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Vice President - Nuclear  
Davis-Besse

Docket Number 50-346

License Number NPF-3

Serial Number 2230

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

Gentlemen:

Subject: Change in Quality Assurance Program External Supplier Audit  
Report Distribution

In accordance with 10 CFR 50.54(a)(3), Toledo Edison Company hereby submits its plans to remove the requirements to distribute External/Supplier Audit Reports to the Vice President - Nuclear. This change as indicated on the attached 10 CFR 50.54(a) review, has been identified as a reduction to the commitments identified in Updated Safety Analysis Report (USAR) Chapter 17.2, Quality Assurance Program for Station Operation. Although this change has been identified as a reduction in commitment, the Quality Assurance Program continues to satisfy the criteria of 10 CFR 50 Appendix B.

If you have any questions concerning this matter, please call  
Mr. William T. O'Connor, Manager - Regulatory Affairs, at (419) 249-2366.

Very truly yours,

A handwritten signature in dark ink, appearing to read 'John P. Stetz'.

JMM/lkg

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

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Operating Companies:  
Cleveland Electric Illuminating  
Toledo Edison

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Docket Number 50-346  
License Number NPF-3  
Serial Number 2230  
Attachment 1  
Page 1

Listing of Submittal Contents

- Attachment 2      Davis-Besse Unit 1 USAR 17.2, Quality Assurance Program  
for Station Operation, Pages Affected By Proposed Change
- Attachment 3      Evaluation of Proposed Quality Assurance Program  
Reductions

An assessment of the Nuclear Quality Assurance Program is conducted through scheduled audits performed under the cognizance of the Company Nuclear Review Board (CNRB), including periodic audit participation by CNRB members and periodic assessments performed by external organizations such as NRC, INPO, and the Joint Utility Management Assessment (JUMA) team. Audits are performed by the Nuclear Assurance Department in accordance with frequency specified in the Technical Specification to assure the performance of activities required by the Nuclear Quality Assurance Program. The results of these audits and assessments are provided to the Vice President - Nuclear, and the CNRB, thus enabling an on-going assessment to be provided for Davis-Besse operations. In addition to reviewing all audit reports, the CNRB provides audit follow-up actions on a selective basis.

The status, adequacy and effectiveness of the Quality Assurance Program is reviewed by the Vice President - Nuclear on an annual basis. Status reports furnished by the Director - Nuclear Assurance, internal audit reports, various trend reports and staff meetings are utilized by the Vice President - Nuclear to assist in this review. The NQAM is also reviewed annually by the Director - Nuclear Assurance and revised as necessary.

Contract organizations participating in the Nuclear Quality Assurance Program are evaluated on an annual basis for the status and adequacy of the part of the program which they are implementing. Contracted organizations are also required by procurement documents to evaluate their lower-tier suppliers that supply items or services within the scope of the Nuclear Quality Assurance Program.

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(excluding external supplier audits)

#### 17.2.18.4 Audit Performance

Procedures have been developed by Nuclear Assurance that contain provisions for audit performance activities. These activities include the conduct of the pre-audit conference, conduct of the audit, and conduct of the post-audit conference.

Audit performance activities include an objective evaluation of quality related practices, procedures, and instructions for compliance with applicable Code requirements the requirements of the Nuclear Quality Assurance Manual and the Technical Specifications. Audits also verify that activities comply with the requirements of the quality related practices, and procedures, and that records reflect that the Nuclear Quality Assurance Program and its implementing procedures are effective and are being properly implemented.

Conditions adverse to quality discovered during an audit that may affect the safe operation of the plant are immediately brought to the attention of the Director - Nuclear Assurance and the Shift Supervisor.

#### 17.2.18.5 Audit Reporting

Upon completion of the audit, an audit report is signed by the Audit Team Leader and approved by the Director - Nuclear Assurance. The content of the audit report complies with ANSI N45.2.12 and is distributed to management of the audited organization; the Vice President - Nuclear; Company Nuclear Review Board, and the Station Review Board if the audit findings involve station activities. The audit report is required to be issued within thirty (30) days of the post-audit conference. For external audits and audits of contractors, the audit report transmittal also includes the responsible management of the contractor and the department responsible for administration and technical control of the project.

A written response to each audit finding is required from the audited organization within thirty (30) days following issuance of the audit finding, except when a shorter period is specified on the audit finding. Each response is required to clearly identify the remedial corrective action, and the corrective action taken to prevent recurrence. In the event that corrective action cannot be completed within thirty days, the reason and the scheduled date for completion is required in the response.

#### 17.2.18.6 Follow-up

Upon notification the remedial/corrective action to prevent recurrence has been completed, appropriate follow-up measures such as reading is

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(excluding external supplier audits)

10 CFR 50.54 EVALUATION FOR UCN 93-062  
(EVALUATION OF PROPOSED QUALITY ASSURANCE PROGRAM REDUCTIONS)

PROPOSED CHANGES:

The proposed changes to the Updated Safety Analysis Report (USAR) Chapter 17.2, Quality Assurance (QA) Program for Station Operation, are shown on the attached marked up pages of USAR Sections 17.2.2.5 (Program Review) and 17.2.18.5 (Audit Reporting).

The purpose of the proposed changes are to remove the requirement that reports of audits on "external suppliers" be distributed to the Vice President - Nuclear.

Description of Changes

In the first paragraph of USAR Section 17.2.2.5 (page 17.2-15), modify the phrase "The results of these audits and assessments are provided to the Vice President - Nuclear ..." by adding the clarification of "(excluding external supplier audits)".

In the second paragraph of USAR Section 17.2.2.5 (page 17.2-15), modify the phrase "Status reports furnished by the Director - Nuclear Assurance, audit reports ..." by adding the clarification of "internal" before audit reports.

In the first paragraph of USAR Section 17.2.18.5 (page 17.2-49), modify the phrase "The content of the audit report complies with ANSI N45.2.12 and is distributed to management of the audited organization; the Vice President - Nuclear ..." by adding the clarification of "(excluding external supplier audits)".

REASON FOR CHANGE

In an effort to improve the use of resources available at Davis-Besse it was determined that the distribution of the detailed external audit reports to the Vice President - Nuclear was not needed. The Company Nuclear Review Board (CNRB) receives and reviews the detailed external audit reports. In addition to reviewing the audit reports, the CNRB also provides audit follow-up actions on a selective basis.

EFFECT OF CHANGE

The changes remove the administrative requirements for distribution of "external supplier" audit reports to the Vice President - Nuclear. There are no effects on any structures, systems or components either directly or indirectly.

External supplier audit reports will continue to be distributed to the Company Nuclear Review Board (CNRB) for review. The CNRB or designated alternate reviews the audit program semi-annually to assure the audits are

Docket Number 50-346  
License Number NPF-3  
Serial Number 2230  
Attachment 3  
Page 2

being conducted in accordance with the requirements of the Technical Specifications and the Nuclear Quality Assurance Manual in accordance with USAR Section 17.2.18.1 (page 17.2-48). The Vice President - Nuclear also assesses the adequacy and effectiveness of the QA Program on a periodic basis in accordance with USAR Section 17.2.1.3 (page 17.2-4) and USAR Section 17.2.2.5 (page 17.2-15).

The proposed changes will not affect existing Technical Specification requirements of Sections 6.5.2.8 and 6.5.2.10.c.

**BASIS FOR CONCLUDING THAT THE PROPOSED CHANGES CONTINUE TO SATISFY  
"EIGHTEEN POINT" QUALITY ASSURANCE CRITERIA OF 10 CFR 50 APPENDIX B:**

Criterion II (Quality Assurance Program) requires that the applicant's management "regularly review the status and adequacy of the quality assurance program". Criterion XVIII (Audits) requires that audit results "be documented and reviewed by management having responsibility in the area audited".

The distribution of audit reports for responsible management's review will still include the Vice President - Nuclear for "internal" audits and the supplier's management for "external" audits. Review of both types of audit reports by the applicant's management will continue to be accomplished via distribution to the CNRB. See matrix shown below:

<u>Type of Audit Report Being Distributed</u>	<u>Applicant's Management (re: Criterion II)</u>	<u>Responsible Management (re: Criterion XVIII)</u>
Internal Audits	Vice President - Nuclear	Vice President- Nuclear
External Audits	CNRB	Supplier's Management