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Docket Number 50-346

License Number NPF-3

Serial Number 2364

April 10, 1996

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

Subject: Request for Change in Quality Assurance Program Audit and Surveillance Finding Processing

Ladies and Gentlemen:

In accordance with 10CFR50.54 (a)(3), Toledo Edison (TE) hereby submits its plans regarding changes in the processing of Quality Assessment (QA) audit and surveillance findings at the Davis-Besse Nuclear Power Station (DBNPS), Unit 1. It is proposed that these QA-originated nonconformance documents be documented and processed through the existing DBNPS nonconformance/ corrective action program (i.e., the Potential Condition Adverse to Quality (PCAQ) Program) in the same manner as other DBNPS-identified nonconformances.

These changes, discussed in the attached 10CFR50.54 (a) review, have been identified as a reduction to the commitments currently contained in the DBNPS Updated Safety Analysis Report (USAR) Chapter 17.2, Quality Assurance Program for Station Operation. Although these changes have been identified as a reduction in commitment, the attached 10CFR50.54 (a) review demonstrates the Quality Assurance (QA) Program continues to satisfy the criteria of 10CFR50, Appendix B.

In addition to changes to the QA Program as described in the USAR, management commitments regarding the audit process were also identified as being affected. These commitments were made in response to Inspection Report (IR) Number 93-019, dated February 11, 1994 (TE Log Number 1-2982).

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They were made to strengthen weaknesses in the QA audit finding resolution process regarding heightening management attention and follow-up, and to improve the adequacy of corrective actions taken in response to nonconformances identified during QA audits.

Toledo Edison's response, dated March 14, 1994 (TE letter Serial Number 1-1036) to IR Number 93-019, committed to have "corrective actions for audit findings completed by the responsible line organization within 120 days or receive Vice President - Nuclear approval for extension." The response also stated, "QA will perform our initial assessment of the corrective actions within two weeks of their completion. Follow-up QA review of corrective action effectiveness and final QA closure will be completed on a schedule appropriate for the corrective actions under consideration." The commitment to complete corrective actions for audit findings within 120 days and to have QA initial assessment and follow-up at prescribed intervals was chosen by TE management to heighten site awareness and ensure corrective actions were performed in a timely manner.

These commitments, made in response to IR Number 93-019, are being modified. Under the proposed changes, nonconformances identified during audits by QA personnel and nonconformances identified by site personnel will be processed similarly under the DBNPS corrective action process (PCAQ). The combining of these processes provides consistency in the processing of corrective action documents by requiring QA-identified nonconformances found during audit/surveillances to be processed, evaluated, reviewed, completed, and closed out by the DBNPS nonconformance (PCAQ) process. Management of the responsible department will review and investigate all documented conditions adverse to quality (nonconformances) to determine and schedule appropriate corrective action and to close-out the condition adverse to quality in a timely manner.

These changes increase line management's accountability for timely and thorough corrective action under the DBNPS corrective action process. This reliance on responsible management for close-out will permit Quality Assessment to focus on verifying the effectiveness of corrective actions for audit/surveillance-identified nonconformances and DBNPS-identified nonconformances through audits and reviews as required by Technical Specifications and the USAR Quality Assurance Program. These changes also provide for more effective allocation of Quality Assessment auditing resources to areas considered more significant.

The proposed changes are based on similar changes which were implemented at the Union Electric Company's Callaway Plant in May, 1992. Toledo Edison requests that the NRC approve these proposed changes for the DBNPS Quality Assurance Program within the next 60 days in accordance with 10CFR50.54 (a)(3)(iv).

If you have any questions regarding this proposal, please contact Mr. James L. Freels, Manager - Regulatory Affairs, at (419) 321-8466.

Very truly yours,

for J. P. Stetz

JCS/llh

Attachments

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

ATTACHMENT 1
DAVIS-BESSE NUCLEAR POWER STATION

USAR CHAPTER 17.2, "QUALITY ASSURANCE PROGRAM FOR STATION OPERATION"

CONTENT AFFECTED BY PROPOSED CHANGE

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17.2.15 NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

17.2.15.1 Nonconformance Identification

Items or activities which deviate from approved specifications, codes, drawings, procedures, or other applicable documents, or any or condition that affects the quality of items, services, or program, or prevent a structure, system or component from performing its intended function is considered to be a nonconformance and is identified as such and documented. 5

When nonconformances are found or suspected, an appropriate status identification such as the station tagging system, or hold tag is used to preclude further activity pending resolution of the adverse condition. Procedures contain provisions to ensure that nonconformances such as equipment malfunctions, procedure deviations, defective material and items, and deviations to regulatory requirements are promptly identified, documented, evaluated for impact on plant operability, reportability and significance, and corrected.

Nonconformances discovered by suppliers during the manufacturing of materials or items are reported to the Nuclear Group. The supplier's disposition is approved by Engineering or their agent. 5 14 19

Whenever a condition adverse to quality is identified that may be detrimental to the safety of personnel or safe operation of the plant, immediate action is taken to notify the Shift Supervisor. If necessary, notification occurs prior to documenting the condition to ensure control of the condition or item. 9 5

The Manager - Quality Assessment has the authority to stop or delay work activities, except reactor operations, at any time after a condition adverse to quality is identified, if proceeding could jeopardize the quality of an item, adversely affect the quality of subsequent work, or degrade the condition. Conditions affecting reactor operations are reported to the Plant Manager for corrective measures. Hold tags are attached to non-installed nonconforming equipment that has been evaluated as non-operable and to nonconforming material and items found deficient during the receipt inspection process. Nonconforming plant installed equipment is identified through the normal station tagging program. When practical, nonconforming items are physically segregated from conforming items. 19 9 5

17.2.15.2 Review and Evaluation

Documented conditions adverse to quality are reviewed by the initiators supervisor to verify the reported condition. If the condition could affect plant operation, the Shift Supervisor evaluates the condition for impact on Technical Specification requirements and for determination of the reportability to the NRC or other regulatory agencies. 19 5

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As part of the evaluation and dispositioning process, nonconforming equipment is evaluated for the ability to perform its intended function and the department responsible for implementing the disposition is designnated. If the nonconforming equipment cannot perform its intended function, an evaluation of the affected system's operability in accordance with Technical Specifications is performed. | 5

Engineering evaluation of the nonconforming condition includes an assessment to ensure that the item meets the functional requirements, including performance, safety, reliability and maintainability. The engineering evaluation is required to be documented and traceable to the applicable corrective action document. | 19 5

The acceptability of repaired or reworked items is determined by verifying through inspection or testing that the level of quality obtained for the item is the same as, or at least equivalent to the original quality requirements. When the nonconformance has been resolved, Nuclear Assurance personnel signify their concurrence on the corrective action document. | 9 18 5

Systems which contain nonconforming material or items and which have been declared inoperable due to the nonconforming condition, are not declared operable until documentary evidence is available to verify the material or item is in conformance with specified requirements or a documented evaluations provided by Engineering to ensure that it will satisfactorily perform its intended function. | 5

17.2.15.3 10CFR21 Reporting

Conditions adverse to quality are evaluated and reported in accordance with the provisions of 10CFR21. | 14 5

Material or items identified by suppliers as reportable in accordance with 10CFR21 are reviewed by Engineering to determine applicability and to initiate corrective actions as appropriate. | 14 10

Items considered to be reportable under 10CFR21 are reported to the Plant Manager and the Regulatory Affairs Section for notification to the NRC in accordance with the requirements of 10CFR21. | 18 5

17.2.15.4 Trending

The Director - Nuclear Assurance has established a trending and analysis program to detect generic problems, adverse quality trends and repetitive conditions. This program includes the review of documented conditions adverse to quality and significant conditions adverse to quality at a minimum. The specific documents included in the trending and analysis program are identified and distributed in accordance with implementing procedures. | 18 5 9 5

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17.2.16 CORRECTIVE ACTION

17.2.16.1 General

Procedures have been established to ensure that significant conditions adverse to quality are promptly identified, documented, evaluated for their significance, and corrected. These procedures require that the completed corrective action be documented and verified, and that the condition be reported to supervisory personnel.

Conditions adverse to quality are also evaluated as to their reportability to the NRC in accordance with the provisions of 10CFR20, 10CFR21, 10CFR50, 10CFR70, OR 10CFR73. 5

For significant conditions, the cause is determined and corrective action to preclude repetition identified, and the status is tracked until corrective action is complete and verified.

Corrective action documents contain provisions for identifying the root cause of the condition adverse to quality, the recommended corrective action, and the corrective action taken to prevent recurrence, in addition to the Nuclear Assurance Department's documented concurrence of the adequacy of the corrective action. The Nuclear Assurance Department also has the final review of all corrective action documents for closeout. 18 5

The quality assurance requirements in procurement documents or contracts require the supplier or contractor not only to identify material or parts that do not conform to the procurement requirements, but also to determine and correct the causes for the condition adverse to quality. When suppliers furnish items that do not conform to procurement requirements, the nonconformance is documented and evaluated for further action. The actions vary depending on the nature of the nonconformance and the supplier's quality history and may involve obtaining supplier corrective action or supplier reevaluation as a prerequisite for future procurement activities with the supplier. 7

17.2.16.2 Significant Conditions Adverse to Quality

Conditions adverse to quality are considered significant when any of the following conditions exist:

a. The condition requires immediate notification to the NRC in accordance with 10CFR50.72. 1

b. A serious failure or breakdown in the implementation of the Nuclear Quality Assurance Program.

c. A significant deficiency in final design as approved and released for implementation, such that the design does not conform to the criteria and basis stated in the Updated Safety Analysis Report (USAR).

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d. A significant deviation from performance specifications or a significant deficiency in construction of, and/or modification to a structure, system or component which requires extensive evaluation, redesign, or repair to meet the criteria and basis stated in the USAR, or to otherwise establish the adequacy of the structure, system, or component to perform its intended safety function is discovered. 5

e. A closed commitment to an outside agency has not been implemented as required.

f. A repetitive or adverse trend exists.

g. Failure to resolve a deficiency in a timely manner or any condition determined to be significant by the Director - Nuclear Assurance such as the existence of a repetitive or adverse trend. 5 18 5

Significant conditions adverse to quality are documented and reported to the Vice President - Nuclear, and the affected Nuclear Group Directors. When the corrective action to a significant condition adverse to quality has been completed, the Nuclear Assurance Department performs a follow-up review or audit to verify the adequacy of the corrective action. 9 5 18 5

17.2.16.3 Tracking and Resolution

Implementing procedures define the methods employed for tracking and resolving corrective action documents. The responsible Department has the responsibility to track the status of conditions adverse to quality until the implementation of the corrective action has been completed and to assure that adequate resources are applied to close out the conditions adverse to quality in a timely manner. 5 8 5

INSERT A →

17.2.17 QUALITY ASSURANCE RECORDS

17.2.17.1 General

Pertinent documentation classified as Quality Assurance Records such as design, procurement, fabrication, inspection, nonconformances and corrective action, tests, audits, and construction reports; document reviews, material analysis, and monitoring of work performance; qualification of personnel, procedures and equipment; drawings, specifications, calibration procedures and reports, NDE procedures and reports; pertinent operating logs; maintenance and modification procedures; reportable occurrences; and other records as required by the Technical Specification are retained and available for review. 5

A Nuclear Records Management Program, as defined in approved implementing procedures, identifies these records in the nuclear records list. This list is reviewed, approved and revised in accordance with written procedures and contains provisions for identifying the records to be retained, identifying the organization(s) with record copy responsibility, specifies the minimum retention period for each record type and specifies the method

INSERT "A"

[Add the following to Section 17.2.16.3, Tracking and Resolution]

The responsible Department is required to review and investigate documented conditions adverse to quality to determine and schedule appropriate corrective action, including action to prevent recurrence for significant conditions. The responsible Department is also required to respond as requested by the corrective action document giving results of the review and investigation, including root cause determination if required. The response shall state the corrective action taken or planned, including actions taken to prevent recurrence, if required.

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The audit program is reviewed semi-annually by the Company Nuclear Review Board or by a Management representative or subcommittee designated by the Vice President - Nuclear, to assure the audits are being conducted in accordance with the requirements of the Technical Specifications and the Nuclear Quality Assurance Manual. | 5 5 9 5

17.2.18.2 Audit Personnel | 5

Audit personnel are provided with appropriate training to ensure that they are competent to perform the required audits. Auditors and Audit Team Leaders are required to be qualified in accordance with the requirements of ANSI N45.2.23 as endorsed by NRC Regulatory Guide 1.146. Technical specialists, who occasionally act as audit team members, receive the required indoctrination and guidance during the audit.

17.2.18.3 Audit Scheduling and Planning | 5

Audits are scheduled in a manner to provide coverage and coordination with ongoing quality assurance program activities, and at a frequency commensurate with the status and importance of the activity and, as specified, in the Technical Specifications. | 9 5 9

The audit system has provisions for scheduling audits on short notice to respond to specific quality problems and for conducting unannounced audits. Regularly scheduled audits are supplemented by additional audits for one or more of the following conditions:

a. When significant changes are made in the Nuclear Quality Assurance Program or an approved Supplier's Quality Assurance Program.

b. When the scope of an approved supplier's activities is significantly increased. | 5

c. When it is suspected that safety, performance, or reliability may be in jeopardy due to deficiencies in the Nuclear Quality Assurance Program or an approved supplier's Quality Assurance Program.

d. When a systematic independent assessment of program effectiveness or item quality or both is considered necessary.

e. To verify implementation of completed corrective actions to previously identified audit findings which require audit follow-up.

The audit schedules for both the internal and external audits are approved by the Manager - Quality Assessment. | 5 19 9

An audit plan is prepared for each audit that identifies the organization and functional activities or projects to be audited, the scope of the audit and requirements or documents to which the audit will be performed, the time frame of the audit and names of audit team members. Checklists are also considered to be part of the audit plan. | 5

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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 Manager - Quality Assessment 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 Manager - Quality Assessment. 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 (excluding external supplier audits); 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

When a condition adverse to quality is identified, the condition is documented and processed as described in Section 17.2.15 and 17.2.16.

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~~used to confirm that these actions have been satisfactorily accomplished. An audit is considered closed on the date when all audit findings have been verified and closed.~~ 5

17.2.18.6

~~17.2.18.7~~ Surveillances

Surveillance activities, planned or unplanned, are used to supplement the audit system and the inspection system to assure adequate coverage of the Nuclear Quality Assurance Program. ~~Surveillance findings are corrected or resolved during the surveillance, if possible, and documented. If the finding cannot be corrected or resolved during the course of the surveillance, the deficiency is documented and processed via a Finding Report.~~ 5 5 5 5 5 9 0

When a condition adverse to quality is identified, the condition is documented and processed as described in Sections 17.2.15 and 17.2.16.

17.2.18.7 Resolution of Audit and Surveillance Findings

Management of the audited organization is required to review and investigate any audit or surveillance findings to determine and schedule appropriate corrective action, including action to prevent recurrence for significant conditions, in accordance with Section 17.2.16.3.

17.2.18.8 Close-out of Audits and Surveillances

Audits and Surveillances can be considered closed after the audit report or surveillance report is issued and responsibilities for resolution of identified nonconforming conditions are transferred to management of the audited organization.

Table 17.2-1 (Continued)

APPLICABLE NRC REGULATORY GUIDES, ANSI STANDARDS, AND INDUSTRY CODES

NRC REGULATORY GUIDE, INDUSTRY CODES	ANSI STANDARDS	DAVIS-BESSE POSITION	
4. ANSI/ANS 3.2 (Continued)		B. Section 1.2 requires the "the administrative controls and Quality Assurance provisions of the standard shall be applied to other important plant equipment at a level commensurate with the importance of the equipment to reliable and efficient plant operation." In lieu of this requirement, the requirements of this standard shall apply to Q-Listed items as discussed above and to AQ-Listed items. The applicability to AQ classified items and to those activities that can affect the quality or safe operation of these items is accomplished in a graded manner.	14
		C. Section 2.2 - In lieu of the definition of "Inspection" in this standard, Davis-Besse commits to the definition of inspection as delineated in ANSI N45.2.10, 1973.	14
		D. Section 3.4.3 requires that personnel qualified in the technical areas indicated be capable of responding within two hours for the purpose of providing technical advice to the Shift Supervisor on a 24 hr.-a-day basis. In lieu of the specified two hour response time, the response times delineated in the Davis-Besse Emergency Plan shall be utilized.	5
		Insert B → E. F. Section 5.2.1.6 - In lieu of the requirements which limit the scheduled work time of the required shift complement of licensed operators and senior operators and the shift technical adviser, Davis-Besse commits to the requirements as delineated in Davis-Besse Nuclear Power Station Unit 1 Technical Specifications, Section 6.0.	16

INSERT "B"

Add new Position 17.2-1.4.E:

"Sections 4.2.10 and 4.2.11 of ANSI/ANS 3.2 require that written programs for both independent audits and reviews contain provisions to:

* Assure timely response to review and audit findings by the subject organization, and
* Require notification of appropriate management if agreed to follow-up action resulting from a review or audit is not implemented within the agreed to time period.

In satisfying the intent of these requirements, all audit findings shall be documented and processed in accordance with the existing Corrective Action program which shall require:

* Responsible management of the audited organization to review and investigate documented conditions adverse to quality to determine and schedule appropriate corrective action, including action to prevent recurrence for significant conditions.
* Responsible management to respond as requested by the corrective action document giving results of the review and investigation, including root cause determination if required.
* Responsible management's response to state the corrective action taken or planned, including actions taken to prevent recurrence, if required.

In addition, the Audit program shall require periodic audits of the Corrective Action program:

* To review results of actions taken to correct deficiencies occurring in unit equipment, structures, systems or method of operation that affect nuclear safety (Tech Spec 6.5.2.8.c).
* To verify implementation of completed corrective actions to previously identified audit findings which require audit follow-up."

Table 17.2-1 (Continued)

APPLICABLE NRC REGULATORY GUIDES, ANSI STANDARDS, AND INDUSTRY CODES

NRC REGULATORY GUIDE, INDUSTRY CODES	ANSI STANDARDS	TOLEDO EDISON POSITION	
4.	ANSI/ANS 3.2 (Continued)	~~F.~~ G. Section 5.2.2 requires that temporary changes which clearly do not change the intent of the approved procedure, shall at a minimum be approved by two members of the plant staff knowledgeable in the areas affected by the procedure. At least one of these shall be a member of plant supervision. For changes to procedures which may affect the operational status of plant systems or equipment, the changes shall be approved by two members of the plant supervision, at least one of whom holds a senior operators license on the unit affected. In lieu of these requirements, Toledo Edison commits to the requirement delineated in the Davis-Besse Nuclear Power Station Unit 1 Technical Specifications, Appendix A to License No. NPF-3, Section 6.0, Paragraph 6.5.3.1.b.	16
		~~G.~~ H. Section 5.2.15 requires that "Plant procedures shall be reviewed by an individual knowledgeable in the area affected by the procedure no less frequently than every two years to determine if changes are necessary or desirable. This requirement for routine follow-up review, can be accomplished in several ways, including (but not necessarily limited to): documented step-by-step use of the procedure (such as occurs when the procedure has a step-by-step checkoff associated with it), or detailed scrutiny of the procedure as part of a documented training program, drill, simulator exercise, or other such activity. A revision of a procedure constitutes a procedure review." In lieu of these requirements, Davis-Besse has many existing programmatic controls, which identify the necessity for procedure alternations to ensure that procedures are appropriate for the circumstance and are maintained current. Changes to procedures are identified through the following processes: plant modification; condition adverse to quality reporting and management corrective action; test control; conduct of operations and maintenance control; control of Udpated Safety Analysis Report (USAR) changes, vendor manual control; operating experience assessment; Operating License Amendment; commitment management; design specification changes; control of procedure changes; Quality Assurance audits and surveillance; setpoint control and document change request. Additionally, Davis-Besse performs an annual Quality Assurance surveillance of randomly selected plant procedures. The surveillance will provide added assurance that existing programmatic controls provide for timely revision of procedures.	16

Table 17.2-1 (Continued)

APPLICABLE NRC REGULATORY GUIDES, ANSI STANDARDS, AND INDUSTRY CODES

NRC REGULATORY GUIDE, INDUSTRY CODES	ANSI STANDARDS	DAVIS-BESSE POSITION	
16. Regulatory Guide 1.123 Continued		B. Section 10.2.d of ANSI N45.2.,13 is interpreted as follows: The person attesting to a certificate shall be an authorized and responsible employee of the supplier and shall be identified by the supplier.	14 14 5
17. Regulatory Guide 1.144, Rev. 1, 9/80 "Auditing of Quality Assurance Program for Nuclear Power Plants"	ANSI N45.2.12-1977, Requirements for Auditing Quality Assurance Program for Nuclear Power Plants".	1. Davis-Besse commits to the regulatory position of this guide.	14 5
		2. Davis-Besse commits to the requirements of this standard with the following clarification:	14 5
		A. Section 2 of ANSI N45.2.12 provides requirements for the training and qualification of auditing personnel. In lieu of this requirement, Davis-Besse shall quality its auditors in accordance with the requirements of Regulatory Guide 1.146.	14 5

INSERT "C"

INSERT "C"

Add Position 17.2-1.17.2.B:
"Sections 3.2.5 and 3.3.7 of ANSI N45.2.12 require that the Audit system provide provisions for verification of effective corrective action of adverse audit findings and identified quality assurance program deficiencies on a timely basis. In lieu of these requirements, the Corrective Action and Audit programs shall contain provisions for the actions outlined in Position 17.2-1.4.E."

Add Position 17.2-1.17.2.C:
"Sections 4.3.2.4 and 4.3.2.5 of ANSI N45.2.12 require that when a nonconformance or quality assurance program deficiency is identified as a result of an audit:

* The audit finding be acknowledged by a member of the audited organization, and
* Further investigation be conducted by the audited organization in an effort to identify the cause and effect and to determine the extent of the corrective action required.

In lieu of these requirements, the Corrective Action and Audit programs shall contain provisions for the actions outlined in Position 17.2-1.4.E."

Add Position 17.2-1.17.2.D:
"Section 4.5.1 of ANSI N45.2.12 requires that:

* Management of the audited organization respond to audit findings as requested by the audit report,
* In the event that corrective action to audit findings cannot be completed within thirty days, the audited organization's response include a scheduled date for the corrective action, and
* The audited organization provide a follow-up report stating the corrective action taken and the date corrective action was completed.

In lieu of these requirements, the Corrective Action and Audit programs shall contain provisions for the actions outlined in Position 17.2-1.4.E."

INSERT "C" (cont'd)

Add position 17.2-1.17.2.E:
"Section 4.5.2 of ANSI N45.2.12 requires that, when necessary, follow-up actions for audit findings be performed by the audit team leader or management of the auditing organization through communication, re-audit, or other appropriate means to:

* Obtain written response to the audit findings from management of the audited organization when required by the audit report,
* Evaluate adequacy of the audited organization's response to the audit findings,
* Assure management of the audited organization identifies and schedules corrective action for each audit finding, and
* Confirm management of the audited organization accomplishes corrective action to audit findings as scheduled."

In lieu of these requirements, the Corrective Action and Audit programs shall contain provisions for the actions outlined in Position 17.2-1.4.E."

ATTACHMENT 2
DAVIS-BESSE NUCLEAR POWER STATION

EVALUATION
OF
PROPOSED QUALITY ASSURANCE PROGRAM
REDUCTIONS

10CFR50.54 EVALUATION FOR UCN 95-033U

(EVALUATION OF PROPOSED QUALITY ASSURANCE PROGRAM REDUCTIONS)

PROPOSED CHANGES

The proposed changes to the Updated Safety Analysis Report (USAR) Chapter 17.2, Nuclear Quality Assurance Program Description, are shown on the marked-up pages of Sections 17.2.16.3, 17.2.18.5, and 17.2.18.6 and Table 17.2-1.

The proposed changes are intended to:

. Eliminate "thirty days' as a prescribed time limit for completion of audit finding responses and required corrective actions,

. Eliminate "root cause determination" and "action to prevent recurrence" as prescribed audit finding actions (except for significant conditions),

. Eliminate Nuclear Assurance/Quality Assessment (also known as "Quality Auditing") in-line responsibilities for audit finding corrective action and verification, and

. Separate audit and surveillance activity completion from closure of associated audit/surveillance-identified deficiencies.

I. CORRECTIVE ACTION REPORTING, INVESTIGATION, CLOSE-OUT, AND FOLLOW-UP

Ia) 17.2.16.3, Page 17.2-45: Add to Section 17.2.16.3 as shown in Insert A: "The responsible department is required to review and investigate documented conditions adverse to quality to determine and schedule appropriate corrective action, including action to prevent recurrence for significant conditions. The responsible Department is also required to respond as requested by the corrective action document giving results of the review and investigation, including root cause determination if required. The response shall state the corrective action taken or planned, including actions taken to prevent recurrence, if required."

Ib) 17.2.18.5, Page 17.2-49: Remove: "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."

Ic) 17.2.18.5, Page 17.2-49: Remove: "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."

Id) 17.2.18.6, Page 17.2-49: Remove: "Upon notification the remedial/ corrective action to prevent recurrence has been completed, appropriate follow-up measures such as reading is used to confirm that these actions have been satisfactorily accomplished."

Ie) Page 17.2-50: Add new Section 17.2.18.7 as shown: "Resolution of Audit and Surveillance Findings - Management of the audited organization is required to review and investigate any audit or surveillance findings to determine and schedule appropriate corrective action, including action to prevent recurrence for significant conditions, in accordance with Section 17.2.16.3."

If) Table 17.2-1: Add new Position 17.2-1.4.E as shown in Insert B: "Sections 4.2.10 and 4.2.11 of ANSI/ANS 3.2 require that written programs for both independent audits and reviews contain provisions to:

* Assure timely response to review and audit findings by the subject organization, and
* Require notification of appropriate management if agreed to follow-up action resulting from a review or audit is not implemented within the agreed to time period.

If) Table 17.2-1:

Add new Position 17.2-1.4.E: (cont'd.)

In satisfying the intent of these requirements, all audit findings shall be documented and processed in accordance with the existing Corrective Action program which shall require:

* Responsible management of the audited organization to review and investigate documented conditions adverse to quality to determine and schedule appropriate corrective action, including action to prevent recurrence for significant conditions.
* Responsible management to respond as requested by the corrective action document giving results of the review and investigation, including root cause determination if required.
* Responsible management's response to state the corrective action taken or planned, including actions taken to prevent recurrence if required.

In addition, the Audit program shall require periodic audits of the Corrective Action program:

* To review results of actions taken to correct deficiencies occurring in unit equipment, structures, systems or method of operation that affect nuclear safety (Tech Spec 6.5.2.8.c).
* To verify implementation of completed corrective actions to previously identified audit findings which require audit follow-up."

Ig) Table 17.2-1:

Add Position 17.2-1.17.2.B as shown in Insert C: "Sections 3.2.5 and 3.3.7 of ANSI N45.2.12 require that the Audit system provide provisions for verification of effective corrective action of adverse audit findings and identified quality assurance program deficiencies on a timely basis. In lieu of these requirements, the Corrective Action and Audit programs shall contain provisions for the actions outlined in Position 17.2-1.4.E."

Ih) Table 17.2-1:

Add Position 17.2-1.17.2.C as shown in Insert C: "Sections 4.3.2.4 and 4.3.2.5 of ANSI N45.2.12 require that when a nonconformance or quality assurance program deficiency is identified as a result of an audit:

* The audit finding be acknowledged by a member of the audited organization, and
* Further investigation be conducted by the audited organization in an effort to identify the cause and effect and to determine the extent of the corrective action required.

In lieu of these requirements, the Corrective Action and Audit programs shall contain provisions for the actions outlined in Position 17.2-1.4.E."

Ii) Table 17.2-1:

Add Position 17.2-1.17.2.D as shown in Insert C: "Section 4.5.1 of ANSI N45.2.12 requires that:

* Management of the audited organization respond to audit findings as requested by the audit report,
* In the event that corrective action to audit findings cannot be completed within thirty days, the audited organization's response include a scheduled date for the corrective action, and
* The audited organization provide a follow-up report stating the corrective action taken and the date corrective action was completed.

In lieu of these requirements, the Corrective Action and Audit programs shall contain provisions for the actions outlined in Position 17.2-1.4.E."

Ij) Table 17.2-1:

Add position 17.2-1.17.2.E as shown in Insert C: "Section 4.5.2 of ANSI N45.2.12 requires that, when necessary, follow-up actions for audit findings be performed by the audit team leader or management of the auditing organization through communication, re-audit, or other appropriate means to:

* Obtain written response to the audit findings from management of the audited organization when required by the audit report,
* Evaluate adequacy of the audited organization's response to the audit findings,
* Assure management of the audited organization identifies and schedules corrective action for each audit finding, and
* Confirm management of the audited organization accomplishes corrective action to audit findings as scheduled."

In lieu of these requirements, the Corrective Action and Audit programs shall contain provisions for the actions outlined in Position 17.2-1.4.E."

II. AUDIT AND SURVEILLANCE ACTIVITY COMPLETION

IIa) 17.2.18.6, Page 17.2-50: Remove: "An audit is considered closed on the date when all audit findings have been verified and closed."

IIb) Page 17.2-50: Add new Section 17.2.18.8 as shown: "Close-out of Audits and Surveillances - Audits and Surveillances can be considered closed after the audit report or surveillance report is issued and responsibilities for resolution of identified non-conforming conditions are transferred to management of the audited organization."

REASON FOR AND EFFECT OF CHANGES

As shown in Changes Ia-Ij, the existing Audit program reliance on prescribed time limits, corrective action levels, and in-line Quality Assessment follow-up for audit finding corrective actions will be modified to make line management accountable for assuring timely and thorough corrective action under the Corrective Action Program. Technical Specification 6.5.2.8.c, USAR 17.2.16.2, and USAR 17.2.18.3.e will appropriately require Nuclear Assurance to verify effectiveness of the corrective action program through such activities as periodic audits and reviews after the corrective actions have been completed.

As shown in Changes IIa and IIb, the existing requirements for audit/surveillance packages to remain open until all identified findings are resolved will be modified to allow closure of audits and surveillances after the applicable report is issued and responsibilities for non-conforming conditions are transferred to line management. Resolution and closure of associated findings will be by responsible management, rather than by Quality Auditing, and will be independent of the audit and surveillance processes.

Elimination of these in-line responsibilities will allow more effective allocation of Quality Auditing resources to selected activities considered more significant.

BASIS FOR CONCLUSION THAT REDUCTIONS CONTINUE TO SATISFY 10CFR50 APPENDIX B

While the changes are considered to be reductions to existing commitments, the requirements of the associated 10CFR50 Appendix B "Nonconformances", "Corrective Action", and "Audits" criteria will not be affected by the proposed changes. All systematic 10CFR50 Appendix B nonconformance, corrective action, and audit programmatic requirements will continue to be satisfied by DBNPS's Nuclear Quality Assurance Program.