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Subject: Response to Inspection Reports 50-346/94012 and 50-346/94016

Gentlemen:

Toledo Edison (TE) has received Inspection Report 94012 (Log Number 1-3536) and Inspection Report 94016 (Log Number 1-3542), and provides the following response. The responses to the Notices of Violation (NOVs) contained in these inspection reports are provided in the attachments to this letter.

Consistent with the Nuclear Regulatory Commission's (NRC's) recent statements encouraging licensees to question the NRC staff where differing professional opinions may exist, three of the alleged violations are being contested by TE. Please note that, in the cases where a NOV is being contested, TE recognizes the need for improvement in the areas identified. As such, actions to address the underlying weaknesses for each of the contested violations have already been taken, as described in the NOV responses. Toledo Edison would also like to respond to inaccurate statements made by the NRC in these inspection reports, as well as respond to a specific item requested by the NRC in Inspection Report 94016 relating to the safety evaluation process.

The cover letter for NRC Inspection Report 94012 contains a statement regarding management inattention relating to certain aspects of the Motor Operated Valve (MOV) program. Toledo Edison contends that committing its resources to the DBNPS MOV program as it did was by informed management decision, not by insufficient management attention. Throughout the evolution of industry MOV programs, it has been TE's perception that the NRC has placed greater emphasis upon completion of actual valve in-situ testing and less emphasis upon follow-on analytical work. Toledo Edison

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also believes that a program based upon actual testing provides better assurance of proper valve operation. As such, TE committed, by letter dated September 16, 1994 (Serial Number 2247), to complete all initial valve testing by the end of the ninth refueling outage (9RFO) in November 1994. As noted in the inspection report, this commitment was met. Follow-on analytical work is presently scheduled to be completed by April 1, 1995 as stated in TE's September 16 letter. Based upon the above information, TE contends that the comment regarding management of the MOV program is inaccurate.

Toledo Edison has noted that most of the weaknesses identified by the NRC in Inspection Report 94012 involved questions of adequacy of TE's analyses. To alleviate this concern, TE is considering extension of the April 1, 1995 commitment date mentioned above to allow more thorough internal reviews and to obviate any questions of adequacy during future inspections of the program. The NRC will be notified under separate cover should TE decide to extend the commitment.

Inspection Report 94016 identified an Inspection Follow-up Item dealing with the DBNPS 10CFR50.59 safety evaluation screening process. As noted in the inspection report, the concern with the 10CFR50.59 safety evaluation screening process was acknowledged by TE and preliminary programmatic improvements were discussed with the inspectors during the inspection. Toledo Edison's plans to improve the screening process are discussed in Attachment 3 to this letter.

The NRC also identified concerns related to configuration control in Inspection Report 94016 and contended that TE's corrective actions in response to related items identified in a 1993 inspection failed to preclude occurrence of these concerns. This contention is inaccurate in that the concerns identified in the 1993 inspection generally dealt with inconsistencies between Piping and Instrumentation Diagrams (P&IDs), Operational Schematic drawings, and plant operating procedures. As such, TE's corrective actions, as described in a March 14, 1994 response to a civil penalty (Serial Number 1-1036), were focused on correcting these procedure and drawing discrepancies, and precluding future discrepancies of this nature. As stated in TE's March 14, 1994 letter, these corrective actions would be completed within 120 days following completion of the ninth refueling outage (this corresponds to a completion date of March 15, 1995). During the November-December 1994 inspection, the NRC did not request any information relating to the status or scope of TE's corrective actions taken in response to the previously identified configuration control deficiencies. Therefore, TE contends that the NRC's statement regarding the adequacy of corrective actions for previously identified configuration control deficiencies misrepresents the scope of previous corrective actions and is misleading.

In the text of Inspection Report 94016, the NRC is critical of the corrective actions taken in the past to resolve problems with two check valves in the auxiliary feedwater system. Toledo Edison recognizes that

MS734 and MS735 have historically presented operational problems. It is important to note that the current mode of system operation is the direct result of energizing the steam supply lines to the auxiliary feedwater pump turbines in 1986. This change in system operation significantly improved the reliability of the auxiliary feedwater system. Considerable effort has been expended and continues in an effort to resolve this problem. Through these efforts, the problem has become better understood and more manageable. In this regard, the inspection report inappropriately criticizes the approach taken in the eighth refueling outage (8RFO) to remedy the problem as being the cause of a licensee event report. Although it is implied that matters were made worse as a result of actions taken during 8RFO, the approach improved the situation to some degree, but added an operator burden and increased reliance on human performance to assure operability of the auxiliary feedwater system. This reliance was determined to be less desirable than the current situation, which imposes a larger maintenance burden. While the current situation is still not optimal, it is believed to be more manageable as less reliance is placed on human performance to assure operability.

Toledo Edison is committed to continuous improvement in all activities at the Davis-Besse Nuclear Power Station. These inspections identified some areas for additional improvements. In this regard, Design Engineering has recently initiated a Program for Excellence. This program is being implemented to improve the quality of Design Engineering products. A key element of this program is to strengthen the self check/check others culture in Design Engineering. This program is intended to address many of the observations noted in the inspection reports.

Should you have any questions or require additional information, please contact Mr. William T. O'Connor, Manager - Regulatory Affairs, at (419) 249-2366.

Very truly yours,

NKP/eld

Attachments

cc: L. L. Gundrum, NRC Project Manager
J. B. Martin, Regional Administrator, NRC Region III
S. Stasek, DB-1 NRC Senior Resident Inspector
Utility Radiological Safety Board

Reply to a Notice of Violation (94012-01 (DRS))

Alleged Violation

10 CFR Part 50, Appendix B, Criterion XVI states, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected.

Contrary to the above, Davis-Besse did not adequately evaluate increased diagnostic equipment inaccuracies described in an ITI-MOVATS 10 CFR Part 21 notification dated February 28, 1992. Consequently, between March of 1992 and October 1, 1994, potential conditions adverse to quality, such as control switch settings set below the minimum setting required to operate a valve under design basis conditions, were not identified or corrected.

This is a Severity Level IV Violation (Supplement I).

TE Response

1. Basis for Disputing the Violation

As discussed in Toledo Edison's (TE's) response to NRC Generic Letter 89-10, Supplement 5 dated September 28, 1993 (Serial Number 2176), the 10CFR21 notification from ITI-MOVATS dated February 28, 1992 dealing with diagnostic equipment inaccuracies was documented in Potential Condition Adverse to Quality Report (PCAQR) 92-0104. The evaluation of the deficiencies mentioned in PCAQR 92-0104 referred to an earlier PCAQR (PCAQR 91-0381) written to address a similar concern with ITI-MOVATS diagnostic equipment. The evaluations contained in these PCAQRs concluded that the affected Motor Operated Valves (MOVs) installed at the Davis-Besse Nuclear Power Station (DBNPS) remained capable of performing their intended functions in light of the identified deficiencies. The corrective actions delineated in these PCAQRs consisted of completing the MOV test program as described in Generic Letter (GL) 89-10, using the VOTES diagnostic equipment. PCAQR 91-0381 was closed on November 21, 1991 and PCAQR 92-0104 was closed on May 21, 1992. The evaluations and the corrective actions specified in these PCAQRs have not changed since these dates.

The NRC conducted an inspection of the DBNPS MOV program between July 13 and July 29, 1992. NRC Inspection Report 50-346/92010(DRS) dated August 20, 1992 (Log Number 1-2721) reported the results of this inspection. During the inspection, the NRC reviewed the methods used in identifying, evaluating, and correcting deficiencies identified internally and by outside entities (e.g., 10CFR21 notifications from vendors). In addition, the inspectors reviewed TE's approach to resolution of the ITI-MOVATS diagnostic testing equipment inaccuracy issue identified in the February 28, 1992 ITI-MOVATS 10CFR21 notification. As documented in the inspection report, the NRC found these items to be acceptable.

With regard to the acceptability of TE's approach in dealing with the ITI-MOVATS equipment inaccuracies, the NRC inspectors did not specifically state that they had reviewed the PCAQRs mentioned above. However, these PCAQRs provided TE's only evaluations of the MOVATS equipment inaccuracy issue and the 1992 inspection report specifically discusses the approach taken to resolve the issue that is described in PCAQR 92-0104. Since the PCAQRs were closed at the time of the 1992 inspection, it was clear that TE's method of evaluation or the corrective actions to be taken would not change unless further new information subsequently became available. The text in Inspection Report 94012 mentions an ITI-MOVATS document that was not included in the ITI-MOVATS Part 21 notification of February 28, 1992 (i.e., ER-5.2). The existence of ER-5.2 was considered in PCAQR 92-0104 before the July 1992 NRC inspection and the evaluation in PCAQR 92-0104 was performed with knowledge of this information.

Toledo Edison's response to NRC GL 89-10, Supplement 5 merely took credit for the approach documented in the previously closed PCAQRs. Toledo Edison reasoned that a detailed reanalysis was not necessary for the GL 89-10, Supplement 5 response. This was because ITI-MOVATS equipment was not in use at the DBNPS and had not been in use since 1990, the existing evaluations provided reasonable assurance of MOV operability, and testing under the GL 89-10 MOV program with VOTES equipment was in progress and would resolve any discrepancies discovered.

During the November-December 1994 MOV program inspection, the inspectors questioned the adequacy of the evaluations performed in 1991 and 1992 regarding the ITI-MOVATS equipment inaccuracies. TE personnel re-evaluated the position taken and again concluded the affected valves were operable. As part of the discussions between TE personnel and the inspectors, information contained in PCAQR 93-0111 was used to corroborate the TE position taken in its GL 89-10, Supplement 5 response. The results of these discussions subsequently have been documented and are on file in PCAQR 95-0099. It is TE's understanding that the inspectors' technical concerns were resolved in these discussions. No further actions are deemed necessary by TE.

The text in Inspection Report 94012 describes the evaluation included in PCAQR 93-0111 as an evaluation done in response to GL 89-10, Supplement 5. This is inaccurate in that PCAQR 93-0111 was initiated as a result of deficiencies identified during the efforts associated with creating design-basis MOV thrust calculations for valves included in the GL 89-10 MOV program. As was described above, information in PCAQR 93-0111 was used to support TE's position in discussions with the inspectors. In the operability evaluations for MOVs for which discrepancies were identified, MOVATS thrust data was used as a "best estimate" of field values. These "best estimates" of thrust values did not take into account the maximum equipment uncertainties. Use of these thrust values provided reasonable assurance that the affected MOVs were operable until VOTES testing could be completed under TE's GL 89-10 program. In November 1994 initial VOTES testing for all of the MOVs included in the GL 89-10 MOV program was completed. This testing confirmed that the affected MOVs were operable, as the earlier evaluations included in PCAQR 93-0111 had concluded.

In Inspection Report 94012, the NRC cites an example from PCAQR 93-0111 of insufficient consideration of MOVATS equipment inaccuracies for valve DH831. At the time PCAQR 93-0111 was initiated in March 1993, calculations for DH831 specified a target thrust range of 11,456 pounds to 12,550 pounds and a maximum allowable total thrust of 13,899 pounds. These calculations were based upon conservative assumptions for valve parameters and included inadvertent mispositioning of the valve as an input into the differential pressure calculation for closing of the valve. Based upon earlier MOVATS test data, the field setting for DH831 was estimated to be 9915 pounds at the torque switch trip and total thrust was estimated to be 11,262 pounds. Valve DH831 is normally closed and its safety function is to open after an accident to cross-connect Low Pressure Injection (LPI) system trains, if necessary. Valve DH831 has no design basis safety function to close, however, if inadvertent valve mispositioning is conservatively assumed, the valve may have to close against a maximum differential pressure of approximately 400 psid. The evaluation of PCAQR 93-0111 completed in May 1993 concluded that DH831 was capable of performing its design-basis functions at lower differential pressures than the maximum (such as if valve mispositioning was not considered). Note that valve mispositioning is not part of the DBNPS design basis and, in light of the information contained in NRC GL 89-10, Supplement 4, dated February 12, 1992 (Log Number 3686), it was unclear whether or not mispositioning would be required to be considered for GL 89-10 programs in the future. Therefore, DH831 was considered to be operable, however, it was recommended that this valve be VOTES tested during the next scheduled maintenance outage. Valve DH831 was VOTES tested in August 1993 and the "as-found" thrust was above the calculated thrust range. However, an evaluation concluded the condition of the valve to be acceptable, considering the valve had been overthrusted. The valve was reset to lower the thrust to an acceptable value prior to returning it to service. The systematic evaluations and actions taken in the case of DH831 are typical for the other MOVs identified in PCAQR 93-0111. Toledo Edison believes the actions taken in response to PCAQR 93-0111 to be consistent with industry practice for resolution of discrepancies discovered in implementation of GL 89-10 MOV programs.

By letter dated May 7, 1993 (Log Number 1-2843) the NRC transmitted their internal guidance for inspections of programs in response to GL 89-10. In this guidance, the NRC provides criteria for issuance of a violation of 10CFR50, Appendix B, Criterion XVI, "Corrective Action" for situations of this nature. According to this document, the NRC would issue a Notice of Violation for inadequate corrective actions in the situation described below:

> "The staff would consider a failure of an MOV as a result of insufficient torque or thrust capability after the licensee's schedule originally committed to in response to GL 89-10 to constitute inadequate corrective action by the licensee if best available test data were not used in sizing and setting the MOV."

In TE's case, the identified deficiencies did not result in any inoperable MOVs, as was acknowledged by the inspectors in Inspection Report 94012. In addition, the deficiency was identified and resolved before the committed program completion date of April 1, 1995 as is provided in TE's letter of September 16, 1994 (Serial Number 2247).

Similarly, in GL 89-10, Supplement 6 (Log Number 4170), the NRC provides another example of a situation where a violation of 10CFR50, Appendix B, Criterion XVI would be considered. In this letter, the NRC states:

> "The requirements in Criterion XVI of Appendix B also apply to new information that might reveal a problem with the design-basis capability of MOVs, such as increased MOV diagnostic equipment inaccuracy."

As discussed above, since the issuance of the 10CFR21 notification of ITI-MOVATS on February 28, 1992 and the subsequent completion of TE's evaluation, no additional information that would lead TE to believe its earlier evaluations were inadequate has become available. The only information that has since become available is VOTES test data that supports the conclusion of TE's original evaluation.

NRC Manual Chapter 0514 provides guidance for NRC staff implementation of 10CFR50.109 relating to plant-specific backfitting. In this guidance, the NRC states:

> "Throughout plant lifetime, many individuals on the NRC staff have an opportunity to review the requirements and occasions when a reviewer concludes the licensee's program in a specific area does not satisfy a regulation, license condition or commitment. In the case where the staff previously accepted the licensee's program as adequate, any staff specified change in the program would be classified as a backfit."

As is described in detail above, it appears the NRC has rereviewed a previously accepted evaluation and has changed its position with regard to compliance with regulations. This change of position was done without the benefit of performing a backfit analysis, as required by 10CFR50.109.

In summary, TE contends that this is not a violation of NRC requirements for reasons stated above. Toledo Edison acknowledges that the industry and NRC knowledge base on MOVs has improved significantly since July 1992, however, it appears that the NRC has changed its position on this issue and now believes the earlier analyses of the ITI-MOVATS 10CFR21 notification are inadequate. Toledo Edison also contends that this deficiency is not consistent with NRC published guidance regarding issuance of a violation for inadequate corrective action.

Reply to a Notice of Violation (94012-0. (DRS))

Alleged Violation

10CFR 50, Appendix B, Criterion V requires, in part, that procedures shall include appropriate quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished.

Contrary to the above, procedure DB-PF-04167, "Periodic Test Procedure Motor Operated Valve Differential Pressure and Flow Test," Revision 1, did not include appropriate quantitative acceptance criteria such as: a comparison of maximum closing thrust or torque to actuator closing and structural limits; a comparison of actuator capability to the closing thrust limits for limit seated valves; an adjustment of control switch trip values for diagnostic extrapolation error; and the margin required prior to returning valves to service.

This is a Severity Level IV violation (Supplement I).

TE Response

1. Basis for Disputing the Violation

NRC Generic Letter (GL) 89-10 was originally promulgated as an approved backfit. According to GL 89-10, following the guidance contained in the GL was necessary to provide assurance of design basis operability in order to meet the requirements of General Design Criteria 1, 4, 18, and 21 of Appendix A to 10CFR50 and Criterion XI of Appendix B to 10CFR50. In GL 89-10, the NRC further states that:

> "Surveillance, adjustment, maintenance, and repair of safety-related MOVs should be performed in accordance with quality assurance program methods that meet the requirements of 10CFR Part 50."

In GL 89-10, Supplement 1, the NRC addresses the applicability of 10CFR50, Appendix B to testing programs imposed by GL 89-10 in two places. First, in response to Question 24 in the enclosure, the NRC states:

> "In any event, the staff expects licensees to ensure that data that are intended for use in demonstrating the operability of an MOV have been obtained under the provisions of a quality assurance program in accordance with Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50."

Second, in response to Question 58 in the same enclosure, the NRC states:

> "The staff is not establishing new quality assurance requirements through the generic letter. Appendix B to 10 CFR Part 50 of the NRC regulations provides the criteria for the establishment of quality assurance programs at nuclear power plants. Activities such as surveillance, adjustment, maintenance, and repair of safety-related MOVs are covered by Appendix B to 10 CFR Part 50. Licensees should be performing these activities, as well as new activities (such as diagnostics and prototype testing) conducted in response to the generic letter, under an Appendix B quality assurance program."

The NRC's position is further reiterated in GL 89-10, Supplement 6, where the NRC states:

> "In response to Question 24 in Supplement 1 to GL 89-10, the staff stated that it expects licensees to ensure that data intended for use in demonstrating the operability of an MOV have been obtained under the provisions of a quality assurance program in accordance with Appendix B of 10 CFR Part 50. As further information, licensees using data from tests performed under an approved program (for example, other licensee data) developed in accordance with Appendix B of 10 CFR Part 50 need not verify or audit the tests covered by other licensee Appendix B procedures or processes."

Clearly, based upon the information provided by the NRC and in the context of diagnostic testing done to meet the guidance contained in GL 89-10, the only 10CFR50 Appendix B criterion that is required to be met is Criterion XI, which was imposed by backfit, although generic letters in and of themselves cannot impose requirements regardless of whether a backfit analysis was performed. Supplements to GL 89-10, with the exception of Supplement 3, have relied upon the original backfit analysis performed by the NRC for GL 89-10. The NRC's contention is that, with the exception of Supplement 3, no additional staff positions or recommendations had been imposed in the Supplements. Ensuring that the GL 89-10 test program meets the other criteria contained in Appendix B to 10CFR50 is a staff expectation and only certain activities requested by GL 89-10 are required to be conducted under an Appendix B quality assurance program. Also of note is that diagnostic testing is listed as an "other activity" and is specifically excluded from the list of activities such as surveillance, adjustment, maintenance or repair for which Appendix B applies. Therefore, citing Toledo Edison (TE) in violation of 10CFR50, Appendix B, Criterion V for inadequate acceptance criteria for diagnostic MOV testing appears to be in error. The NRC published guidance clearly indicates that compliance with this criterion is not a requirement for this activity.

GL 89-10 was issued as a request for information in accordance with 10CFR 50.54(f). In response to the GL, TE submitted a response (Serial Number 1748) describing its program for testing of MOVs that generally met the guidance contained in the GL. By virtue of the fact that a description of the program was provided under a 10CFR50.54(f) request for information does not cause the program commitments to assume the status of a regulation or a condition of the operating license of the Davis-Besse Nuclear Power Station (DBNPS). As such, failure to meet the commitments specified in the program description cannot result in a violation of a regulation, but may result in a Notice of Deviation as described in 10CFR2, Appendix C. However, TE is being cited as being in violation of NRC requirements.

As is also described in GL 89-10 and clarified in the NRC responses to Questions 48 and 49 of GL 89-10, Supplement 1, it was not the intent of the NRC to supplant existing test requirements for MOVs with programs formulated in response to GL 89-10. As such, testing of MOVs in accordance with GL 89-10 is not considered a condition of component or system operability in the sense that surveillance testing (including that testing imposed by Technical Specification 4.0.5) is considered. Absent any information to the contrary, surveillance testing provides reasonable assurance of component or system operability. Therefore, for surveillance testing where plant personnel are generally constrained by a component or system allowable outage time, it is desirable to have clear, quantitative acceptance criteria in test procedures. In the case of MOV diagnostic testing, acceptance criteria need not be as definitive as that for surveillance test procedures, as it was intended that data obtained during diagnostic testing be evaluated in some detail prior to making a determination of MOV operability. Toledo Edison agrees that, in cases where MOV diagnostic testing provides a clear indication that a valve is incapable of performing its intended safety function, the valve should be considered inoperable and appropriate actions should be taken. However, in those cases where MOV diagnostic testing data does not provide definitive indications of MOV inoperability, the MOV is assumed to be operable and use of the guidance contained in GL 91-18 is the most appropriate method of determining continued continued MOV operability. Generic Letter 91-18 provides guidance for the resolution of degraded and nonconforming conditions as they relate to operability of plant equipment. In this guidance, it is recognized that resolution of these issues is often complex, and operability determinations evolve as information becomes available and is subsequently evaluated. This is the approach taken by TE in evaluating MOV diagnostic test data and is as described in TE's letter of September 16, 1994 (Serial Number 2247).

In test procedures used at DBNPS for MOV diagnostic testing, the acceptance criteria used to determine initial MOV operability were qualitative. However, quantitative data was available and was used by the test leaders to determine MOV operability. This approach was believed to be adequate as an initial determination of MOV operability and relied on the MOV test leader's experience, qualifications, and sound engineering judgment. As a matter of practice, prior to performing a test, test leaders reviewed information such as pertinent test conditions, results of previous static and dynamic tests, and valve differential pressure and thrust calculations. The reviews enabled the test leaders to develop expectations as to the anticipated behavior of a particular MOV during a diagnostic test. If a valve behaved as expected or the calculations indicated the MOV had ample margin to predetermined limits, the initial operability determinations were not detailed. However, in diagnostic tests where MOV behavior was not as expected or where limits were approached, more information was sought before making an initial operability determination. It was TE's intent to use the data obtained in the MOV diagnostic tests to perform more detailed analyses prior to closeout of the MOV test program. This approach is consistent with that described in GL 91-18.

During the MOV program inspection in November-December 1994, the inspectors questioned the adequacy of TE's qualitative approach described above. An acceptable engineering aid was developed to more accurately assess MOV operability, as is acknowledged in Inspection Report 94012. In using this engineering aid, TE demonstrated that all initial operability determinations made prior to returning the affected MOVs to service upon conclusion of diagnostic testing were, in fact, correct.

Toledo Edison agrees that more detailed acceptance criteria are desirable in order to better support MOV operability determinations for a third party reviewer. To this end, TE has enhanced the acceptance criteria contained in procedure DB-PF-04167 by incorporating the information in the engineering aid mentioned above. This procedure change has been incorporated. However, TE contends that the acceptance criteria in existence at the time of the inspection were adequate to provide reasonable assurance of MOV operability, as evidenced by the correct conclusions being reached upon returning MOVs to service following diagnostic testing.

Toledo Edison has reviewed a number of MOV program inspection reports for NRC Region III plants. In a number of the reports, it was evident that the inspectors raised concerns with MOV diagnostic testing acceptance criteria or the methods employed to evaluate data obtained from MOV diagnostic testing. The issues raised by the inspectors appear to be similar to those raised by the inspectors during the November-December 1994 inspection at the DBNPS, yet none of the licensees were cited as being in violation of

NRC requirements. It appears that the enforcement policy is not being uniformly applied, even in inspections conducted within Region III.

Therefore, TE contests this violation on the basis that the cited regulation is not applicable to the activity conducted at the DBNPS, the acceptance criteria in existence at the time of the inspection were adequate to serve their intended purpose, and enforcement actions in this area have not been uniformly applied.

Reply to a Notice of Violation (94016-01(DRS))

Alleged Violation

10CFR50.59(2)(b)(1) states, in part, the licensee shall maintain records of changes in the facility to the extent that these changes constitute changes in the facility as described in the safety analysis report. These records must include a written safety evaluation which provides the bases for the determination that the change does not involve an unreviewed safety question.

Contrary to the above, as of the end of the inspection, a written safety evaluation was not provided to address a potential unreviewed safety question associated with a change to the facility resulting in the repetitive chattering of the auxiliary feedwater system turbine driven steam supply line check valves.

This is Severity Level IV violation (Supplement I).

TE Response

1. Basis for Disputing the Violation

Toledo Edison (TE) contests this violation on the basis that the subject facility modification (Modification 93-0047) does not constitute a change to the facility as described in the Safety Analysis Report (SAR), and therefore is not subject to the requirements of 10CFR50.59. In citing the violation, NRC states that a written safety evaluation was required for this change on the basis that it involved a potential unreviewed safety question, predisposing the conclusion as to whether the change was a change to the facility as described in the SAR. A violation of 10CFR50.59(2)(b)(1) can occur only if it can be shown that the facility change constitutes a change to the facility as described in the SAR. In citing this violation it is necessary to demonstrate, consistent with existing regulatory guidance, that the modification in question is a change to the facility as described in the SAR. Absent such a demonstration, there can be no violation of the cited regulation.

The most recent NRC guidance regarding determination as to whether a facility change constitutes "a change to the facility as described in the SAR" is contained in the NRC Inspection Manual, Inspection Procedure 37001, dated December 29, 1992. Section 37001-03.01.c.1(a) provides specific guidance regarding 10CFR50.59 applicability determinations (i.e., screening process) for changes in the facility or procedures. In this section, the NRC states:

> "The criterion for requiring a Section 50.59 safety evaluation for a change in the facility (or procedure) is "a change to the facility or procedure as described in the safety analysis report." This criterion means that a change in a structure, system, or component (SSC) or a procedure requires a Section 50.59 safety evaluation only if the following statements are both true:
>
> 1. The SSC (or procedure) being changed is described in the most recently updated FSAR submitted to the NRC in accordance with Section 50.71(e).
>
> 2. The FSAR description of the SSC (or procedure) being changed would be affected by the change."

Further, Section 37001-03.01.c.1(a) states:

> "The FSAR description of a SSC or procedure must be affected by the change in order for a Section 50.59 evaluation to be required. For example, changing a procedure just listed in the updated FSAR would not require a Section 50.59 safety evaluation. However, a temporary change to a SSC that would affect its FSAR description must be evaluated in accordance with Section 50.59, even though the change in the FSAR would not be permanent."

The important points to note from this guidance are: (1) the guidance appears to be narrow in focus, limited in scope to only consideration of the most recently updated FSAR submitted to the NRC in accordance with 10CFR50.71(e); (2) the SSC or procedure must be described, not merely listed or identified in the SAR; and, (3) the FSAR description must be affected such that SAR must be changed to remain true. It is recognized that a change to a SSC could have a material influence on a SAR description without the SSC being directly described. For example, a change to a SSC could have an impact on the SAR description of how that SSC performs in mitigating an event.

Interpretation of this guidance centers on the definition of the terms "describe" and "affect". "Describe" commonly means to represent or give an account of in words; or, to represent by a figure, model, or picture; or, delineate. "Affect" commonly means to produce an effect on; or, to produce a material influence upon, or alteration in.

The cited violation and supporting inspection report neither demonstrates how the SSCs being modified (valves MS734 and MS735) are described in the SAR, nor how the SAR description is affected by the modification. While the identified condition may represent a weakness in documentation, it is not, in and of itself, a violation of 10CFR50.59 unless the conclusion from the screening process is incorrect and a 10CFR50.59 evaluation is required within the scope of the above guidance.

Section 3.3.4 of Inspection Report 94016 provides the NRC supporting basis for citing this violation. The inspection report states:

> "The Safety Review done in December 1993, and reviewed in February 1994, stated, "The detailed design of these valves is not defined in the USAR....". Again, the review was narrowly focused, and failed to address the effects of check valve disc chatter that could produce wear and tear on the valve components, and render the valve incapable of meeting the leak test acceptance criteria."

This statement implies that the TE's sole basis relied upon to reach the conclusion that a 10CFR50.59 safety evaluation was not required was that the detailed design was not described in the Updated Safety Analysis Report (USAR). It also implies that there was neither recognition nor consideration given to the function of the valves in mitigating high energy line breaks. Additionally, the statement implies that the administrative leakage test acceptance criteria established for the valves represents design basis requirements relative to their function. In fact, the administrative limit provided a large margin to allow for wear.

When quoted in full, the referenced safety review states:

> "The detailed design of these valves is not defined in the USAR; however, they are relied upon to close in the event of a High Energy Line Break (HELB) and a single failure of an isolation valve. Modification 93-0047 will not change the description of the function of these valves as described in the USAR."

Clearly, the effects of this change on the HELB analysis were recognized and considered during the safety review. Toledo Edison recognizes, however, that the basis for the conclusion that the function of these valves as described in the USAR is not affected by the modification, is not documented in the safety review. This, however, does not constitute a violation of 10CFR50.59 unless this conclusion is incorrect. This conclusion would only be incorrect if the modification resulted in the check valves not being able to function as required by the USAR, in which case this would be a change to the facility as described in the SAR.

By modifying the check valves, essentially returning them to the original licensed configuration, TE increased the "tapping" of the check valves. The tapping is believed to occur in response to pressure pulses originating in the main steam line. Thus, the valves would continue to be subjected to additional wear which degrades the performance of the valves over time. Provided that the valve performance continues to exceed the minimum performance necessary to fulfill its USAR-credited function, then no change to the facility as described in the SAR resulted from this change. Toledo Edison's safety review documents this conclusion. Toledo Edison acknowledges that the information supporting this conclusion is not included in the modification package. However, all of the information supporting this conclusion was available at the time the safety review was performed, with the exception of information from maintenance and testing activities conducted during the ninth refueling outage (9RFO). The 9RFO maintenance and testing did not provide new information that would have altered TE's safety review conclusion.

The conclusion of the safety review is based on the fact that the administrative leakage limit includes substantial margin which allows for future wear. There are large conservatisms in the supporting calculations for the administrative limit. These calculations are based on maintaining the maximum flexibility in equipment available to mitigate a HELB with the minimum of operator distractions due to consequential effects of the HELB. The calculations do not take credit for alternative means for mitigating the HELB event which are credited in the USAR (e.g., use of the Motor Driven Feed Pump). Additionally, significant analysis of the degradation mechanisms of the original design check valves previously installed in this application had been performed in 1989. This evaluation of check valve degradation is conservative when applied to the current design check valve because of design differences which tend to reduce the susceptibility of the valves to the previously evaluated degradation mechanisms. The information, which existed when the safety review was performed, supports the conclusion that the check valves will continue to fulfill their USAR functional requirements under current operating conditions. Therefore, the change to the design did not constitute a change to the facility as described in the SAR.

In response to concerns raised by the inspectors and to address remedial actions for Potential Condition Adverse to Quality Report (PCAQR) 94-1259, which is referenced in the inspection report, TE prepared an Engineering Evaluation. The Engineering Evaluation consolidates and explains the supporting bases for TE's safety review conclusion in one document. This PCAQR and the associated Engineering Evaluation have been made available onsite to the NRC Resident Inspector.

Toledo Edison would also like to point out an error in Section 6 of the inspection report regarding the screening of changes for 10CFR50.59 applicability. The inspection report states:

> "The 10CFR50.59 screening process did not ensure that the seven questions used to determine whether an unreviewed safety question existed were reviewed. An unreviewed safety issue could result from any design modification. Even though these questions were listed on the licensee screening form after the questions for determining if a 10CFR50.59 Safety Evaluation was required, the questions were often either bypassed because of the narrow focus of

the system description in the USAR and TS, or marked "no" on every answer due to a narrow interpretation of the system descriptions."

This view is in conflict with 10CFR50.59 in that it appears to advocate using the unreviewed safety question determination criteria of 10CFR50.59(a)(2) to determine whether a safety evaluation is required in addition to, or in lieu of, TE's safety review screening criteria. The NRC would expect that the basis for a "no" answer to each of these questions to be documented. This essentially would result in 10CFR50.59 Safety Evaluation being performed for every change as part of the screening process to determine whether 10CFR50.59 even applies to the change under consideration. Clearly, a 10CFR50.59 safety evaluation is required only for facility changes that constitute a change to the facility as described in the SAR.

It should be noted that the screening form discussed in the inspection report is entitled "Safety Review and Evaluation" and includes the 10CFR50.59(a)(2) unreviewed safety question determination criteria. However, the form is procedurally used only for the safety review. The procedure currently does not dictate the use of the safety evaluation portion of the form.

Even though Toledo Edison is contesting this particular violation for reasons described above, Toledo Edison acknowledges the NRC concern with the 10CFR50.59 screening process. Preliminary programmatic improvements for this process were discussed with the inspectors. In fact, the documentation associated with the safety review forms and concerns with the screening process had been identified by TE in June 1994. In evaluating the 10CFR50.59 safety review and evaluation program at DBNPS, TE concluded that the existing program is adequate to meet regulatory requirements and current industry guidance. However, as a result of an internal programmatic review TE concluded that additional improvements could be made in the training program and in the communication of management expectations to individuals performing the evaluations. Accordingly, TE is upgrading the 10CFR50.59 safety review and evaluation program. Specific improvements include implementation of a new computer-based training program, revision of the training manual, and revision of the 10CFR50.59 safety review procedure and screening form. These improvements encourage reviewers to provide more extensive written justification for each answer on the screening form and to more clearly articulate the required elements of a satisfactory safety review or evaluation. These changes are expected to be implemented by June 1, 1995. Toledo Edison will continue to closely monitor the safety review and evaluation process at DBNPS and will make further improvements as appropriate. However, as stated previously, TE believes that the existing program is adequate to satisfy regulatory requirements and is consistent with industry and NRC guidance. The noted improvements will serve to enhance program implementation.

Reply to a Notice of Violation (94016-02(DRS))

Alleged Violation

10CFR50, Appendix B, Criterion III, states, in part, that design changes shall be subject to design control measures commensurate with those applied to the original design and that design control measures shall provide for verifying the adequacy of design, such as, by the performance of design reviews for compatibility of materials.

Contrary to the above, as of the end of the inspection, the licensee had failed to verify the adequacy of design of two commercial grade 1/2" stainless steel tees specified in the Bill of Material attached to a design package for Facility Change Request No. 86-0303.

This is a Severity Level IV violation (Supplement I).

TE Response

1. Reason for the Violation

Facility Change Request (FCR) 86-0303, Reactor Coolant System (RCS) Hot Leg Narrow Range Level Monitoring System, was implemented to address INPO Significant Operating Experience Report 85-4, Loss or Degradation of Residual Heat Removal Capabilities in PWRs, and NRC Generic Letter 88-17, Loss of Decay Heat Removal. The modification installed dual RCS hot leg narrow range level indication and alarm capability. The purpose of the modification was to improve plant operators' control and response capabilities to low RCS level conditions during plant shutdown.

Safety Evaluation (SE) 89-0211 for FCR 86-0303 identified this modification as important to safety, but not as nuclear safety related. The SE additionally identified that the new instrument lines installed for this modification would be designed to ASME Section III, Class 2 requirements.

The ASME Section III, Class 2 requirements were not appropriately documented in the quality requirements block of the bill of materials (BOM) which identified necessary parts for implementation of FCR 86-0303. The quality requirements blocks should have indicated ASME requirements, but were incorrectly marked "not applicable". This allowed the acceptability of unqualified parts to be provided by the Davis-Besse warehouse and staged for FCR 86-0303. In the specific case of the two subject half-inch stainless steel tees, unqualified material was provided and installed in the plant under FCR 86-0303.

The cause of this violation was the incorrect identification of the quality requirements for the procurement of the two half-inch stainless steel tees from the warehouse. A contributing factor was a lack of clear understanding in the Design Engineering Instrumentation and Control (DEIC) unit regarding the inputs to the quality requirements block of the BOM. At the time this modification was being designed and implemented, the TE augmented quality assurance program was in its infancy. Since that time, significant process improvements have been made to alleviate concerns of this nature.

2. Corrective Actions Taken and Results Achieved

Potential Condition Adverse to Quality Report (PCAQR) 94-1288 was initiated on December 6, 1994 to document the lack of required ASME certification for the two half-inch stainless steel tees installed under FCR 86-0303.

Safety Evaluation (SE) 95-0002 was completed on January 16, 1995 and evaluated the condition identified in PCAQR 94-1288. The SE concluded that this condition did not involve an unreviewed safety question. The SE further concluded that the current as-built configuration of the hot leg level monitoring system is capable of performing its intended function without a decrease in reliability.

The evaluation of PCAQR 94-1288 included the verification of proper documentation for pressure retaining components installed in this modification. It was determined that fourteen "5-way" manifold valves were installed under this modification without the required engineering approval of the vendor's seismic qualification report. The condition was documented in PCAQR 94-1341 on December 21, 1994. Engineering subsequently reviewed and approved the seismic qualification report and determined that there was no impact on the valves or on the hot leg level monitoring system.

The evaluation of PCAQR 94-1288 additionally identified that incorrect stock code and purchase order numbers for the subject stainless steel tees were referenced in the associated weld traveler and work history forms for Maintenance Work Order (MWO) 2-86-0303-09. These discrepancies have been corrected such that the MWO documentation now reflects current as-built conditions.

3. Corrective Actions to Prevent Recurrence

The DEIC unit will conduct training related to this event with emphasis on lessons learned, the ASME Code and its applicability to instrument tubing, and quality classification as it relates to modification documents. This training will be completed by March 23, 1995.

The text of Inspection Report 94016 states that Toledo Edison, "...committed to replace the tees with qualified fittings during the next refueling outage." While this action is documented in PCAQR

94-1288, it does not constitute a commitment to the NRC. Toledo Edison is evaluating several options to rectify this condition, including seeking ASME Code relief under 10CFR50.55a. Regardless of the option Toledo Edison chooses, this condition will be rectified no later than the end of the Tenth Refueling Outage (10RFO).

4. Date When Full Compliance Will Be Achieved.

Full compliance will be achieved when the identified condition of the two half-inch stainless steel tees has been resolved. This will occur no later than the end of the 10RFO.