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10 CFR 2.201

October 12, 2012

UN#12-106

ATTN: Document Control Desk  
U.S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

Subject: UniStar Nuclear Energy, NRC Docket No. 52-016  
Calvert Cliffs Nuclear Power Plant, Unit 3  
Reply to a Notice of Violation

Reference: Letter from Kerri A. Kavanagh (NRC) to Gregory T. Gibson (UniStar Nuclear Energy)  
NRC INSPECTION REPORT NO. 05200016/2012-201 AND NOTICE OF  
VIOLATION, dated September 14, 2012

The referenced letter provided the results of the July 30 to August 2, 2012 NRC inspection of the UniStar Nuclear Energy (UNE) Quality Assurance program. The letter also included two violations of NRC requirements and requested that UNE provide a response in accordance with 10CFR 2.201 by October 14, 2012. The Enclosure to this letter provides UNE's response to the Notice of Violation.

This letter does not contain any proprietary or sensitive information.

If there are any questions regarding this transmittal, please contact me at (410) 369-1905.

A handwritten signature in black ink, appearing to read "Greg Gibson", is written over a horizontal line.

Greg Gibson

Enclosure: As Stated

cc: Kerri A. Kavanagh, Chief, Quality Assurance Branch, Division of Construction  
Inspection and Operational Programs, Office of New Reactors

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MRO

ENCLOSURE

Reply to Notice of Violation

During a U.S. Nuclear Regulatory Commission (NRC) inspection conducted at the UniStar Nuclear Energy, LLC (UNE) facility in Baltimore, MD on July 30 – August 2, 2012, NRC inspectors identified violations of NRC requirements. The UniStar Nuclear Energy reply to the violations, is as follows:

VIOLATION A

The Notice of Violation states in part:

*“A. Criterion V, “Instructions, Procedures, and Drawings,” of Appendix B, “Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,” to Title 10 of the Code of Federal Regulations (10 CFR) Part 50, “Domestic Licensing of Production and Utilization Facilities,” states, in part, that activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings.*

*“Criterion XVII, of Appendix B to 10 CFR Part 50, “Quality Assurance Records,” requires, in part, that sufficient records shall be maintained to furnish evidence of activities affecting quality.*

*“Contrary to the above, as of August 2, 2012, UNE failed to prescribe the QA Records program by documented instructions, procedures, or drawings. Specifically, UNE is in the process of transitioning between two electronic records management systems (RMS). UNE retired their old electronic records management system in May 2012 and failed to proceduralize its interim QA records management program over a period of 2 months. UNE RM-1, “Records Management Program,” describes how the new electronic RMS will be used once it is fully implemented; however, UNE RM-1 failed to include the following provisions:*

- 1. “Interim procedures to recover, identify, index, authenticate, validate, verify, retain and retrieve QA records, from Team Center, the old electronic RMS and SharePoint, the new electronic RMS, that is not yet fully implemented.*
- 2. “Interim procedures for maintaining hard copies of QA records*

*“These issues have been identified as Violation 05200016/2012-201-01.*

*“This is a Severity Level IV violation (Section 6.5.d)”*

RESPONSE

1. The Reason For The Violation

The reason for the violation was personal error in that Management failed to recognize that an interim procedure was required until compliance was achieved.

2. The Corrective Steps That Have Been Taken And The Results Achieved

UNE Procedure UNE-RM-1-991, Rev 0, "Interim Records Management", was issued on October 8, 2012. UNE-RM-1-991 addresses how to recover, identify, index, authenticate, validate, verify, retain and retrieve QA records, from Team Center, the old electronic RMS to SharePoint, the new electronic RMS. The procedure defines the process for the interim transfer and storage of Quality Records generated by each Functional Area, and will remain in place until all legacy records from Team Center are processed. Additionally, UNE-RM-1-991 provides direction for maintaining hard copies of QA records.

On October 2, 2012, UNE re-trained the senior management team on the criteria for when a procedure is required. Additionally, by October 4, 2012, all UNE personnel were re-trained on the criteria for when a procedure is required.

3. The Corrective Steps That Will Be Taken

No further corrective steps are required.

4. The Date When Full Compliance Will Be Achieved

Full compliance was achieved on October 8, 2012, when Procedure UNE-RM-1-991 was issued.

VIOLATION B

The Notice of Violation states in part:

*"B. Criterion XVI, of Appendix B to 10 CFR Part 50, "Corrective Action," 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."*

*"UNE Quality Assurance Program Description, Topical Report No. UN-TR-06-001-A, "Quality Assurance Program Description – UniStar Nuclear Energy QAPD," Revision 2, dated November 30, 2010, Section 16, "Corrective Action," states, in part, that "UNE has established the necessary measures and governing procedures to promptly identify, control, document, classify and correct conditions adverse to quality. UNE procedures assure that corrective actions are documented and initiated following the determination of conditions adverse to quality in accordance with regulatory requirements and applicable quality standards."*

*"UNE-CA-1-101, "Corrective Action Program (CAP) Procedure," Revision 0, dated May 15, 2012, states, in part, that "For each [corrective action], assign a Responsible Individual (RI) and an achievable and timely due date... Perform the assigned Corrective Action or CAPR prior to the assigned due date." CA-1-101 also states, in part, that the condition report owner shall, "review completed corrective actions... for adequacy in addressing the identified condition [and] verify that the corrective actions... have been completed and implemented."*

*“Contrary to the above, as of August 2, 2012, UNE failed to promptly correct conditions adverse to quality and to correct repetitive conditions adverse to quality. Specifically for a sample of 65 condition reports, UNE had not closed ten corrective actions by the established due date or establish new due dates for completion of corrective actions. The corrective actions were open for a period of one month to one year after the established due dates.*

*“These issues have been identified as Violation 05200016/2012-201-02.*

*“This is a Severity Level IV violation (Section 6.5.d).”*

## RESPONSE

### 1. The Reason For The Violation

The reasons for the violation were: (1) inadequate management attention and oversight over the Corrective Action system; (2) failure to establish timely and effective corrective actions as a priority; and (3) inadequate training of personnel on the Corrective Action Program.

Executive Management, beginning in 2008 through 2011, failed to set objective performance goals for the timely completion of corrective actions, failed to establish appropriate priority for completing corrective actions, failed to hold effective Management Review Committee (MRC) meetings to identify and correct untimely corrective actions, and/or by increasing priority, providing additional resources, and/or holding delinquent personnel accountable for poor performance. Senior Management was similarly ineffective in managing the corrective action backlog, creating a sense of urgency to completing corrective actions in a timely manner, and holding personnel accountable for untimely completion of corrective actions.

### 2. The Corrective Steps That Have Been Taken And The Results Achieved

In November 2011, the Chief Nuclear Officer (CNO) commissioned a comprehensive and extensive "audit recovery plan" to address deficient performance, deficient processes and upgrade procedural inadequacies. At that time, a task force was established to create and execute an action plan with a focus on improving the timeliness and effectiveness of completing corrective actions and establishing a training program to meet the requirements and expectations of the UNE Executive Management.

Corrective actions included a "stand down" training session for all UNE employees where the CEO/CNO provided explicit direction on the importance of becoming a learning organization, embracing the Corrective Action Program, and completing corrective actions in a timely manner.

The MRC has significantly increased its meeting frequency; thereby enabling Management to place increased attention on the timely completion of corrective actions.

In addition, the following corrective steps have been taken:

1. The Director, Quality and Performance Improvement, has attended the UNE Senior Staff meetings since November 2011. Additionally, he engages the senior team by presenting

results of quality issues, and discussing new and overdue corrective actions and condition report evaluations.

2. During the second quarter of 2012, a new tool, TrackWise, was adopted to provide enhanced tracking and status of Condition Reports and Corrective Actions. The new tool has enabled increased visibility of the Corrective Action Program and strengthened Management's ability to hold personnel accountable.
3. The CNO has emphasized the priority for timely completion of CR evaluations, and effective corrective actions to prevent recurrence.
4. At the October 5 MRC meeting, the CNO reinforced the expectation that senior management should use constructive feedback to drive personal accountability. Additionally, the CNO directed senior management to ensure that adequate resources are applied to appropriately assess and close corrective actions and condition reports effectively and in a timely manner.

On October 10, 2012, training on the UNE Corrective Action Program was complete. The training addressed management expectations, principles, best practices, and key philosophies. Training was performance-based with a focus on writing problem statements, performing evaluations, developing effective corrective actions, and proper corrective action closure.

3. The Corrective Steps That Will Be Taken

No further corrective actions are required.

4. The Date When Full Compliance Will Be Achieved

Full compliance was achieved on October 10, 2012 with the completion of the CAP Training corrective actions.