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Docket Number 50-346

License Number NPF-3

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United States Nuclear Regulatory Commission  
Attention: Document Control Desk  
Washington, D.C. 20555

Subject: Response to NRC Inspection Report Number 50-346/97002

Ladies and Gentlemen:

Toledo Edison has received Inspection Report 97002 (Log Number 1-3800) and the enclosed Notice of Violation. The Response to the Notice of Violation is attached.

The violation involves the establishment of reliability performance criteria to demonstrate that the performance or condition of structures, systems, and components was being effectively controlled through adequate preventive maintenance.

Additionally, as requested in your cover letter, a response is provided for the unresolved item identified in the Inspection Report.

Should you have any questions or require additional information, please contact Mr. James L. Freels, Manager - Regulatory Affairs, at (419) 321-8466.

Very truly yours,

GMW/dlc

attachment

cc: ✓ A. B. Beach, Regional Administrator, NRC Region III  
A. G. Hansen, NRC Project Manager  
S. Stasek, DB-1 NRC Senior Resident Inspector  
Utility Radiological Safety Board

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Reply to a Notice of Violation (50-346/97002-01[DRS])  
Alleged Violation.

10 CFR 50.65(a)(1) requires, in part, that each holder of an operating license under 50.21(b) or 50.22 shall monitor the performance or condition of structures, systems, or components against licensee established goals. Such goals shall be established commensurate with safety.

Contrary to the above, as of January 17, 1997, the licensee had not established adequate reliability performance criteria for 26 risk-significant systems to demonstrate that the performance or condition for some structures, systems, and components were being effectively controlled through adequate preventive maintenance. (50-346/97002-01[DRS])

Reason for Violation

Performance criteria were established based on the guidance provided in 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," 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." The value established for the performance criteria took into account industry experience and safety considerations. The effects of predicted reliability and the number of expected demands were considered. Also considered was the "Public Workshop to Review the Lessons Learned from Early Implementations of the Maintenance Rule at Nine Nuclear Power Plants," dated June 27, 1995, where the NRC strongly discouraged setting the reliability performance criteria at zero maintenance-preventable functional failures. Taking into account all the appropriate considerations, including risk, the performance criteria for risk significant systems was set at what was believed to be the most conservative value that was acceptable to the NRC.

When this generic industry issue surfaced from the baseline inspections, Toledo Edison evaluated the established performance criteria against performance criteria from other plants that had been determined by the NRC to be commensurate with safety. It was discovered that Davis-Besse's performance criteria were generally two to six times more conservative than those approved at other plants. However, it was incorrectly presumed that a rigorous calculation was not required because of the conservatism of the performance criteria, and that a more simplistic technical basis would suffice.

Corrective Steps Taken and Results Achieved

Steps Taken

In response to this violation, a calculation (C-NSA-99.16-20) was initiated to determine the effect on core damage frequency (CDF) that results from unavailability and reliability at the maximum level allowed by the maintenance rule criteria. This calculation also compared the reliability criteria for risk significant systems with the expected number of failures calculated using Probabilistic Risk Assessment (PRA) reliability data. This calculation has been completed and is currently in the

checking and approval process. Based on insights gained from performing this evaluation, several changes were made to the reliability criteria. These changes included adding conditional monitoring for some systems.

The first part of this calculation was performed by making the following changes to the plant PRA:

- (1) Maintenance unavailability assumed in the PRA was replaced with the maximum unavailability performance criteria documented in the Maintenance Rule Program Manual.
- (2) The reliability performance criteria of the Maintenance Rule Program Manual was used to revise the failure rates of equipment in risk significant systems.

Two different methods were used to revise the failure rates. One method involved the replacement of the failure rate in the PRA with a simple ratio of the number of failures to the number of demands or run times. This method is simple and provides a very conservative bounding evaluation of the effect on CDF, but neglects all past information concerning equipment failure rates. Therefore, an additional estimation of the effect on CDF was performed using Bayesian updating of the prior failure rates. This approach more heavily weights the most recent data without neglecting the past generic and plant specific information.

Additionally, the calculation compared the reliability criteria that was established for risk significant systems with the expected number of failures for each of the systems during a 24 month operating cycle. This part of the evaluation involved calculating the expected number of failures for each of the risk significant systems based on the PRA failure rates and the estimated number of demands or run time for a 24 month operating cycle.

Also, in response to this violation, existing calculation C-NSA-99.16-19 was revised. The existing revision of this calculation evaluated the effect on CDF from the maintenance unavailability that was recorded for the period from July 1, 1993, to June 30, 1996. This calculation was revised to include the effect of functional failures for this time period.

#### Results Achieved

The calculations described above are presently in the review process and have not been formally approved. However, the following conclusions can be based on the preliminary results.

When the PRA was modified in the calculation (C-NSA-99.16.20) using a simple ratio of the number of failures to demands or run time, this resulted in an increase in CDF of approximately  $8.0E-5$ . It should be noted that the effect on CDF was very dependent on the particular failure that was assumed to occur for each system, but the approach in the calculation was to assume the failure that would have the greatest effect on the CDF. Considering the criteria in the EPRI *PSA Applications Guide*, this increase in CDF of  $8.0E-5$  from the base case of  $6.57E-5$  exceeds the range that is considered non-risk-significant, but since the change does not exceed  $1.0E-4$ , it would not be considered unacceptable.

An increase in the CDF of this magnitude would not be desirable, but the CDF calculated using the simple ratio of failures to demands is highly conservative and is a bounding approach rather than a realistic estimation of the effect on CDF for the following reasons:

- (1) All past information concerning failure rates is neglected by this method. For example, if a piece of equipment fails on one start out of twenty during a cycle, the method of using a ratio of failure to demands would assume a five percent failure rate, despite both generic and plant specific data that would indicate a much lower failure rate for that piece of equipment.
- (2) It can be argued that if failures occur each cycle at the reliability criteria rate for each system, the expected failure rate over an extended period of time would approach the reliability criteria failure rate. However, this argument assumes the improbable condition where all systems experience repeated failures at the maximum rate allowed by the performance criteria.
- (3) Most systems have numerous failures that constitute a functional failure modeled in the PRA. However, only one failure mode can be assumed for the PRA revision. This has the effect of overstating the effect of the failure on the CDF. For example, the estimated number of failures for the Makeup System is 1.3 per cycle, which indicates that the functional failure criteria of 1.0 used for the maintenance rule is conservative. However, in the calculation, the one functional failure could not be split between various pieces of equipment, so a single failure of the makeup pump to run had to be assumed even though not all functional failures would actually cause the makeup pump to fail to run. This caused the failure rate used in the PRA for the makeup pump to run to increase by a factor of six. The increase in this failure probability has a significant effect on the CDF, despite the fact that the functional failure criterion for the makeup system is conservative.

As a result of the limitations of the simple ratio method of determining failure rates, this method is appropriate only to determine a conservative bounding value of CDF. In this case, the bounding CDF value would be higher than desired but not unacceptable, based on the criteria in the EPRI *PSA Applications Guide*.

Due to the limitations of the simple ratio approach, Bayesian updating of the existing failure rates was used to provide a more accurate determination of the effect on CDF that results from the maximum acceptable number of functional failures documented in the maintenance rule performance criteria. This approach updated the equipment failure rate distributions used in the PRA with one cycle of data that assumes functional failures, for all risk significant systems, at the maximum acceptable number from the performance criteria. Using the Bayesian updating approach, the CDF increases approximately 17 percent from the base case of  $6.57E-5$ . The EPRI *PSA Applications Guide* provides one criterion for evaluating the impact of permanent changes in CDF that is dependent on the baseline CDF. Applying the Davis-Besse baseline, the maximum change in CDF considered to be non-risk-significant is determined to be approximately 12 percent. The change in CDF calculated with the number of functional failures and system unavailability at the maximum acceptable per the

maintenance rule performance criteria exceeds this 12 percent criterion; therefore, the change cannot be considered non-risk significant by this criterion. However, this change is only slightly above the non-risk significant criteria and is not close to the range of approximately 150 percent that is considered to be unacceptable. The EPRI *PSA Application Guide* recommends further evaluation to determine if changes in the range identified are acceptable. One method to evaluate the significance of this result is to consider that the maintenance rule performance criteria represent the upper limits of normal operation. It is not expected that all components within the scope of the criteria will operate at or just below these levels. This conclusion is supported by the results of a separate calculation (C-NSA-99.16-19, revision 2) which calculated the CDF using the unavailability and failure data from July 1, 1993, to June 30, 1996. This evaluation shows a CDF decrease from the base case value of approximately 13 percent.

Calculation C-NSA-99.16-20 also calculated the expected number of failures for each of the risk significant systems. The results of this calculation indicate that the maintenance rule criteria appear to be generally appropriate for risk significant systems although not all systems are modeled in the PRA to the level of detail required to make this comparison. For several important systems, including Auxiliary Feedwater, Emergency Diesel Generators and Essential AC Electrical Power, the number of failures per cycle predicted using PRA data significantly exceeds the maximum acceptable number of functional failures per the maintenance rule performance criteria. For only one system, the High Pressure Injection System, the results of the calculation indicated a predicted number of failures that was less than the criteria by a substantial margin. For this system, the calculated number of failures was approximately one every four cycles, which is less than the original criteria of one failure per cycle. The High Pressure Injection System performance criterion was changed to one failure every four cycles.

#### Corrective Steps to Avoid Further Violations

The calculation evaluating the reliability performance criteria for risk significant systems (C-NSA-99.16-20) will be maintained, as appropriate, to demonstrate that the performance criteria and goals are commensurate with safety.

To ensure the continued demonstration that the condition of structures, systems, and components is effectively controlled through adequate preventive maintenance, the procedure governing the Periodic Maintenance Effectiveness Assessment Report was revised on March 5, 1997. Future Periodic Maintenance Effectiveness Assessment Reports will include an assessment of the risk impact of the observed equipment reliability and availability for the cycle.

#### Date When Full Compliance Will Be Achieved

The calculation documenting that the reliability performance criteria for risk significant systems are commensurate with safety (C-NSA-99.16-20) will be approved by May 30, 1997.

Additional Response Information

In NRC Inspection report 50-346/97002(DRS), the NRC identified one unresolved item. This unresolved item, 50-346/97002-02(DRS), documents an NRC concern with the monitoring of structures. There were two areas of concern identified as part of this open item. The first issue is that the portion of the baseline walk-down of structures performed by Mechanical/Structural Unit of Design Basis Engineering does not include supports contained within the building. Credit is being taken for previously completed walk-downs to the maximum extent practical for the baseline inspection. The Seismic Qualification Utility Group (SQUG) and the Individual Plant Examination of External Events (IPEEE) walk-downs consisted of 616 pieces of electrical and mechanical equipment, cable trays, conduit supports, and yard tanks. These walk-downs, performed from 1993 to 1995, consisted of detailed reviews of the anchorage and foundation of equipment, as well as any potential seismic interaction concerns directly above the equipment. Considering this sample size, it is concluded that the equipment, cable trays, and conduits are adequately baselined. In addition, all nuclear safety related and seismic category 1 piping systems within the scope of IE Bulletin 79-14 were re-inspected during the period 1985 to 1989. Based on this effort, the nuclear safety-related and seismic category 1 piping supports have been adequately baselined. However, as the baseline inspections and System Engineering walk-downs continue, the current condition of the structures within the scope of the maintenance rule, as well as the supports contained within the buildings, will be evaluated.

The second issue associated with this unresolved item involves the dispositioning of structures within the maintenance rule from (a)(1) to (a)(2) and from (a)(2) to (a)(1). Guideline DG-26, "Design Guideline for Maintenance Rule Evaluation of Structures," contains criteria similar to that contained in the memorandum "Summary of January 9, 1997, meeting with the Nuclear Energy Institute (NEI) on Maintenance Rule Issues" dated February 4, 1997. When revision 2 of Regulatory Guide 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants" is issued, the related procedural guidance for structural aspects of Davis-Besse's Maintenance Rule Program will be reviewed to ensure they are in compliance with the new guidance and that a clear method exists for the expert panel to disposition structures from (a)(1) to (a)(2) and from (a)(2) to (a)(1).