The action evaluated in this regulatory analysis will be implemented through the promulgation of a final regulation. A regulation has been selected as the appropriate mechanism for this implementation because regulatory guides do not constitute requirements and, with NRC orders, the benefit of public participation and comment are not utilized. The notice that publishes the final rule will specify that the rule will be effective 120 days after the issuance of regulatory guidance that is currently being developed.

ATTACHMENT 3

CONGRESSIONAL LETTERS

The Honorable Joe Barton, Chairman
Subcommittee on Energy and Power
Committee on Commerce
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

On September 30, 1998, the U.S. Nuclear Regulatory Commission published a proposed rule, a revision to 10 CFR 50.65, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants" (63 FR 52201-52206). In that Federal Register notice, the Commission proposed to require commercial nuclear power plant licensees to assess and manage the increases in risk that may result from proposed maintenance activities. Although 10 CFR 50.65, the maintenance rule, currently addresses such assessments, it states that assessments "should" be performed, the legal effect of which is to serve as a recommendation.

The public comment period expired December 14, 1998. The Commission received 34 responses from industry, States, and individuals, the majority of which suggested modifications to the rule as proposed. Those comments have been considered and incorporated into this final rule, which will make the pre-maintenance assessments a requirement.

In today's environment of rate deregulation of the electric utility industry and the resulting pressure to enhance operational efficiencies and produce power, nuclear power plant licensees

are conducting more of their maintenance activities while at power than ever before. The Commission wants to ensure that these licensees consider and manage risk in the prioritizing, planning, scheduling, and performance of maintenance. A major aspect of this risk management process is the appropriate performance and use of the pre-maintenance assessments.

Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:

Federal Register Notice

cc: Representative Ralph Hall

The Honorable James M. Inhofe, Chairman
Subcommittee on Clean Air, Wetlands, Private
Property and Nuclear Safety
Committee on Environment and Public Works
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

On September 30, 1998, the U.S. Nuclear Regulatory Commission published a proposed rule, a revision to 10 CFR 50.65, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants" (63 FR 52201-52206). In that Federal Register notice, the Commission proposed to require commercial nuclear power plant licensees to assess and manage the increases in risk that may result from proposed maintenance activities. Although 10 CFR 50.65, the maintenance rule, currently addresses such assessments, it states that assessments "should" be performed, the legal effect of which is to serve as a recommendation.

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Sincerely,

Dennis K. Rathbun, Director
Office of Congressional Affairs

Enclosure:

Federal Register Notice

cc: Senator Bob Graham

ATTACHMENT 4

PUBLIC ANNOUNCEMENT

***NRC TO REQUIRE NUCLEAR POWER PLANTS TO ASSESS AND MANAGE
INCREASES IN PLANT RISK BEFORE PERFORMING MAINTENANCE***

The Nuclear Regulatory Commission is revising its Maintenance Rule to require that nuclear power plant licensees assess and manage the potential increase in risk that could result from proposed maintenance activities. At present, the rule says that licensees “should” perform such an assessment, but does not require it.

NRC took public comments on the proposed rule change last year and incorporated them in the final rule to be published in an upcoming edition of the Federal Register. The rule is scheduled to become effective 120 days following the issuance of Revision 3 to Regulatory Guide 1.160, “Monitoring the Effectiveness of Maintenance at Nuclear Power Plants.” Revision 3 to the Regulatory Guide is scheduled to be issued before the end of this year.

NRC has long been concerned about a trend in the nuclear power industry to take key equipment out of service for maintenance while a plant is operating, without a thorough risk evaluation. Published NRC reports on 68 inspections conducted since the Maintenance Rule was first adopted in 1991 show that all nuclear power plant licensees have programs in place requiring a review of the risk impact on the plant before equipment is taken out of service for

maintenance. But at seven sites, licensees had not performed such assessments, and at 35 others, assessment weaknesses were found.

The present rulemaking results from a directive given the NRC staff by the Commission after it was informed in 1997 that the Maintenance Rule language on safety assessments is permissive, rather than mandatory. Also at the Commission's direction, the amendment specifies that the Maintenance Rule applies during all conditions of plant operations, including shutdowns, and that assessments are to be performed for all maintenance activities.

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ATTACHMENT 5

CONGRESSIONAL REVIEW ACT

FORMS