

April 11, 2001

MEMORANDUM TO: Bruce A. Boger, Director  
Division of Inspector Program Management  
Office of Nuclear Reactor Regulation

FROM: Farouk Eltawila, Acting Director **/RA by J. E. Rosenthal Acting for/**  
Division of Systems Analysis and Regulatory Effectiveness  
Office of Nuclear Regulatory Research

SUBJECT: FEASIBILITY OF AN EFFECTIVENESS STUDY OF THE  
MAINTENANCE RULE

The purpose of this memorandum is to transmit the results of a feasibility study (attached) completed by the Regulatory Effectiveness Assessment and Human Factors Branch, (RES), in response to a request from the Quality Assurance, Vendor Inspection, Maintenance and Allegations Branch, (NRR) dated January 2, 2001 (ADAMS Accession No. ML010020206). The request from NRR was for RES to complete the feasibility study by the end of March 2001.

NRR requested that RES determine if an effectiveness assessment of the Maintenance Rule is feasible. Such a determination is needed because NRR has been tasked with providing the Commission with a report in 2002 regarding the "efficacy" of 10 CFR 50.65. Based on the attached study, RES has determined that an effectiveness review is feasible, subject to certain constraints:

1. The term "efficacy" is synonymous with the term "regulatory effectiveness." The model to assess effectiveness of the Maintenance Rule will involve comparing the expectations articulated by the Commission from promulgating the regulation with the outcomes associated with issuance of the regulation. Given the nature of the Maintenance Rule, many aspects of such a comparison are likely to rely on qualitative factors.
2. Industry and NRC experienced many changes over the period that the Maintenance Rule was issued, and time was given for provisions to come into force when specific guidance documents were also issued. Hence, it may not be possible to uniquely associate outcomes with specific requirements of the Maintenance Rule.
3. The comparison between expectations and outcomes is not necessarily conducted at a level of detail where data on specific systems, structures or components are required. Higher level information, such as the manner in which risk information is incorporated into the maintenance process, would provide an equally valid basis for the assessment.

CONTACT: Prasad Kadambi (NPK) REAHFB:DSARE:RES  
(301) 415-5896

B. Boger

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We propose that the next step in the consideration of an effectiveness review of the Maintenance Rule should be a meeting between NRR and RES if NRR feels that this matter should be pursued further. The objective of such a meeting would be to determine what measures would be used, and how the appropriate information would be collected. If you have any questions, please contact Prasad Kadambi of my staff at 301-415-5896.

Attachment: As stated

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## **FEASIBILITY OF AN EFFECTIVENESS ASSESSMENT OF THE MAINTENANCE RULE**

### **BACKGROUND:**

The Commission has expressed itself quite clearly and at considerable length since the mid-1980s on the subject of maintenance. It issued a policy statement stressing the importance of maintenance in March 1988. The initial steps to rulemaking were begun later that year. Criteria were articulated which might lead the Commission to conclude that rulemaking was not necessary. Finally, in July 1991, 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants" was issued to give regulatory force to its determination that proper maintenance is essential to plant safety.

A large amount of data was collected, including that during conduct of numerous Maintenance Team Inspections, to provide the basis for the rulemaking. The data did not show an imminent safety problem that had to be addressed right away. In fact, the staff observed a generally improving trend in the maintenance programs. The regulatory options developed by the staff did not specifically recommend a new rule.

### **DETERMINATION OF NEED FOR THE MAINTENANCE RULE:**

The Commission used the following criteria in determining the need for maintenance rulemaking:

- Criterion 1 – Licensees have effectively implemented an adequate maintenance program or are committed to and proceeding towards this goal.
- Criterion 2 – Licensees exhibit a favorable trend in performance related to maintenance.
- Criterion 3 – Licensees are committed to the implementation of a maintenance performance standard acceptable to the NRC.
- Criterion 4 – Licensees have in place or are committed to an evaluation program for ensuring sustained performance in the maintenance area.

The Commission reached its conclusions on the issue of going forward with rulemaking based on the results of the Maintenance Team Inspections (MTIs) and other considerations. The results of the MTIs indicated that licensees had adequate maintenance programs and exhibited an improving trend in program implementation (Criterion 1). However, some common maintenance-related weaknesses were identified, such as inadequate root cause analysis leading to repetitive failures, lack of equipment performance trending, and the consideration of plant risk in the prioritization, planning and scheduling of maintenance. In general, as evidenced by plant operational performance data and the results of NRC assessments, the industry had exhibited a favorable trend in maintenance performance (Criterion 2).

With regard to licensee commitment to an NRC-approved maintenance performance standard (Criterion 3), the industry, through the Nuclear Management and Resources Council (NUMARC), expressed to the Commission its commitment, in general, to the goal of improving performance in the area of maintenance. The industry asserted that all licensees were committed, by virtue of their membership in the industry-sponsored Institute for Nuclear Power Operations (INPO), to meeting, or striving to meet, the performance objectives contained in INPO 90-008, "Maintenance Programs in the Nuclear Power Industry." INPO 90-008 was primarily a compilation of preexisting objectives and criteria developed by INPO relating to maintenance. These objectives and criteria largely relate to maintenance program content and programmatic measures of performance. No written commitments were received from licensees and the industry-wide commitment which was received was at best indirect. The Commission believed that a sufficient commitment by licensees to a maintenance standard approved by the NRC had not been received.

With regard to licensees having in place or being committed to an evaluation program for ensuring sustained performance in the area of maintenance (Criterion 4), the industry, through NUMARC, indicated that all licensees would perform a comprehensive assessment of their maintenance programs against the performance objectives of INPO 90-008. These one-time assessments were to be conducted over a 4-year period. Additionally, periodic INPO evaluations which include the maintenance area, would continue to be performed. However, the Commission believed that the industry's largely programmatic assessments and evaluations of licensee maintenance programs would alone not suffice. Instead, the Commission believed that the effectiveness of maintenance must be assessed on an ongoing basis in a manner which ensured that the desired result, reasonable assurance that key structures, systems, and components are capable of performing their intended function, was consistently achieved. Further, there is a continuing need for feedback of the results of such assessments and to factor those results into programmatic requirements, where assessment results indicate ineffective maintenance.

Considering the above points, the Commission was satisfied that the industry had been generally successful in bringing about substantial improvement in maintenance programs. Further, the improving trend established over the previous several years had continued. However, the necessity for ongoing results-oriented assessments of maintenance effectiveness was indicated by the fact that, despite significant industry accomplishment in the areas of maintenance program content and implementation, plant events caused by the degradation or failure of plant equipment continued to occur as a result of instances of ineffective maintenance. Additionally, operational events had been exacerbated by or resulted from plant equipment being unavailable due to maintenance activities. Under then existing requirements and industry maintenance initiatives, with relatively few exceptions, the availability of safety significant structures, systems, and components were not routinely assessed. These events and circumstances further attested to the need for ongoing results-oriented assessment of maintenance effectiveness since, together with equipment reliability, equipment availability is an important measure of maintenance effectiveness.

Regarding the additional factors considered by the Commission in determining the need for a maintenance rule, the Commission believed that there existed a need to broaden its capability to take timely enforcement action where maintenance activities fail to provide reasonable assurance that safety significant SSCs are capable of performing their intended function. With regard to the presence of a strengthened industry commitment to monitor equipment

performance to identify problematic components, systems and functions, to conduct root cause analysis, to track corrective actions, and to feedback information into maintenance programs, the Commission had determined, based upon the weaknesses identified by the MTIs and the lack of sufficient commitments by licensees to a maintenance standard, that additional regulatory attention to these matters was warranted. Concerning the provision of a mechanism by which the NRC could verify the effectiveness of maintenance programs, neither the Commission nor the industry had been able to develop overall performance indicators which would readily provide unambiguous indication of overall maintenance effectiveness at any given plant. Thus, the Commission's consideration of these additional factors also weighed in favor of promulgating a rule that required the monitoring and assessment of maintenance effectiveness. Additionally, consideration of these factors led the Commission to conclude that it was necessary for such a rule to include requirements for corrective action to address instances of ineffective maintenance, and feed back of the results of monitoring and assessment into licensee maintenance programs.

In consideration of the above, the Commission had determined that a regulatory framework must be put in place which provides a mechanism for evaluating the overall continuing effectiveness of licensee maintenance programs, particularly as the plants continue to age. As noted previously, areas directly related to this issue were identified as common weaknesses during the NRC's Maintenance Team Inspections. These areas included inadequate root cause analysis, lack of equipment performance trending, and lack of consideration of risk in the prioritization, planning, and scheduling of maintenance. Therefore, the Commission concluded that a rule requiring that licensees monitor and assess the effectiveness of maintenance activities was necessary.

In addition to all of the above considerations, the Commission's conclusion that a rule requiring that the effectiveness of maintenance be monitored was also predicated on the fact that the Commission's then current regulations, regulatory guidance, and licensing practice did not clearly define the Commission's expectations with regard to ensuring the continued effectiveness of maintenance programs at nuclear power plants. The Commission had many individualized requirements relative to maintenance, including SSCs in the balance of plant (BOP), throughout the regulations. These include 10 CFR 50.34(a)(3)(i); 50.34(a)(7); 50.34(b)(6)(i), (ii), (iii), and (iv); 50.34(b)(9); 50.34(f)(1)(i), (ii), and (iii); 50.34(g); 50.34a(c); 50.36(a); 50.36(c)(2), (3), (5), and (7); 50.36a(a)(1); 50.49(b); 50.55a(g); Part 50, Appendix A, Criteria 1, 13, 18, 21, 32, 36, 37, 40, 43, 45, 46, 52, 53; and Part 50, Appendix B. More generally, 10 CFR 50.34(b)(6)(iv) required licensees to address their plans for the conduct of "maintenance, surveillance, and periodic testing of structures, systems, and components." However, there was no guidance on exactly what these "plans for the conduct of maintenance" should include with regard to the monitoring of maintenance effectiveness.

The Commission's rules, guidance, and practice also required clarification on what structures, systems, and components should be subject to maintenance requirements. Although Section 50.34(b)(6)(iv) references maintenance for "structures, systems, and components" without further qualification, the guidance in Regulatory Guide 1.70, "Standard Format and Content of Safety Analysis Reports for Nuclear Power Plants -- LWR Edition," (Revision 3, November 1978) was silent on the scope of SSCs that the maintenance program should cover (see Regulatory Guide 1.70, Section 13.5.2). Regulatory Guide 1.70 also referred to Regulatory Guide 1.33, "Quality Assurance Program Requirements (Operation)." Regulatory Guide 1.33, which implemented portions of 10 CFR Part 50, Appendix B, indicated in Appendix A that

"maintenance that can affect the performance of safety-related equipment should be properly preplanned and performed in accordance with written procedures....". The sample listing of maintenance operations requiring procedures also was limited to safety-related equipment. Regulatory Guide 1.70 also endorsed industry standards for nuclear power plant operations that were limited to maintenance or modifications "which may affect the functioning of safety-related structures, systems, or components....". The Commission had previously interpreted its rules and guidance as requiring licensees to address the safety aspects of certain SSCs in the BOP, for example, 10 CFR 50.34(g) required applicants for licenses after 1982 to evaluate their facility against the Standard Review Plan (SRP), NUREG-0800. The SRP required licensees to evaluate a number of SSCs in the BOP.

Requirements and guidance for monitoring maintenance effectiveness and for taking corrective action when maintenance was ineffective were expected to enhance the Commission's capability to take timely and effective action against licensees with inadequate or poorly conducted maintenance in order to ensure prompt resumption of effective maintenance activities.

For these reasons, the Commission concluded that a regulation that required all nuclear power plant licensees to monitor the effectiveness of maintenance activities was warranted. The rule provided for continued emphasis on the defense-in-depth principle by including selected BOP SSCs, integrated risk consideration into the maintenance process, provided an enhanced regulatory basis for inspection and enforcement of BOP maintenance-related issues, and provided a strengthened regulatory basis for ensuring that the progress achieved to date was sustained in the future.

#### EXPECTATIONS FROM THE MAINTENANCE RULE:

The study to develop and articulate the Commission's expectations from the promulgation of the Maintenance Rule included review of a voluminous amount of material, which REAHFB gratefully acknowledges was provided by the Quality Assurance, Vendor Inspection, Maintenance and Allegations Branch. It was determined that the expectations were sufficiently captured in the Statement of Considerations for the final rule published in the *Federal Register* on July 10, 1991 (56 FR 31306). If a more comprehensive assessment of regulatory effectiveness is done beyond this feasibility study, more expectations may be added to the compilation. For the purposes of the feasibility study, the following expectations are sufficiently demonstrative:

- Fill the gap in the Commission's regulations, regulatory guidance, and licensing practice which do not clearly define the Commission's expectations with regard to ensuring the continued effectiveness of maintenance programs.
- Develop ongoing results oriented assessments of maintenance effectiveness.
- Integrate risk considerations into the maintenance process.
- Provide enhanced regulatory basis for inspection and enforcement of BOP maintenance-related issues.

- Progress achieved, evidenced by improving trends regarding maintenance, is sustained in the future.
- Assure continued emphasis on the defense-in-depth principle by including selected BOP systems, structures and components.
- Offer maximum flexibility to licensees in establishing and modifying their monitoring activities.
- Monitor to identify problematic SSCs.
- Conduct root-cause analysis.
- Track corrective actions.
- Feedback information into the maintenance program.
- Failures of non-safety related equipment resulting in scrams and unnecessary actuations of safety related systems are minimized.

#### EVALUATION OF OUTCOMES:

The current version of the Maintenance Rule includes amendments issued in 1996 and 1999. The 1996 amendment addressed decommissioned facilities. The 1999 amendment addressed the need to take account of the growing amounts of on-line maintenance (i.e., maintenance during power operation) being performed by licensees and a concern on the part of the Commission regarding the quality of pre-maintenance assessments. The feasibility study has only focused on the 1991 version of the rule.

The period of time after promulgation of the Maintenance Rule has witnessed major changes in the way the NRC and the industry conduct their business. The Maintenance Rule has been an integral part of the changed environment in which economic deregulation, industry consolidation, and the potential for new plant orders are developing. Also, over this period, NRC staff has undertaken extensive efforts to establish guidance which will provide confidence that industry will be in a position to effectively implement the rule. A significant part of such efforts included on-site inspections and discussions with industry stakeholders. Additionally, the staff (formerly AEOD and now RES) monitor operating experience and issue reports on system and component reliability, including identification of causes of failures. The Reactor Oversight Program also includes performance assessments in specific areas, such as the cornerstones of initiating events and mitigation systems. Therefore, a substantial documentary record exists from which various perspectives can be reflected to assess the outcomes from the Maintenance Rule.

REAHFB has developed, on a preliminary basis, potential sources of information which could be compiled to offer objective evidence regarding the outcomes related to each of the expectations as follows:

- *Fill the gap in the Commission's regulations, regulatory guidance, and licensing practice which do not clearly define the Commission's expectations with regard to ensuring the continued effectiveness of maintenance programs.*

Sources of information: Internal and external stakeholder input.

- *Develop ongoing results oriented assessments of maintenance effectiveness.*

Sources of information: Reliability studies; ROP.

- *Integrate risk considerations into the maintenance process.*

Sources of information: Consideration of how many plants use PRA to set goals.

- *Provide enhanced regulatory basis for inspection and enforcement of BOP maintenance-related issues.*

Sources of information: Internal stakeholder input.

- *Progress achieved, evidenced by improving trends regarding maintenance, is sustained in the future.*

Sources of information: Reliability studies; ROP.

- *Assure continued emphasis on the defense-in-depth principle by including selected BOP systems, structures and components.*

Sources of information: Internal stakeholder input; ROP.

- *Offer maximum flexibility to licensees in establishing and modifying their monitoring activities.*

Sources of information: Internal and external stakeholder input.

- *Monitor to identify problematic SSCs.*

Sources of information: Internal stakeholder input; ROP.

- *Conduct root-cause analysis.*

Sources of information: Internal and external stakeholder input; ROP; LERs.

- *Track corrective actions.*

Sources of information: Internal and external stakeholder input.

- *Feedback information into the maintenance program.*

Sources of information: Internal and external stakeholder input.

- *Failures of non-safety related equipment resulting in scrams and unnecessary actuations of safety related systems are minimized.*

Sources of information: Internal and external stakeholder input; ROP; LERs.

As observations are made relative to each of the factors considered under expectations from the Maintenance Rule, it is quite likely that it may not be possible to separate out the unique contribution of the Maintenance Rule. However, given that the objective of the Maintenance Rule was to be results-oriented (which, in current Commission terminology, is called performance-based), it may not be important to examine only the unique contributions by the Maintenance Rule. The contribution of the Maintenance Rule, in some cases, may have been marginal. But if the outcomes are consistent with the objectives of the Rule (or, if the outcomes, unexpectedly, are contrary to the objectives of the Rule), the information should be included in the assessment.

A key aspect of the effectiveness assessments done thus far have included cost considerations. The July 10, 1991 *Federal Register* notice provided cost information used by the Commission for the Backfit Analysis. It was estimated that for the 110 power reactors operating at the time, the implementation and operating costs would amount to \$1050 million. Of this amount, it was expected that licensees would save \$998 million by way of replacement power costs they would not incur from increased availability. An amount of \$9 million was allocated to savings under "Onsite cleanup and power replacement". Thus, the total industry cost of the Maintenance Rule was estimated to be \$44 million. Given the major role that the Maintenance Rule has played in the operations of licensees, the costs of the Maintenance Rule, if any, may not ever be possible to determine. Hence, it is recommended that cost not be considered as a factor in the assessment.

#### CONCLUSION:

REAHFB has concluded that objective evidence (a combination of qualitative and quantitative information from diverse sources) can be obtained or developed for each of the factors enumerated under "Expectations from the Maintenance Rule", and that corresponding outcome measures can be developed to conduct an effectiveness assessment. In some cases, the measures may be purely qualitative, such as whether an enhanced regulatory basis has been provided for inspection and enforcement of BOP maintenance-related issues. The assessment should be sufficiently robust to fulfill NRR's requirements in reporting to the Commission.