ATTACHMENT 1

OQAM, CN 90-10

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IDENTIFICATION OF CHANGES

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16.0 CORRECTIVE ACTION

324 16.1 Measures shall be established to assure that conditions adverse to quality are promptly identified,
1870 reported, and corrected. Nonconformances shall be
1903 controlled in accordance with the requirements
2978 described in Section 15. Each of the Nuclear Division Managers is responsible for developing and implementing a program for identifying and controlling adverse conditions. This responsibility may be satisfied by one or more programs. As a minimum each program shall provide for developing and analyzing trends on a semiannual basis. Trending of conditions adverse to quality identified at supplier's facilities is performed as part of the annual supplier evaluation per OQAM, Section 18.12. Procedures shall provide instructions for identifying, reporting, and initiating corrective action to preclude recurrence of adverse conditions. It is understood that the term "corrective action" includes remedial action necessary to correct the deficiency, as well as corrective action necessary to preclude recurrence.

16.2 Conditions adverse to quality which impede the implementation or reduce the effectiveness of the Operating QA Program shall be controlled by the measures described herein. Adverse conditions may include, but are not limited to, noncompliance with procedural requirements; reportable occurrences required by regulations; adverse nonconformance trends; deficiencies identified in the OQAP; recurring conditions for which past corrective action has been ineffective; or breakdowns in administrative and managerial control systems which could result in a system designed to prevent or mitigate serious events not being able to perform its intended function.

16.3 Corrective action documents which record defects in basic components or deviations from technical requirements in procurement documents shall be reviewed for reporting applicability under 10CFR21 and other Federal reporting requirements.

3599 16.4 Corrective action documents shall be transmitted
3600 to the responsible organization. The responsible organization shall investigate the findings and identify the cause(s) of the deficiency, and specify and initiate the action(s) necessary to correct the conditions and prevent recurrence.

16.5 Nuclear Engineering shall review documented conditions adverse to quality which involve design deficiencies or design changes which are recommended as corrective action. Licensing and Fuels should review documented conditions adverse to quality for fuel-related issues. The ORC shall review significant adverse conditions. Examples of such conditions include those identified by Callaway Plant Technical Specifications 6.5.1.6(f), 6.5.1.6(g), 6.5.1.6(h), 6.5.1.6(l), and 6.5.1.6(m); and NPDES violations.

16.6 Corrective action documents shall be closed by verifying the implementation and adequacy of corrective action. The Quality Assurance Department shall close QA-originated corrective action documents by verifying the implementation and adequacy of corrective action. Copies of completed corrective action documents shall be available for management review (hardcopy or electronic media) to keep them apprised of conditions adverse to quality. The Quality Assurance Department shall periodically prepare summaries of significant corrective action documents and submit them to the NSRB and appropriate levels of management.

16.7 The closure of corrective action documents shall be accomplished as promptly as practicable but shall occur only after the corrective action taken has been verified. Verification may be accomplished through direct observations, written communications, re-audit, surveillances, or other appropriate means. The nature of the deficiency may be such that remedial actions need to be taken immediately whereas development and implementation of corrective action to preclude recurrence may take substantially longer.

16.8 Summaries of corrective action documents shall be reviewed for the effectiveness of the corrective actions taken and analyzed for potential adverse quality trends. Quality Assurance shall evaluate the analyses, the identification of adverse trends, and the acceptability of actions taken on these trends through routine audit and surveillance activities; and shall report the results of these assessments to management.

16.0 CORRECTIVE ACTION

16.1 Measures shall be established to assure that conditions adverse to quality are promptly identified, reported, and corrected. Such measures shall be established in a program or programs which are proceduralized. Those procedures, as a minimum, shall:

1. Define responsibilities for identifying and correcting conditions adverse to quality. Such corrections may be defined as remedial action.

2. Define responsibility for verifying that remedial action was taken for conditions adverse to quality.

3. Define responsibilities for determination of those conditions adverse to quality which are significant. Significant conditions adverse to quality will require both remedial action and action to prevent recurrence.

4. Define responsibility for performing root cause evaluation, determining necessary actions to prevent recurrence, implementing those actions and verifying completion of those actions for significant conditions adverse to quality.

5. Provide a method for documenting the identification of conditions adverse to quality. This documentation shall also include the root cause or causes and the action implemented to prevent recurrence for significant conditions adverse to quality.

6. Provide methods for reporting significant conditions adverse to quality to appropriate levels of management. Acceptable methods include direct address, distribution of copies, electronic access or review of summaries of the conditions. These methods shall include reporting of selected significant conditions adverse to quality to review committees.

7. Provide methods for submitting reports required by external agencies concerning conditions adverse to quality.

8. Provide for developing and analyzing trends on a semiannual basis. Trending of conditions adverse to quality identified at supplier's facilities is performed as part of the annual supplier evaluation per OQAM, Section 18.12.

16.2 Conditions adverse to quality which are classified as nonconformances shall be controlled in accordance with the additional requirements described in OQAM, Section 15.

16.3 Conditions adverse to quality which impede the implementation or reduce the effectiveness of the Operating QA Program shall be considered significant conditions adverse to quality. Conditions adverse to quality may include, but are not limited to, noncompliance with procedural requirements which impact nuclear or personnel safety; reportable occurrences required by regulations; adverse nonconformance trends; deficiencies identified in the OQAP; recurring conditions for which past corrective action has been ineffective; or breakdowns in administrative and managerial control systems which could result in a system designed to prevent or mitigate serious events not being able to perform its intended function.

16.4 Conditions adverse to quality which involve defects in basic components or deviations from technical requirements in procurement documents shall be reviewed for reporting applicability under 10CFR21 and other Federal reporting requirements.

16.5 The nature of the condition adverse to quality may be such that remedial actions need to be taken immediately, whereas development and implementation of corrective action to preclude recurrence may take substantially longer.

16.6 Regardless of the program used, Nuclear Engineering personnel shall review all documented conditions adverse to quality which involve design deficiencies or which involve recommending design changes as corrective action. Licensing and Fuels should review documented conditions adverse to quality for fuel-related issues. The ORC shall review significant conditions adverse to quality. Examples of such conditions include those identified by Callaway Plant Technical Specifications 6.5.1.6(f), 6.5.1.6(g), 6.5.1.6(h), 6.5.1.6(l), and 6.5.1.6(m); and NPDES violations.

16.7 Corrective action documents shall be closed by verifying the implementation and adequacy of corrective action. The closure of corrective action documents shall be accomplished as promptly as practicable but shall occur only after the corrective action taken has been verified. Verification may be accomplished through direct observations, written communications, re-audit, surveillances, or other appropriate means.

16.8 Copies of completed corrective action documents shall be available for management review (hardcopy or electronic media) to keep them apprised of conditions adverse to quality. The Quality Assurance Department shall periodically review corrective action documents and identify significant conditions. Summaries of these conditions shall be submitted to the NSRB and appropriate levels of management.

324 16.9 Corrective action documents shall be reviewed for the effectiveness of the corrective actions taken and analyzed for potential adverse quality trends. Quality Assurance shall evaluate the analyses, the identification of adverse trends, and the acceptability of actions taken on these trends through routine audit and surveillance activities; and shall report the results of these assessments to management.

REGULATORY GUIDE 1.144 (cont.)

With regard to Section 2.3 (and subsections 2.3.1 through 2.3.3) of ANSI N45.2.12 - 1977 titled Training: The training of UE audit personnel shall be accomplished as described to meet the requirements of Regulatory Guide 1.146 (ANSI N45.2.23 - 1978) as endorsed in this Appendix and OQAM Section 18.

With regard to Section 2.4 of ANSI N45.2.12 - 1977 titled Maintenance of Proficiency: The maintenance of proficiency of UE audit personnel shall be accomplished as described to meet the requirements of Regulatory Guide 1.146 (ANSI N45.2.23 - 1978) as endorsed in this Appendix and OQAM Section 18.

With regard to Section 3.3 of ANSI N45.2.12 - 1977 titled Essential Elements of the Audit System: UE shall comply with subsection 3.3.5 as it was originally written (subsection 3.2.5) in ANSI N45.2.12, Draft 3, Revision 4: "Provisions for reporting on the effectiveness of the Quality Assurance Program to the responsible management." For the auditing organization (UE), effectiveness shall be reported as required by the Callaway Plant Technical Specifications. Other than audit reports, UE may not directly report on the effectiveness of the quality assurance programs to the audited organization when such organizations are outside of UE.

Subsection 3.3.6 requirements are considered to be fulfilled by compliance with the organization and reporting measures outlined in this Operating QA Manual and the Callaway Plant Technical Specifications. In every case either identical or equivalent controls are provided in the sections of the referenced documents.

Subsection 3.3.7 requires verification of effective corrective action on a "timely basis." ~~Timely basis is interpreted to mean within the framework or period of time for completion of corrective action that is accepted by the Quality Assurance Department or Quality Services Department. Each finding requires a response and a corrective action completion date; these dates are subject to revision (with the approval of the Quality Assurance Department or Quality Services Department) and must be escalated to higher authority when there is a disagreement between the audited and the auditing organizations on what constitutes timely corrective action.~~"

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With regard to Section 3.4 of ANSI N45.2.12-1977 titled Audit Planning: Identical or equivalent controls are provided in this OQAM, Section 18.

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Verification of the implementation of corrective action is performed as indicated in Section 16 of this OQAM. The effectiveness of previous corrective action is determined through audit or surveillance as described in Section 18 of this OQAM, using previously issued corrective action documents as input to the scope of audits and surveillances. Additionally, trending of corrective action documents will be used to reveal potentially ineffective corrective actions.

REGULATORY GUIDE 1.144 (cont.)

(c) Audit reports may not necessarily contain an evaluation statement regarding the effectiveness of the Quality Assurance Program elements which were audited, as required by subsection 4.4.4, but they shall provide a summary of the audited areas and the results which identify the importance of any adverse findings.

With regard to Section 4.5.1 of ANSI N45.2.12 - 1977 titled By Audited Organization: UE shall comply with the following clarification of the Section: ~~Management of the audited organization or~~ activity shall review and investigate adverse audit findings, as necessary, (e.g. where the cause is not already known, another organization has not already investigated and found the cause, etc.) to determine and schedule appropriate corrective action including action to prevent recurrence. They shall clearly state the corrective action taken or planned to prevent recurrence and the results of the investigation, if conducted. In the event that corrective action is not completed within thirty days, the audited organization's response shall include a scheduled date for completion of planned corrective action. The audited organization shall take appropriate action to assure that corrective action is accomplished as scheduled. Since the auditing organization tracks scheduled corrective action completion dates and verifies corrective action completion, a follow-up response by the audited organization stating the corrective action taken and the date that the action was completed is not necessary, provided corrective actions are completed as specified. If corrective actions are not completed as specified, the audited organization shall provide a revised response stating the corrective action that has been taken, the corrective action yet to be completed, ~~and the date that all corrective action will be completed~~.

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REGULATORY GUIDE 1.146 INITIAL ISSUE DATED 8/80

Qualification of Quality Assurance Program Audit Personnel for Nuclear Power Plants (Endorses ANSI N45.2.23-1978)

DISCUSSION:

UE complies with the recommendations of this Regulatory Guide with the following clarifications:

With respect to Section 1.4 of ANSI N45.2.23-1978 titled Definitions: Definitions in this Standard which are not included in ANSI N45.2.10 shall be used: "Audit" which is included in this Standard and ANSI N45.2.10 shall be used as clarified in this Appendix under Regulatory Guide 1.74.

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Management of the audited organization or activity shall review and investigate adverse audit findings, as necessary, (e.g. where the cause is not already known, another organization has not already investigated and found the cause, etc.) to determine and schedule appropriate remedial action. The audited organization shall assure documentation of remedial action taken is provided. Adverse audit findings shall be evaluated to determine the need for action to prevent recurrence. If such action is deemed necessary, the results of the investigation (root cause analysis), the corrective action taken or planned to prevent recurrence, and a schedule for implementation shall be provided by the audited organization. Such evaluations and implementation of actions shall be scheduled and performed consistent with the safety significance of the item. The audited organization shall take appropriate action to assure corrective action is accomplished as scheduled. In the event the action or schedule of implementation must be changed, the audited organization shall provide a revised response stating the corrective action which has been taken, the corrective action yet to be completed, and the date that all corrective action will be completed. Tracking of evaluation progress and corrective action implementation will be performed in accordance with provisions of Section 16 of the Union Electric Operating Quality Assurance Manual.

With regard to Section 4.5.2 of ANSI N45.2.12-1977 titled By Auditing Organization: UE shall comply with the following clarification of the section: For internal audits, performed by or for the Quality Assurance Department, follow-up actions will be taken by the audited organization as described in Section 16 of this OQAM. The audit program implemented in Section 18 of this OQAM provides assurance that responses are adequate and actions are identified, scheduled, and accomplished. Therefore, the auditing organization will not necessarily evaluate the adequacy, assure action is identified or scheduled or confirm that corrective action is accomplished as scheduled for audit findings. For external audits this section shall be complied with as written.

ATTACHMENT 2

OQAM, CN 90-10

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EXPLANATIONS OF AND JUSTIFICATIONS FOR PROPOSED CHANGES TO THE OQAM

EXPLANATIONS OF AND JUSTIFICATIONS FOR PROPOSED CHANGE TO THE OPERATING QUALITY ASSURANCE MANUAL (OQAM)

1) Justification for clarification of Section 16 of the OQAM.

Section 16 has been rewritten to clarify the sections and reorder them to make the sections more user friendly.

Additionally, the requirement to have the Quality Assurance (QA) Department close QA originated internal corrective action documents has been deleted. Implementing procedures currently require the management, of the group(s) required to take action to address conditions adverse to quality, verify the implementation of remedial action and action to prevent recurrence prior to closing the corrective action document. QA verification is not done until after the appropriate management has performed their verification and is thus redundant. QA has and will continue to verify, through the normal audit and surveillance process described in Chapter 18 of this OQAM, the effectiveness of management's verification. Requiring an additional verification of action implementation based on who originated the corrective action document is unnecessary. Additionally, since many conditions adverse to quality identified by QA are not significant, imposing the additional verification activity may detract from the assessments of more significant areas. This revision is a lessening of our previous quality program commitment, however, it will not result in a lessening of the overall effectiveness of the Operating Quality Assurance Program. The OQAM continues to meet 10CFR50, Appendix B.

Conditions adverse to quality, identified during audits or surveillances of suppliers, will continue to be evaluated, accepted, and verified by QA or Quality Services Division personnel. this is done in accordance with procedures which implement the provisions of Chapter 16 of this OQAM. This clarification and revision of Chapter 16 will require no revision to our practices for conditions adverse to quality identified relative to suppliers.

2) Justification for changes to clarification to Section 3.3.7 of ANSI N45.2.12-1977:

This section needs to be revised to eliminate the QA acceptance and approval of initial responses and completion

date revisions for QA originated conditions adverse to quality. The basis for this change is explained in Justification 1, for revision to Chapter 16 of this OQAM. Since QA is no longer interpreting timeliness based on corrective action schedule acceptance, no further clarification to Section 3.3.7 of ANSI N45.2.12-1977 is needed. Our previous clarification also referred to escalation due to disagreements regarding timeliness of corrective action. Measures for resolution of disagreements, including those over corrective action and scheduled implementation dates are addressed in this OQAM, Section 2.8 and thus do not need to be restated here. Verification of effectiveness of previous corrective actions is through the normal audit and surveillance process and trending of corrective action documents.

Either QA or Quality Services Department personnel will continue to review and approve responses to corrective action documents sent to suppliers. Verification of the effectiveness of action on supplier issues is typically performed at the time of re-audit of the vendor per Sections 18.2 (scope) and 18.11 (frequency) of this OQAM, Additional clarification is not needed for this section of ANSI N45.2.12.

3) Justification for clarification to Section 4.5.1 of ANSI N45.2.12-1977:

This clarification more clearly defines UE's expectation for resolution of internal audit findings. Such findings are reported via a common corrective action system used by plant departments as well as QA. This system provides for the evaluation of items consistent with their significance. Significance is based on nuclear safety, radiological safety, industrial safety, and regulatory considerations; and other factors deemed prudent by management. In using this system some audit findings will require remedial action only. The plant trending program as well as periodic re-audit by QA will indicate if further action is needed. Other audit findings will be of a significance to warrant remedial action, root cause analysis, and specific action designed to prevent recurrence. Items identified by personnel other than QA will also be evaluated by appropriate management to fit one of the above mentioned criteria. As such the QA identified issues do not need to be evaluated within an arbitrary time period, e.g. thirty days. They will now be evaluated and resolved based on their significance.

This clarification is consistent with provisions of Regulatory Guide 1.33 for corrective action programs at operating nuclear power plants as well as the UE Operating

Quality Assurance Program requirements for corrective action. While the elimination of the 30 day response time for audit findings may be considered a lessening of previous commitments, this change does not reduce effectiveness of the quality assurance program nor its adherence to provisions contained in Appendix B of 10CFR50.

4) Justification for clarification to Section 4.5.2 of ANSI N45.2.12-1977

As stated in the justification for the clarification for Section 4.5.1 of this standard, the auditing organization {QA for internal audits} reports findings via a common corrective action system used by both QA and plant departments. Implementation of the program described in Chapter 16 of the OQAM requires the generation of written responses to adverse findings, evaluation of the adequacy of responses, identification of corrective action, identification of action implementation schedules and confirmation of action accomplishment. As stated in the justification for the clarification of Chapter 16, verification of adequacy of response and implementation of action by QA is redundant to that required of management of the audited organization. Plant trending as well as periodic audit and surveillance will provide assurance that audited management performs their verifications effectively. This section needed to be changed to be consistent with other changes proposed herein. Requirements for external audits do not need clarifications as those audit findings do need to be evaluated for adequacy and implementation verified by either QA or Quality Services Department.

Union Electric considers this reduction to be justified and the OQAM to continue to meet the requirements of 10CFR50, Appendix B.