CENTERIOR ENERGY

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United States Nuclear Regulatory Commission
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Subject: Elimination Of Quality Assurance Director In-line Review of Measuring and Test Equipment Evaluations

Gentlemen:

In accordance with 10 CFR 50.54(a)(3), Toledo Edison Company hereby submits its plans regarding the elimination of the Quality Assurance (QA) Director's in-line review of measuring and test equipment (M&TE) evaluations at the Davis-Besse Nuclear Power Station, Unit 1. It is proposed that evaluations of M & TE that indicate conditions adverse to quality do not exist, need not be reviewed and approved by the QA Director. An analysis of several years worth of QA evaluations was conducted and the results indicated that there were no subsequent "conditions adverse to quality".

This change, as indicated in the attached 10 CFR 50.54(a) review, has been identified as a reduction to the commitments identified in USAR Chapter 17.2, Quality Assurance Program for Station Operation. Although this change have been identified as a reduction in commitment, the Quality Assurance Program continues to satisfy the criteria of 10 CFR 50, Appendix B as it removes only a self-imposed "non-regulatory" in-line review.

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If you have any questions regarding this proposal, please contact Mr. Robert W. Schrauder, Manager - Nuclear Licensing, at (419) 249-2366.

Very truly yours,

JMM/dlc

cc: A. B. Davis, Regional Administrator, NRC Region III
J. B. Hopkins, NRC Senior Project Manager
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Utility Radiological Safety Board

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REVIEW OF MEASURING AND TEST EQUIPMENT EVALUATIONS

source standards required to be traceable to the National Institute of Standards and Technology (formerly National Bureau of Standards).

17.2.12.4 Calibration Intervals

Calibration intervals are established and controlled by the section providing calibration of the device or standard. The selection of intervals is based on the type of device, stability and reliability characteristics, required accuracy, purpose, frequency of usage, manufacturer's recommendations and past performance. Unscheduled calibrations are performed when the accuracy of a device or standard is questionable.

17.2.12.5 Records

Detailed records are maintained for each device and standard to demonstrate the accuracy of the equipment being calibrated and that established calibration schedules and procedures have been followed. Use records of the device or standard are maintained in a manner that allows traceability of the equipment to the item being measured or tested. Calibration records contain at minimum, the identification and accuracy of the standard used for calibration, repair history, history for plant installed process instrumentation, identification and accuracy of the device being calibrated, calibration data including deviations, and the limited use range when applicable.

17.2.12.6 Conditions Adverse to Quality

Devices and standards found to be out of tolerance when calibrated or which have not been properly maintained or calibrated, subjected to possible damage, or are lost, are identified and removed from service until corrective measures have been taken. All equipment inspected, tested or calibrated by the device since the last calibration are identified. Investigations are performed and evaluated to either reestablish the acceptability of the equipment or to establish that a condition adverse to quality exists. The results of such investigations and evaluations are documented. ~~When the results of an evaluation indicate that a condition adverse to quality does not exists, the evaluation is revieved and approved by the Director, Quality Assurance.~~ Devices or standards consistently ~~lond~~ found to be out of calibration are repaired or replaced.

When a condition adverse to quality is identified, the condition is documented and processed as described in Section 17.2.15.

17.2.12.7 Supplier Control

The requirements for calibration control imposed on vendors, contractors or supplier calibration services are contained in procurement documents and processed as described in Section 17.2.4.

PROPOSED ELIMINATION OF QUALITY ASSURANCE (QA) DIRECTOR IN-LINE REVIEW OF MEASURING AND TEST EQUIPMENT (M&TE) EVALUATIONS.

Affected Paragraph

USAR 17.2.12.6 (M&TE - Conditions Adverse to Quality), page 17.2-38.

Description of Change

Deletes the USAR 17.2.12.6 requirement that: "When the results of an evaluation indicate that a condition adverse to quality does not exist, the evaluation is reviewed and approved by the Director - Quality Assurance.".

Reason for Change

Eliminate the requirement for the QA Director's in-line review and approval of "evaluations of devices and standards found to be out of tolerance when calibrated or which have not been properly maintained or calibrated, subjected to possible damage, or are lost", which indicate that conditions adverse to quality do not exist.

Analysis of approximately fourteen-hundred such evaluations since mid-1989 (400 per year) determined that the in-line QA reviews had not discovered any subsequent "conditions adverse to quality".

Additionally, QA audits and surveillances provide assurance that quality-related procedures, including the controls for M&TE evaluations, comply with applicable QA program requirements and are properly implemented.

Effect of the Change on USAR QA Program Description (Chapter 17.2) Commitments Previously Accepted by the NRC

This proposed change would eliminate an existing QA review commitment from the QA Program Description previously accepted by the NRC. This represents a reduction in commitment and, under the provisions of 10CFR50.54, NRC approval is required prior to implementation.

Basis for Concluding that the USAR QA Program Description (Chapter 17.2) Continues to Satisfy 10CFR50 Appendix B

The requirements of associated 10CFR50 Appendix B Criteria (i.e., XII-Control of M&TE, XV-Nonconforming Materials..., XVI-Corrective Action, and XVIII-Audits) are still fully satisfied by USAR 17.2, which continues to describe how the requirements of 10CFR50 Appendix B are satisfied. The proposed change only removes a self-imposed "non-regulatory" in-line review which has been determined to be unnecessary and does not alter remaining programmatic controls.