

March 14, 2007

R. M. Krich, Senior Vice President  
Regulatory Affairs  
UniStar Nuclear  
750 E. Pratt Street  
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Baltimore, MD 21202-3106

SUBJECT: FINAL SAFETY EVALUATION FOR TOPICAL REPORT (TR) UN-TR-06-0001,  
"QUALITY ASSURANCE PROGRAM DESCRIPTION" (PROJECT NO. 746)

Dear Mr. Krich:

By letters dated July 31, (ML062130539), August 8 (ML062220296), October 27 (ML063050194), and December 22, 2006 (ML063630199), and February 26, 2007 (ML070580438), UniStar Nuclear submitted its Quality Assurance Program Description (QAPD) Topical Report (TR) to the U.S. Nuclear Regulatory Commission (NRC) staff for review.

On the basis of its review, the NRC staff concludes that the UniStar Nuclear QAPD TR, as documented in the referenced letters, adequately describes the UniStar Nuclear quality assurance program. Accordingly, the NRC staff finds that the UniStar Nuclear QAPD complies with the applicable NRC regulations and industry standards and can be used by UniStar Nuclear for early site permit (ESP), combined license (COL), construction, pre-operation and/or operation activities, for the U.S. Evolutionary Power Reactor (EPR). The enclosed safety evaluation (SE) defines the basis for acceptance of the TR.

Our acceptance applies only to material provided in the subject TR. We do not intend to repeat our review of the acceptable material described in the TR. When the TR appears as a reference in regulatory applications, our review will ensure that the material presented applies to the specific application involved. Licensing requests that deviate from this TR will be subject to a plant- or site-specific review in accordance with applicable review standards.

In accordance with the guidance provided on the NRC website, we request that UniStar Nuclear publish the accepted version of this TR within three months of receipt of this letter. The accepted version shall incorporate this letter and the enclosed SE after the title page. Also, the accepted version must contain historical review information, including NRC requests for additional information and your responses. The accepted versions shall include a "-A" (designating accepted) following the TR identification symbol.

R. Krich

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If future changes to the NRC's regulatory requirements affect the acceptability of this TR, UniStar Nuclear will be expected to revise the TR appropriately, or justify its continued applicability for subsequent referencing.

If you have any questions, please contact me at [ljb3@nrc.gov](mailto:ljb3@nrc.gov) or (301) 415-1311.

Sincerely,

*/RA/*

Larry J. Burkhart, Senior Project Manager  
EPR Projects Branch  
Division of New Reactor Licensing  
Office of New Reactors

Project No. 746

Enclosure:  
Final Safety Evaluation

cc w/encl: See next page

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3/14/07	3/5/ 07	3/1/07	3/14/07	3/14/07

FINAL SAFETY EVALUATION BY THE OFFICE OF NEW REACTORS

TOPICAL REPORT UN-TR-06-0001

"QUALITY ASSURANCE PROGRAM DESCRIPTION", REVISION 3

UNISTAR NUCLEAR

PROJECT NO. 746

1.0 INTRODUCTION

By letter dated July 31, 2006 (Reference 1), as supplemented by letters dated August 8, October 27, and December 22, 2006 (References 2, 3 and 4), and February 26, 2007 (Reference 5), UniStar Nuclear submitted Topical Report UN-TR-06-001, "Quality Assurance Program Description [QAPD]" Revision 3, for review and approval by the U. S. Nuclear Regulatory Commission (NRC) staff. The UniStar Nuclear QAPD topical report describes the quality assurance measures applied to the activities of siting; design; fabrication; construction, including pre-operational testing; operation, including testing; maintenance; and modification of a U. S. Evolutionary Power Reactor (EPR). The quality assurance program described in the QAPD topical report commits to the guidance of the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA) standard NQA-1-1994, "Quality Assurance Requirements for Nuclear Applications" (Reference 6). UniStar Nuclear used the guidance of Draft Standard Review Plan (NUREG-0800), Section 17.5 (SRP 17.5), "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants" (Reference 7), to determine the appropriate regulatory guidance that applies to the proposed QAPD.

2.0 REGULATORY EVALUATION

The Commission's regulatory requirements related to quality assurance programs are set forth in 10 CFR 52.79(b), 10 CFR 50.34(a)(7), and Appendix B to 10 CFR Part 50 (Appendix B).

10 CFR 52.79(b) requires, in part, that a combined license (COL) application contain the technically relevant information required for applicants for an operating license by 10 CFR 50.34.

10 CFR 50.34(a)(7), in turn, requires that a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility be included as part of the minimum information in the preliminary safety analysis report. 10 CFR 50.34(a)(7) further requires that the description of the quality assurance program for a nuclear power plant include a discussion of how the applicable requirements of Appendix B will be satisfied.

Appendix B establishes quality assurance requirements for the design, fabrication, construction, and testing of structures, systems, and components (SSCs) of the facility. The pertinent requirements of Appendix B apply to all activities affecting the safety-related functions of those

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SSCs and include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying SSCs.

### 3.0 EVALUATION

In evaluating the adequacy of the format and level of detail of the QAPD, the NRC staff followed Draft SRP Section 17.5 for guidance. Draft SRP Section 17.5 provides an outline of a QA program for design certification, ESP, COL, construction permit, and operating license applicants. Draft SRP Section 17.5 was developed using ASME NQA standard NQA-1-1994, as supplemented by additional regulatory guidance and industry guidance for nuclear operating facilities.

#### 3.1 QAPD Overview

##### 3.1.1 Organization

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.A, for providing an organizational description that includes an organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The UniStar Nuclear QAPD establishes independence between the organization performing checking functions and the organization responsible for performing the function. In addition, the UniStar Nuclear QAPD provides for management to be responsible to size the QA organization commensurate with the duties and responsibilities assigned. Responsibility and authority for executing an effective overall quality assurance program and delegation of program responsibilities are clearly described and defined.

The UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 1 and Supplement 1S-1.

##### 3.1.2 Quality Assurance Program

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.B, for establishing the necessary measures to implement a quality assurance program to ensure that the design, construction and operation of nuclear power plants is in accordance with governing regulations and license requirements. The quality assurance program comprises those planned and systematic actions necessary to provide confidence that SSCs will perform their intended safety function, including certain nonsafety-related SSCs and activities that are significant contributors to plant safety. A list or system identifying SSCs and activities to which the QAPD applies is maintained at the appropriate facility.

The UniStar Nuclear QAPD provides measures to assess the adequacy of the QAPD and ensure its effective implementation, at least once each year or, at least once during the life of the activity, whichever is shorter. The period for assessing the QAPD during the operations phase may be extended to once every two years. In addition, consistent with Draft SRP 17.5, paragraph II.B.8, the QAPD applies a grace period of 90 days to activities that are required to be performed on a periodic basis. The grace period does not allow the "clock" for a particular activity to be reset forward. However, the "clock" for an activity is reset backwards by performing the activity early. This is conservative and consistent with staff guidance.

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraphs II.S and II.T, for describing the necessary measures to establish and maintain formal indoctrination and training programs for personnel performing, verifying, or maintaining activities within the scope of the QAPD to assure that suitable proficiency is achieved and maintained. The plant and support staff minimum qualifications requirements are delineated in plant technical specifications. Training for positions identified in 10 CFR 50.120 is accomplished according to programs accredited by the National Nuclear Accrediting Board of the National Academy for Nuclear Training. The UniStar Nuclear QAPD provides the minimum training requirements for managers responsible for the implementation of the QAPD, in addition to the minimum training requirements for individuals responsible for planning, implementing, and maintaining the QAPD.

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.W, Option II, regarding the establishment of an independent review program for activities occurring during operational phase.

The UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3, and 2S-4, with the following clarifications and exceptions:

- As an alternative to NQA-1-1994, Supplement 2S-2 for qualification of nondestructive examination personnel, the UniStar Nuclear QAPD provides guidance to follow the applicable standard cited in the version(s) of Section III and Section XI of the ASME Boiler and Pressure Vessel Code. This is consistent with 10 CFR 50.55a, "Codes and Standards," which requires the use of the latest edition and addenda of Section III of the ASME Boiler and Pressure Vessel Code incorporated by reference into the regulation, as well as the version of Section XI of the Code incorporated by reference into the regulations pursuant to 10 CFR 50.55a(g). Therefore, the staff finds the use of the Section III and Section XI of the ASME Boiler and Pressure Vessel Code for qualification of nondestructive examination personnel acceptable.
- As an alternative to the requirement of NQA-1-1994, Supplement 2S-3, that prospective Lead Auditors have participated in a minimum of five (5) audits in the previous three (3) years, the UniStar Nuclear QAPD follows the guidance provided in Draft SRP Section 17.5, paragraph II.S.4.c: "The prospective Lead Auditor shall demonstrate his/her ability to properly implement the audit process, as implemented by the company, to effectively lead an audit team, and to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification." The staff finds this alternative to be acceptable because it is consistent with established requirements for Lead Auditors, and focuses on a more recent time frame for participation in a nuclear audit.

### 3.1.3 Design Control

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.C, for establishing the necessary measures to control the design, design changes and temporary modifications (e.g., temporary bypass lines, electrical jumpers and lifted wires, and temporary

setpoints) of items that are subject to the provisions of the QAPD. The UniStar Nuclear QAPD design process includes provisions to control design inputs, outputs, changes, interfaces, records, and organizational interfaces with the applicant and its suppliers. These provisions ensure that the design inputs (such as design bases and the performance, regulatory, quality and quality verification requirements) are correctly translated into design outputs (such as analyses, specifications, drawings, procedures, and instructions). In addition, the UniStar Nuclear QAPD provides for design documents to be reviewed by individuals knowledgeable in QA to ensure that the documents contain the necessary QA requirements.

The UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 3 and Supplement 3S-1, for establishing the program for design control and verification, and Subpart 2.7 for the standards for computer software quality assurance controls.

#### 3.1.4 Procurement Document Control

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.D, for establishing the necessary administrative controls and processes to ensure that applicable regulatory, technical, and QA program requirements are included or referenced in procurement documents. Applicable technical, regulatory, administrative, quality and reporting requirements (such as specifications, codes, standards, tests, inspections, special processes, and 10 CFR Part 21) are invoked for procurement of items and services.

The UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 4 and Supplement 4S-1, with the following clarifications and exceptions:

- As an alternative to NQA-1-1994, Supplement 4S-1, Section 2.3, for the requirement that procurement documents must require suppliers to have a documented QA program that implements NQA-1-1994, Part I, the QAPD requires that suppliers have a documented QA program that is determined to meet Appendix B and the UniStar Nuclear QAPD, as applicable to the circumstances of the procurement. Appendix B, Criterion IV, "Procurement Document Control," requires suppliers to have a QA program consistent with Appendix B. This alternative is consistent with Draft SRP Section 17.5, paragraph II.D.2.d. and, therefore, is acceptable.
- The QAPD provides for procurement documents to allow the supplier to work under the UniStar Nuclear QAPD, including implementing procedures, in lieu of the supplier having its own QA program. Criterion IV of Appendix B requires suppliers to have a QA program consistent with Appendix B. This alternative is consistent with Draft SRP Section 17.5, paragraph II.D.2.d. and, therefore, is acceptable.
- Procurement documents for commercial grade items or services that will be procured by UniStar Nuclear as safety-related items, shall contain technical and quality requirements such that the procured item or service can be appropriately dedicated. This alternative is consistent with staff guidance in Generic Letter (GL) 89-02, "Actions to Improve the Detection of Counterfeit and Fraudulently

Marketed Products,” dated March 21, 1989, and GL 91-05, “Licensee Commercial-Grade Procurement and Dedication Programs,” dated April 9, 1991, as delineated in Draft SRP Section 17.5, paragraphs II.U.1.c and II.U.1.d, and, therefore, is acceptable.

### 3.1.5 Instructions, Procedures, and Drawings

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.E, for establishing the necessary measures and governing procedures to ensure that activities affecting quality are prescribed by, and performed, in accordance with documented instructions, procedures, and drawings.

The UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 5 for establishing procedural controls.

### 3.1.6 Document Control

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.F, for establishing the necessary measures and governing procedures to control the preparation, review, approval, issuance, and changes of documents that specify quality requirements or prescribe how activities affecting quality, including organizational interfaces, are controlled. Measures are provided to assure that documents, including revisions or changes, are reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated. A list of all controlled documents identifying the current approved revision, or date, is maintained so personnel can readily determine the appropriate document for use.

To ensure effective and accurate procedures during operational phase, applicable procedures are reviewed and updated as necessary, to be consistent with staff guidance provided in Draft SRP Section 17.5, paragraph II.F.8. Where temporary procedure changes are necessary during the operational phase, changes that clearly do not change the intent of the approved procedure may be implemented provided they are approved by two (2) members of the staff knowledgeable in the areas affected by procedure. In addition, during the operational phase, temporary changes include a designation of the period of time during which it is acceptable to use them.

In establishing provisions for document control, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 6 and Supplement 6S-1.

### 3.1.7 Control of Purchased Material, Equipment, and Services

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.G, for establishing the necessary measures and governing procedures to control the procurement of items and services to ensure conformance with specified requirements. The program provides measures for evaluating prospective suppliers and selecting only qualified suppliers. In addition, the program provides for auditing and evaluating suppliers to ensure that qualified suppliers continue to provide acceptable products and services.

The program provides for acceptance actions, such as source verification, receipt inspection, post-installation tests, and review of documentation, such as certificates of conformance, to ensure that the procurement, inspection and test requirements have been satisfied before relying on the item to perform its intended safety function. Purchased items (components, spares, and replacement parts necessary for plant operation, refueling, maintenance and modifications) and services are subject to quality and technical requirements at least equivalent to those specified for original equipment or specified by properly reviewed and approved revisions to assure the items are suitable for the intended service, and are of acceptable quality, consistent with their effect on safety.

In establishing procurement verification control, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 7 and Supplement 7S-1, with the following clarifications and exceptions:

- The UniStar Nuclear QAPD contains provisions consistent with regulatory guidance provided in Draft SRP Section 17.5, paragraph II.L.8, for procurement of commercial-grade calibration services for safety related applications. The UniStar QAPD does not require supplier audit, commercial-grade survey, or in-process surveillance provided each of the following conditions are met:
  - Purchase documents impose additional technical and administrative requirements to satisfy QAPD and technical requirements.
  - Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.
  - Calibration laboratory holds a domestic accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP) or by the American Association for Laboratory Accreditation (A2LA) as recognized by NVLAP through the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement.
  - The accreditation is based on ANS/ISO/IEC 17025.
  - The published scope of the accreditation for the calibration laboratory covers the contracted services.
  - Purchase documents require reporting as-found calibration data when calibrated items are found to be out-of-tolerance.
  - Purchase documents require identification of the laboratory equipment/standards used.
  - This method is limited to domestic calibration service suppliers and is applicable to subsuppliers of calibration service suppliers, provided the above conditions are met.
- As an alternative to NQA-1-1994, Supplement 7S-1, Section 10, requirements for the control of commercial-grade items and services, the UniStar Nuclear QAPD

commits to follow NRC guidance discussed in GL 89-02 and GL 91-05 as delineated in Draft SRP Section 17.5, paragraphs II.U.1.c and II.U.1.d.

- Consistent with the guidance mentioned above for commercial-grade items and services, the commercial-grade program provides for special quality verification requirements to be established and described in procedures, to provide the necessary assurance that the item will perform satisfactorily in service. In addition, the procedures provide for determining critical characteristics that ensure an item is suitable for its intended use, technical evaluation of the item, receipt requirements, and quality evaluation of the item.

### 3.1.8 Identification and Control of Materials, Parts, and Components

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.H, for establishing the necessary measures for the identification and control of items such as materials, including consumables and items with limited shelf life, parts, components, and partially fabricated assemblies. The identification of items is maintained throughout fabrication, erection, installation and use so that the item can be traced to its documentation, consistent with the item's effect on safety.

In establishing provisions for identification and control of items, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 8 and Supplement 8S-1.

### 3.1.9 Control of Special Processes

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.I, for establishing and implementing programs, procedures, and processes to assure that special processes requiring interim process controls to assure quality, such as welding, heat treating, chemical cleaning, and nondestructive examinations, are controlled in accordance with the applicable codes, specifications, and standards of the specific work.

In establishing measures for the control of special processes, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 9 and Supplement 9S-1.

### 3.1.10 Inspection

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.J, for establishing the necessary measures to implement inspections that assure items, services and activities affecting safety meet established requirements and conform to applicable documented specifications, instructions, procedures and design documents. The inspection program establishes requirements for planning inspections, determining applicable acceptance criteria, the frequency of inspection to be applied, and identification of special tools needed to perform the inspection. Inspections are carried out by properly qualified persons independent of those who performed or directly supervised the work.

In establishing inspection requirements, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 10, Supplement 10S-1, and Subparts 2.4, 2.5 and 2.8, with the clarifications and alternatives that follow below.

- As an alternative to the NQA-1-1994, Subpart 2.4, subsection 3.3, "Procedures and Instructions," requirement to utilize a checklist and mark as required or not appropriate the listed items during preparation of procedures or instructions, UniStar Nuclear utilizes administrative controls to ensure the appropriateness and correctness of procedures and instructions including reviews against standards that may not require a checklist to be marked. The NRC staff determined that this alternative was acceptable, as documented in a previous safety evaluation (Reference 8) and, therefore, is also acceptable for the UniStar Nuclear QAPD.
- As an alternative to the NQA-1-1994, Subpart 2.4, subsection 7.2.1, "Equipment Tests," requirement to label instrumentation and control devices installed in operating facilities, UniStar Nuclear will maintain the information related to the calibration of these devices in suitable documentation traceable to the device. The NRC staff determined that this alternative was acceptable as documented in a previous safety evaluation (Reference 8) and, therefore, is also acceptable for the UniStar Nuclear QAPD.
- As an alternative to the NQA-1-1994, Subpart 2.5, subsection 7.7, "Curing," requirement, UniStar Nuclear added ASTM C 1315 to the first paragraph as another applicable standard for test methods for curing compounds. The NRC staff determined that this alternative was acceptable, as documented in a previous safety evaluation (Reference 8) and, therefore, is also acceptable for the UniStar Nuclear QAPD.

### 3.1.11 Test Control

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.K, for establishing the necessary measures and governing provisions to demonstrate that items subject to the provisions of the QAPD will perform satisfactorily in service, that the plant can be operated safely as designed, and that the operation of the plant as a whole is satisfactory.

In establishing provisions for testing, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 11, Supplement 11S-1, and Subparts 2.4 and 2.8.

In establishing provisions to ensure that computer software used in applications affecting safety are prepared, documented, verified and tested, and used such that the expected outputs are obtained and configuration control maintained, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Supplement 11S-2 and Subpart 2.7.

### 3.1.12 Control of Measuring and Test Equipment

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.L, for establishing the necessary measures to control the calibration, maintenance, and use of measuring and test equipment that provides information important to safe plant operation.

In establishing provisions for control of measuring and test equipment, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 12 and Supplement 12S-1 with the following alternative:

- As an alternative for NQA-1-1994, Subpart 2.4, Section 7.2.1, calibration labeling requirements, the UniStar Nuclear QAPD provides for measuring and test equipment and requires calibration information to be maintained in suitable documentation traceable to the device for equipments. This alternative is consistent with staff guidance provided in Draft SRP 17.5, paragraph II.L.3 and is, therefore, acceptable.

### 3.1.13 Handling, Storage, and Shipping

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.M, for establishing the necessary measures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss, and to minimize deterioration.

In establishing provisions for handling, storage, and shipping, the UniStar QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 13 and Supplement 13S-1. The UniStar Nuclear QAPD also commits to implement, during the construction phase of the plant, the requirements of NQA-1-1994, Subparts 2.1, 2.2 and 2.15.

### 3.1.14 Inspection, Test, and Operating Status

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.N, for establishing the necessary measures to identify the inspection, test, and operating status of items and components subject to the provisions of the QAPD, in order to maintain personnel and reactor safety and avoid inadvertent operation of equipment.

In establishing the status of inspection and test activities, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 14.

### 3.1.15 Nonconforming Materials, Parts, or Components

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.O, for establishing the necessary measures to control items, including services that do not conform to specified requirements, to prevent inadvertent test installation or use. Nonconformances are evaluated for impact on operability of quality SSCs, to ensure that the final condition does not adversely affect safety, operation, or maintenance of the item or service. Results of evaluations of conditions adverse to quality are analyzed to identify quality trends, documented, and reported to upper management in accordance with applicable procedures.

In addition, the UniStar Nuclear QAPD provides for establishing the necessary measures to implement a reporting program in accordance with the requirements of 10 CFR Part 52, 10 CFR 50.55(e) and/or 10 CFR Part 21, as applicable.

In establishing measures for nonconforming material, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 15 and Supplement 15S-1.

### 3.1.16 Corrective Action

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.P, for establishing the necessary measures to promptly identify, control, document, classify, and correct conditions adverse to quality. The UniStar Nuclear QAPD requires personnel to identify known conditions adverse to quality. Reports of conditions adverse to quality are analyzed to identify trends. Significant conditions adverse to quality are documented and reported to responsible management. In case of suppliers working on safety related activities, or similar situations, UniStar Nuclear may delegate specific responsibility of the corrective action program but UniStar Nuclear maintains responsibility for the program's effectiveness.

Section P of the UniStar Nuclear QAPD details that the corrective action program (CAP) includes the following processes, including closure:

- Prompt identification and correction of conditions adverse to quality by all personnel;
- Determining cause and corrective actions, including action to preclude recurrence, for significant conditions adverse to quality;
- Provision to ensure that corrective actions are not nullified by subsequent action;
- Follow-up actions to verify implementation of corrective actions taken for significant conditions adverse to quality.

In addition, the UniStar Nuclear QAPD provides for establishing the necessary measures to implement a reporting program in accordance with the requirements of 10 CFR Part 52, 10 CFR 50.55(e) and/or 10 CFR Part 21, as applicable.

In establishing procurement verification control, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 16.

### 3.1.17 Quality Assurance Records

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.Q, for establishing the necessary measures to ensure that sufficient records of items and activities affecting quality are generated, identified, retained, maintained, and retrievable.

When using electronic records storage and retrieval systems, the UniStar Nuclear QAPD provides for compliance with NRC guidance given in Generic Letter 88-18, Regulatory Issue

Summary 2000-18 and associated Nuclear Information and Records Management Association, Inc. (NIRMA) Guidelines TG 11-1998, TG 15-1998, TG 16-1998, and TG 21-1998.

In establishing provisions for records, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 17 and Supplement 17S-1.

### 3.1.18 Quality Assurance Audits

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.R, for establishing the necessary measures to implement audits to verify that activities covered by the QAPD are performed in conformance with the requirements established. The audit program is also reviewed for effectiveness as part of the overall audit process. The QAPD provides for conducting periodic internal and external audits. Internal audits are conducted to determine the adequacy of program and procedures, and to determine if they are meaningful and comply with the overall QAPD. Internal audits are performed with a frequency commensurate with safety significance and in such a manner as to assure that an audit of all applicable QA program elements is completed, for each functional area, within a period of two years. External audits determine the adequacy of a supplier's and contractor's quality assurance program. Audit results are documented and reviewed by the responsible management. Management responds to all audit findings and initiates corrective action where indicated. In addition, where corrective action measures are indicated, documented follow-up of applicable areas through inspections, review, re-audits, or other appropriate means, is conducted to verify implementation of assigned corrective action.

In establishing the independent audit program, the UniStar Nuclear QAPD commits to implement the quality standards described in NQA-1-1994, Basic Requirement 18 and Supplement 18S-1.

## 3.2 Nonsafety-Related SSC Quality Assurance Control

### 3.2.1 Nonsafety Related SSCs - Significant Contributors to Plant Safety

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.V.1, for establishing specific program controls applied to nonsafety-related SSCs that are significant contributors to plant safety, for which Appendix B is not applicable. The UniStar Nuclear QAPD applies specific controls to those items in a selected manner, targeted at those characteristics or critical attributes that render the SSC a significant contributor to plant safety consistent with applicable sections of the QAPD.

### 3.2.2 Nonsafety Related SSCs Credited for Regulatory Events

In establishing the quality requirements for nonsafety-related SSCs credited for regulatory events, the UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.V.2, and commits to implement the following regulatory guidance:

- The quality requirements to the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in Regulatory Guide 1.189, "Fire Protection for Operating Nuclear Power Plants."

- The quality requirements to anticipated transient without a scram (ATWS) equipment in accordance with GL 85-06, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related," dated January 16, 1985.
- The quality requirements to station blackout (SBO) equipment in accordance with Regulatory Position 3.5, "Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related," and Appendix A, "Quality Assurance Guidance for Non-Safety Systems and Equipment," in Regulatory Guide 1.155, "Station Blackout."

### 3.3 Regulatory Commitments

The UniStar Nuclear QAPD follows the guidance of Draft SRP Section 17.5, paragraph II.U, for establishing QA program commitments. Further, UniStar Nuclear QAPD commits in Section U to comply with the following NRC Regulatory Guides and other quality assurance standards to supplement and support the QAPD.

- Regulatory Guide 1.26, Revision 3, "Quality Group Classification and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants," dated February 1976.
- Regulatory Guide 1.29, Revision 3, "Seismic Design Classification," dated September 1978.
- ASME NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," Part I and II, as described above in Sections 3.1.1 through 3.1.18 of this Safety Evaluation Report (SER).
- ASME NQA-1-1994, Subpart 2.20, "Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants." UniStar Nuclear commits to this subpart for subsurface investigation activities.
- Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guides, as described in Section 3.1.17 of this SER.

### 4.0 CONCLUSION

The UniStar Nuclear QAPD follows the guidance and conforms to the format of Draft SRP Section 17.5. The NRC staff used acceptance criteria of Draft SRP Section 17.5 as the basis for evaluating the acceptability of the UniStar Nuclear QAPD in conformance with the provisions of 10 CFR 52.79(b), 10 CFR 50.34(a)(7), and Appendix B to 10 CFR Part 50. On the basis of the NRC staff's review of the UniStar Nuclear QAPD, the NRC staff concludes that:

1. The UniStar Nuclear QAPD adequately describes the authority and responsibility of management and supervisory personnel, performance/verification personnel, and self-assessment personnel.
2. The UniStar Nuclear QAPD adequately provides for organizations and persons to perform verification and self-assessment functions with the authority and independence

to conduct their activities without undue influence from those directly responsible for costs and schedules.

3. The UniStar Nuclear QAPD adequately applies to activities and items that are important to safety.
4. The UniStar Nuclear QAPD adequately establishes controls that, when properly implemented, comply with the requirements of 10 CFR Part 52, Appendix B to 10 CFR Part 50, 10 CFR Part 21, and 10 CFR 50.55(e), with the criteria contained in Draft SRP Section 17.5, and with the commitments to regulatory guidance.

On the basis of its review, the NRC staff concludes that the UniStar Nuclear QAPD adequately describes the UniStar Nuclear's quality assurance program. Accordingly, the NRC staff concludes that the UniStar Nuclear QAPD complies with the applicable NRC regulations and industry standards and can be used by UniStar Nuclear for ESP, COL, construction, pre-operation and/or operation activities, for the EPR.

## 5.0 REFERENCES

- 5.1 Krich, R. M., UniStar Nuclear, to the U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Pre-application Submittal of the Quality Assurance Program Description," July 31, 2006 (ML062130539).
- 5.2 Krich, R. M., UniStar Nuclear, to the U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Submittal of the Quality Assurance Program Description as a Topical Report," August 8, 2006 (ML062220296).
- 5.3 Krich, R. M., UniStar Nuclear, to the U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Submittal of Revised Quality Assurance Program Description (QAPD) Topical Report," October 27, 2006 (ML063050194).
- 5.4 Krich, R. M., UniStar Nuclear, to the U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Response to Request for Additional Information Regarding Proposed Revision 1 of the Quality Assurance Program Description Topical Report," December 22, 2006 (ML063630199).
- 5.5 Krich, R. M., UniStar Nuclear, to the U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Submittal of Corrections to the Quality Assurance Program Description Topical Report Proposed Revision 3," February 26, 2007 (ML070580438).
- 5.6 American Society for Mechanical Engineers (ASME). NQA-1-1994 Edition, "Quality Assurance Requirements for Nuclear Facility Applications." New York. 1994.
- 5.7 NUREG-0800, "Standard Review Plan," Draft Section 17.5, "Quality Assurance Program Description - Design Certification, Early Site Permit and New License Applicants."
- 5.8 Holden, C. F., USNRC, to D. A. Christian, Dominion Nuclear Connecticut, Inc., "Approval of Dominion Nuclear Connecticut and Virginia Electric and Power Company Quality Assurance Program Description Topical Report for Millstone Power Station, Unit Nos. 1,

2 and 3, North Anna Power Station Unit Nos. 1 and 2, and Surry Power Station, Unit Nos. 1 and 2 (TAC Nos. MC4414, MC4415, MC4416, MC4417, MC4418, MC4419, and MC4420),” September 9, 2005 (ML052490337).

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