R. M. Krich
Senior Vice President, Regulatory Affairs

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410.864.6441

10 CFR 50.4

UniStar NUCLEAR

April 9, 2007

UN# 07-003

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

Subject: UniStar Nuclear, NRC Project No. 746
Submittal of the Published UniStar Nuclear Topical Report No. UN-TR-06-001-A, "Quality Assurance Program Description," Revision 0

References:
1) Letter UN# 06-007, from R. M. Krich (UniStar Nuclear) to U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Pre-application Submittal of the Quality Assurance Program Description," dated July 31, 2006
2) Letter UN# 06-008, from R. M. Krich (UniStar Nuclear) to U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Submittal of the Quality Assurance Program Description as a Topical Report," dated August 8, 2006
3) Letter UN# 06-010, from R. M. Krich (UniStar Nuclear) to U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Submittal of Revised Quality Assurance Program Description (QAPD) Topical Report," dated October 27, 2006
4) Letter UN# 06-014, from R. M. Krich (UniStar Nuclear) to 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," dated December 22, 2006
5) Letter UN# 07-002, from R. M. Krich (UniStar Nuclear) to U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Submittal of Corrections to the Quality Assurance Program Description Topical Report Proposed Revision 3," dated February 26, 2007
6) Letter from Larry J. Burkhart (NRC) to R. M. Krich (UniStar Nuclear), "Final Safety Evaluation for Topical Report (TR) UN-TR-06-0001, 'Quality Assurance Program Description' (Project No. 746)," dated March 14, 2007
7) Letter from Larry J. Burkhart (NRC) to R. M. Krich (UniStar Nuclear), "Replacement Pages for the Final Safety Evaluation for Topical Report (TR) UN-TR-06-0001, 'Quality Assurance Program Description' (Project No. 746)," dated March 16, 2007

By letter dated July 31, 2006 (Reference 1), as amended by letter dated August 8, 2006 (Reference 2), UniStar Nuclear, LLC submitted its proposed Quality Assurance Program Description (QAPD) as a topical report (TR) designated UN-TR-06-001 for NRC review and

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approval. By letters dated October 27, 2006, December 22, 2006, and February 26, 2007 (References 3, 4, and 5), UniStar Nuclear submitted revisions to its proposed QAPD TR.

By letter dated March 14, 2007 (Reference 6), as amended by letter dated March 16, 2007 (Reference 7), the NRC issued its final safety evaluation (SE) for UniStar Nuclear's QAPD TR, and accepted the TR for referencing in a licensing application. Both the March 14 and 16, 2007 letters requested that UniStar Nuclear publish the accepted version of the TR within three months of receipt of the March 14, 2007 letter, in accordance with the guidance provided on the NRC website. The guidance provided on the NRC website states, in pertinent part, under the heading entitled "Publication of Approved Reports," "After the NRC accepts a topical report for referencing in a licensing application, the sponsoring organization must publish the approved report and submit [it] to the NRC. This organization inserts NRC's transmittal letter and evaluation and all requests for additional information and their responses immediately after the title page...."

Accordingly, this letter submits the published TR No. UN-TR-06-001-A, "Quality Assurance Program Description." As stated in our letter dated December 22, 2006, the published version of the TR is designated Revision 0. The published TR is enclosed and in accordance with the direction in the March 14 and 16, 2007 NRC letters and the guidance provided on the NRC website, the enclosed TR incorporates the March 14, 2007 letter and the enclosed SE, as amended by the March 16, 2007 letter, after the title page, and also contains historical review information in the form of letters to the NRC, including the NRC request for additional information and UniStar Nuclear's response. We note that the UniStar Nuclear TR designation for this report is UN-TR-06-001, whereas the NRC designation is UN-TR-06-0001. We consider that both designations apply to the same report.

If you have any questions or need additional information, please contact me at (410) 864-6441.

Respectfully,

R. M. Krich
UniStar Nuclear Development, LLC

Enclosure: UniStar Nuclear Topical Report No. UN-TR-06-001-A, "Quality Assurance Program Description," Revision 0

cc: NRC Project Manager, U.S. Evolutionary Power Reactor (EPR) Combined License Application
NRC Project Manager, U.S. EPR Design Certification Application

ENCLOSURE

UniStar Nuclear Topical Report No. UN-TR-06-001-A,
"Quality Assurance Program Description," Revision 0

Topical Report No. UN-TR-06-001-A

QUALITY ASSURANCE PROGRAM DESCRIPTION

UniStar Nuclear QAPD

Revision 0

Effective Date: 3/31/07

Approved by _____ Date 3/31/07

G. Vanderheyden
President, UniStar Nuclear

March 14, 2007

R. M. Krich, Senior Vice President
Regulatory Affairs
UniStar Nuclear
750 E. Pratt Street
14th Floor
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.

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 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

I 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.

f you have any questions, please contact me at 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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*SE from TB incorporated with no significant changes
ADAMS Accession No.: ML070610261

DNRL/NAR1:PM	LA	DCIP/CQVB:BC	OGC	DNRL/NAR1:BC
LBurkhart	KGoldstein	JNakosi*	BPoole (NLO)	JColaccino
3/14/07	3/5/ 07	3/1/07	3/14/07	3/14/07

Official Record Copy

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 provides 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 a corrective action program, 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 nonsafey-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," April 2001.

- 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," August 1988.

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 Revision1 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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10 CFR 50.4

UniStar NUCLEAR

February 26, 2007

UN# 07-002

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

Subject: UniStar Nuclear, NRC Project No. 746
Submittal of Corrections to the Quality Assurance Program Description Topical Report Proposed Revision 3

References:
1) Letter UN# 06-007, from R. M. Krich (UniStar Nuclear) to U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Pre-application Submittal of the Quality Assurance Program Description," dated July 31, 2006
2) Letter UN# 06-008, from R. M. Krich (UniStar Nuclear) to U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Submittal of the Quality Assurance Program Description as a Topical Report," dated August 8, 2006
3) Letter from Stephanie M. Coffin (NRC) to R. M. Krich (UniStar Nuclear), "Acceptance for Review of Topical Report No. UN-TR-06-0001, Quality Assurance Program Description, UniStar Nuclear, Revision 0 (Project No. 746)," dated August 30, 2006
4) Letter UN# 06-010, from R. M. Krich (UniStar Nuclear) to U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Submittal of Revised Quality Assurance Program Description (QAPD) Topical Report," dated October 27, 2006
5) Electronic mail from Joelle Starefos (NRC) to Rod Krich (UniStar Nuclear), "RAI: UniStar QAPD UN-TR-06-0001 Revision 1," dated Tuesday, November 28, 2006, 4:17 PM
6) Letter from Stephanie M. Coffin (NRC) to R. M. Krich (UniStar Nuclear), "Revised Schedule for Review of Topical Report No. UN-TR-06-0001, Quality Assurance Program Description, UniStar Nuclear, Revision 1 Submitted October 27, 2006 (Project No. 746)," dated November 29, 2006
7) Letter from Larry J. Burkhart (NRC) to R. M. Krich (UniStar Nuclear), "Request for Additional Information (RAI) Regarding Topical Report No. UN-TR-06-0001, Quality Assurance Program Description (QAPD), UniStar Nuclear (Project No. 746)," dated December 18, 2006
8) Letter UN# 06-014, from R. M. Krich (UniStar Nuclear) to 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," dated December 22, 2006

By letter dated July 31, 2006 (Reference 1), as amended by letter dated August 8, 2006 (Reference 2), UniStar Nuclear, LLC submitted proposed Revision 0 of its Quality Assurance Program Description (QAPD) Topical Report (TR) UN-TR-06-001 for NRC review. This TR described the UniStar Nuclear Quality Assurance (QA) Program covering activities of siting; design; fabrication; construction, including pre-operational testing; operation, including testing; maintenance; and modification of a U.S. Evolutionary Power Reactor (EPR).

Proposed Revision 0 of the QAPD was developed based on applicable NRC guidance, including draft guidance, available at that time. The QAPD was accepted by the NRC for it to begin its comprehensive review as documented in NRC letter dated August 30, 2006 (Reference 3). As a result of the NRC issuing revised draft guidance on September 22, 2006, UniStar Nuclear submitted proposed Revision 1 of the QAPD by letter dated October 27, 2006 (Reference 4).

Electronic (e) mail from Joelle Starefos of the NRC, dated November 28, 2006, transmitted the NRC Request for Additional Information regarding proposed Revision 1 of the QAPD (Reference 5). The NRC issued its revised review schedule by letter dated November 29, 2006 (Reference 6), and by letter dated December 18, 2006 (Reference 7), the NRC confirmed that the RAI had been transmitted by e-mail and that UniStar Nuclear had agreed to respond by December 29, 2006. By letter dated December 22, 2006 (Reference 8), UniStar Nuclear provided its response to the RAI and submitted proposed Revision 2 of the TR.

As a result of NRC questions raised during a conference call between representatives of the NRC and UniStar Nuclear on February 20, 2007, and in an e-mail from Larry Burkhart of the NRC dated February 22, 2007, we identified a number of omissions in proposed Revision 2 of the QAPD. Accordingly, the enclosure to this letter contains the corrected pages of the QAPD. These pages are identified as proposed Revision 3 and the changes are identified by bars in the right-hand margin.

If you have any questions or need additional information, please contact me at (410) 864-6441.

Respectfully,

R. M. Krich
UniStar Nuclear Development, LLC

Enclosure: Proposed Revision 3 of Topical Report UN-TR-06-001 containing corrected pages only

cc: NRC Project Manager, U.S. EPR Combined License Application
NRC Project Manager, U.S. EPR Design Certification Application

ENCLOSURE

Proposed Revision 3 of Topical Report UN-TR-06-001 containing corrected pages only

Topical Report No. UN-TR-06-001

QUALITY ASSURANCE PROGRAM DESCRIPTION

UniStar Nuclear QAPD

Revision 3

Approved by _____ Date_____

G. Vanderheyden
President, UniStar Nuclear

SUMMARY OF ALTERATIONS

Revision	Summary of Revision or Change
0	Initial Issue
1	Revised to address changes made in the Final Revision to Standard Review Plan NUREG-0800 Section 17.5, "Quality Assurance Program Description – Design Certification, Early Site Permit and New License Applicants," and to make editorial corrections.
2	Revised to address NRC Request for additional information
3	Revised: Pages 1 and 2 to Revision 3. Pages 16, 18, and 93 to include the word "fabrication" in the sentences covering siting, design, and construction. Pages 46 and 47 to add a commitment to Supplement 2S-2 of NQA-1-1994, except for qualification of Nondestructive Examination personnel. Page 57 to add risk-significant nonsafety-related equipment to the scope of cleanliness controls during the operations phase.

SECTION B

QUALITY ASSURANCE PROGRAM

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 2, Quality Assurance Program, of 10 CFR 50, Appendix B; and
- Basic Requirement 2 and Supplement 2S-4 of NQA-1-1994.

PROGRAM BASIS

The UniStar Nuclear Quality Assurance Program complies with 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and applies to all levels of the organization, including contractors, who perform QA Level 1 activities. The QA program provides control over activities affecting the quality of the identified structures, systems, and components to an extent consistent with their importance to safety. ASME NQA-1-1994 Parts I and Part II, "Quality Assurance Requirements for Nuclear Facility Applications" are used in conjunction with 10 CFR 50, Appendix B, and provide additional detailed quality assurance guidelines which are committed to in this QAPD. The UniStar Nuclear QAPD describes the UniStar Nuclear overall compliance with 10 CFR 50, Appendix B and commitments to ASME NQA-1-1994. This document states the UniStar Nuclear policies, assigns responsibilities, and specifies requirements governing implementation of the QA Program to the siting, design, fabrication, construction, and operation of the UniStar Nuclear facilities. All 18 criteria of 10 CFR 50, Appendix B have been addressed to identify the scope of the QA Program applied to UniStar Nuclear facilities. QA requirements will also apply to contractors as delineated in procurement documents controlled under Section D, "Procurement Document Control," of this QAPD. The necessary management measures to control the quality of subcontracted activities for the UniStar Nuclear design, procurement, and installation and testing of QA Level 1 components and activities have been established in this QAPD. The QAPD will be reviewed for needed revisions as described in Appendix 1, Provisions For Change.

Specific processes and controls, which implement the provisions of 10 CFR 50, Appendix B and the commitment to ASME NQA-1-1994, as specified in this QAPD, are delineated in procedures.

The QA Program provides for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, such as adequate cleanness, and assurance that all prerequisites for the given activity have satisfied. The UniStar Nuclear QA Program provides for special controls, processes, test equipment, tools and skills to attain the required quality and verification of quality. QA requirements contained in this QAPD are also invoked on UniStar Nuclear contractors for their contracted scope of work. When work cannot be accomplished as specified in implementing QA procedures, or accomplishment of such work would result in an adverse condition, work is stopped until proper corrective action is

The QA Level 2 program description is provided in Section V, "Nonsafety-related SSC Quality Controls," of this QAPD, which includes Nonsafety-Related SSCs That Perform Safety Significant Functions and Nonsafety-Related SSCs Credited for Regulated Events. These requirements are implemented by UniStar Nuclear and UniStar Nuclear contractors through the use of approved QA programs and procedures. The UniStar defined QA Level 2 SSCs and their associated activities i.e., those SSCs that are not Quality Level 1 and do not affect the functions of the safety-related or important to safety SSCs, are evaluated against the requirements in Section V of this QAPD. This evaluation identifies which QA controls are needed to ensure these SSCs meet their intended functions and do not affect the functions of the safety-related SSCs. This evaluation may also include nuclear industry precedent in the application of these augmented QA requirements.

The two QA Levels have been established and apply throughout the life of the facility from licensing and siting through design, fabrication, construction, testing, startup, operation, maintenance, and modification.

QA LEVEL 1 REQUIREMENTS

The QA Level 1 Program shall conform to the criteria established in 10 CFR 50, Appendix B, and the commitment to NQA-1-1994. The QA Level 1 program shall be applied to those structures, systems, components, and administrative controls that have been determined to be safety-related.

QA LEVEL 2 REQUIREMENTS

The QA Level 2 program is an owner-defined QA program that uses the ASME NQA-1 standard as guidance. The general QA Level 2 requirements are described in Section V, "Nonsafety-Related SSC Quality Controls." For contractors, the QA Level 2 program shall be described in documents that must be approved by UniStar Nuclear. The QA Level 2 program shall be applied to Owner designated structures, systems, components, and activities.

QUALITY ASSURANCE TRAINING

UniStar Nuclear employees who perform QA Level 1 activities receive UniStar Nuclear QA Indoctrination Training. This training includes general criteria, including introduction to applicable codes, standards, QA Procedures, QA Program elements, and job responsibilities and authorities. UniStar Nuclear personnel assigned to perform QA Level 1 activities are also required to complete training in the specific UniStar Nuclear QA procedures needed to perform their job roles and responsibilities as assigned by their supervisor. Detailed QA training is provided on the UniStar Nuclear QA Program and job specific QA procedures prior to an employee beginning QA Level 1 work. Supervision is responsible for ensuring that personnel performing work under their supervision are appropriately trained and qualified to perform assigned work. Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable UniStar procedures. UniStar Nuclear will also include a version of QA Indoctrination Training as part of the general employee training given to all full-time employees. The Management Position

SECTION I

CONTROL OF SPECIAL PROCESSES

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 9, Control of Special Processes, of 10 CFR 50, Appendix B; and
- Basic Requirement 9 and Supplement 9S-1 of NQA-1-1994.
- Supplement 2S-2 of NQA-1-1994, except for qualification of Nondestructive Examination personnel which is addressed here.

Processes affecting the quality of items or services shall be controlled by written procedures using drawings, checklists, travelers or other appropriate means. These means shall ensure that the process parameters are controlled and that specified environmental conditions are maintained. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

SPECIAL PROCESSES

For the purpose of this section, a special process is a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

Special processes that control or verify quality shall be controlled according to the requirements of this section whether or not they are covered by existing codes and standards, or whether or not the quality requirements specified for an item exceed those of existing codes or standards

PERSONNEL, IMPLEMENTING DOCUMENTS, AND EQUIPMENT QUALIFICATIONS

Implementing UniStar Nuclear documents shall be used to ensure that process parameters are controlled and that the specified environmental conditions are maintained. Each special process shall be performed in accordance with appropriate implementing documents and these implementing documents shall include or reference:

- The responsibility of the organization performing the special process to adhere to the approved procedures and processes,
- Qualification requirements for personnel, implementing documents and equipment,
- Conditions necessary for accomplishment of the special process. These conditions shall include proper equipment, controlled parameters of the process and calibration requirements, and/or

- Requirements of applicable codes and standards, including acceptance criteria for the special process.

For special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in the procedures or instructions.

QUALIFICATION/CERTIFICATION OF NONDESTRUCTIVE EXAMINATION (NDE) PERSONNEL

Nondestructive Examination (NDE) personnel performing QA Level 1 activities shall be certified in accordance with specified requirements.

In lieu of Supplement 2S-2, for qualification of Nondestructive Examination personnel, certification shall be to the applicable versions of the standards referenced in Section XI of the ASME code, as permitted for use by 10 CFR Part 50.55a, for performing nondestructive examinations required by ASME Code Sections III or Section XI, or design specifications, provided that other applicable rules contained in Section XI of the ASME Code are met

DOCUMENTATION

Records shall be maintained as appropriate in accordance with Section Q, "Records," for currently qualified personnel, processes and equipment of each special process.

- Controls for hoisting, rigging, and transport activities are established that protect the integrity of the item involved as well as potentially affected nearby structures and components. Applicable hoisting, rigging, and transportation regulations and codes shall be followed.

- Cleanliness controls for work on safety–related and risk-significant nonsafety-related equipment are required to be established that minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. Procedures require documented verification of absence of foreign material prior to system closure.

SPECIAL HANDLING TOOLS AND EQUIPMENT

Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with procedures to verify that the tools and equipment are adequately maintained.

Operators of special handling and lifting equipment shall be experienced or trained in the use the equipment.

MARKING AND LABELING

Measures shall be established for marking and labeling for the packaging, shipping, handling and storage of items as necessary to adequately identify, maintain and preserve the item. Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.

APPENDIX 1

PROVISIONS FOR CHANGE

This QAPD is reviewed and revised as necessary to reflect any changes that occur during the siting, fabrication, design, construction, operation, including maintenance and modifications. In addition, this QAPD is revised when corrective actions, regulatory, organizational, or work scope changes warrant changes to the UniStar Nuclear QA Program. The UniStar Nuclear QAPD is maintained current through design, construction, and operation. The UniStar Nuclear QAPD is kept current as the design, construction, and operation activities progress, and appropriate changes are made based on any of the following:

- UniStar Nuclear lessons learned from audit and assessment findings,
- Program improvements identified from analysis of trends, and
- Changes due to regulations, commitments, reorganizations, revised project schedule, or program improvements from continuous review of assessment results and process improvement initiatives.

Any changes that reduce commitments in the approved QAPD, including those commitments that affect the QA Level requirements in this QAPD, will be submitted to the NRC for review and approval prior to implementation as required by 10 CFR 50.54(a)(3) and 10 CFR 50.55(f)(3). Changes that do not reduce commitments will be submitted in accordance with 10 CFR 50.54 and 10 CFR 50.55(f)(3), as applicable.

For the purposes of 10 CFR 50.54(a)(3) and 10 CFR 50.55(f)(3) the following are not considered a reduction in commitment.

- Quality assurance program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items,
- The use of a QA standard approved by the NRC which is more recent than the QA standard in the licensee's current QA program at the time of the change;
- The use of a quality assurance alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility;
- The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;
- The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;
- The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed; and

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10 CFR 50.4

UniStar NUCLEAR

December 22, 2006

UN# 06-014

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U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Subject: UniStar Nuclear, NRC Project No. 746
Response to Request for Additional Information Regarding Proposed Revision 1 of the Quality Assurance Program Description Topical Report

References:
1) Letter UN# 06-007, from R. M. Krich (UniStar Nuclear) to U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Pre-application Submittal of the Quality Assurance Program Description," dated July 31, 2006.
2) Letter UN# 06-008, from R. M. Krich (UniStar Nuclear) to U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Submittal of the Quality Assurance Program Description as a Topical Report," dated August 8, 2006.
3) Letter from Stephanie M. Coffin (NRC) to R. M. Krich (UniStar Nuclear), "Acceptance for Review of Topical Report No. UN-TR-06-0001, Quality Assurance Program Description, UniStar Nuclear, Revision 0 (Project No. 746)," dated August 30, 2006.
4) Letter UN# 06-010, from R. M. Krich (UniStar Nuclear) to U.S. NRC, "UniStar Nuclear, NRC Project No. 746, Submittal of Revised Quality Assurance Program Description (QAPD) Topical Report," dated October 27, 2006.
5) Electronic mail from Joelle Starefos (NRC) to Rod Krich (UniStar Nuclear), "RAI: UniStar QAPD UN-TR-06-0001 Revision 1," dated Tuesday, November 28, 2006, 4:17 PM.
6) Letter from Stephanie M. Coffin (NRC) to R. M. Krich (UniStar Nuclear), "Revised Schedule for Review of Topical Report No. UN-TR-06-0001, Quality Assurance Program Description, UniStar Nuclear, Revision 1 Submitted October 27, 2006 (Project No. 746)," dated November 29, 2006.
7) Letter from Larry J. Burkhart (NRC) to R. M. Krich (UniStar Nuclear), "Request for Additional Information (RAI) Regarding Topical Report No. UN-TR-06-0001, Quality Assurance Program Description (QAPD), UniStar Nuclear (Project No. 746)," dated December 18, 2006.

By letter dated July 31, 2006 (Reference 1), as amended by letter dated August 8, 2006 (Reference 2), UniStar Nuclear LLC submitted proposed Revision 0 of its Quality Assurance Program Description (QAPD) Topical Report (TR) UN-TR-06-001 for NRC review. This TR

described the UniStar Nuclear Quality Assurance (QA) Program covering 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). Proposed Revision 0 of the QAPD was developed based on applicable NRC guidance, including draft guidance, available at that time. The QAPD was accepted by the NRC for it to begin its comprehensive review as documented in NRC letter dated August 30, 2006 (Reference 3). As a result of the NRC issuing revised draft guidance on September 22, 2006, UniStar Nuclear submitted proposed Revision 1 of the QAPD by letter dated October 27, 2006 (Reference 4). Electronic (e) mail from Joelle Starefos of the NRC, dated November 28, 2006, transmitted the NRC Request for Additional Information regarding proposed Revision 1 of the QAPD (Reference 5). The NRC issued its revised review schedule by letter dated November 29, 2006 (Reference 6), and by letter dated December 18, 2006 (Reference 7), the NRC confirmed that the RAI had been transmitted by e-mail and that UniStar Nuclear had agreed to respond by December 29, 2006. Conference calls to clarify the RAI questions were conducted with NRC representatives on December 7 and 15, 2006.

Accordingly, Enclosure 1 to this letter contains our responses to the RAI questions. Enclosures 2 and 3 contain proposed Revision 2 of the UniStar Nuclear QAPD incorporating the RAI responses as indicated by bars in the margin and by highlighted strikeouts and additions, respectively. It is our intent that upon NRC approval of the proposed QAPD, UniStar Nuclear will issue a signed Revision 0 of the approved QAPD for implementation.

If you have any questions or need additional information, please contact me at (410) 230-4892.

Respectfully,

R. M. Krich

Enclosures:
1) UniStar Nuclear Response to NRC Request for Additional Information Regarding Proposed Revision 1 of the UniStar Nuclear Quality Assurance Program Description Topical Report UN-TR-06-001
2) Proposed Revision 2 of Topical Report UN-TR-06-001 incorporating responses to RAI questions as indicated by bars in the margin
3) Proposed Revision 2 of Topical Report UN-TR-06-001 incorporating responses to RAI questions as highlighted by strikeouts and additions

cc: NRC Project Manager, U.S. EPR Combined License Application
NRC Project Manager, U.S. EPR Design Certification Application

ENCLOSURE 1

UniStar Nuclear Response to NRC Request for Additional Information Regarding Proposed Revision 1 of the UniStar Nuclear Quality Assurance Program Description Topical Report UN-TR-06-001

UniStar Nuclear Response

To

Request for Additional Information

Regarding Proposed Revision 1 of the UniStar Nuclear Quality Assurance Program Description Topical Report UN-TR-06-001

1. Draft Standard Review Plan (SRP) 17.5, dated September 22, 2006, paragraph II.A.1 states that at the most senior management level, the applicant or holder is to issue a written quality assurance program description (QAPD) that establishes the quality policy and commits the organization to implement it. Revision 1 of the UniStar QAPD is proposed to be signed by the Director of Quality and Performance Improvement. The Director of Quality and Performance Improvement is not at the most senior management level according to the UniStar QAPD. The UniStar QAPD must be signed by the Chief Executive Officer or their designee.

   UniStar Nuclear response:

   UniStar Nuclear has reviewed its organizational structure and reporting relations to its parent company. It has been determined that for the purposes of the Combined License (i.e., COL), the most senior management position within the UniStar organization will be the President-UniStar Nuclear. Therefore it is appropriate for the President- UniStar Nuclear to approve the proposed QAPD.

Introduction

2. Proposed 10 CFR 52.72(a)(25) will require that an application must contain a final safety analysis report that includes the following information, at a level of information sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a combined license: ... (25) A description of the quality assurance program, applied to the design, and to be applied to the fabrication, construction, and testing, of the structures, systems, and components of the facility. The Introduction states that the UniStar QAPD covers siting, design, construction (including pre-operational testing), operation (including testing), maintenance and modification of the facility. This program basis is also stated in Section B and Appendix 1 of the UniStar QAPD. Fabrication is not mentioned in the program basis. Describe how proposed 10 CFR 52.72(a)(25) will be met based on the current description of the applicability of the QAPD.

   UniStar Nuclear response:

   The term "fabrication" has been included in the proposed QAPD Introduction (2 places) and in Section A.

3. 10 CFR 50.34(f)(3)(ii) requires that the applicant provide sufficient information to "(e)nsure that the quality assurance (QA) list required by Criterion II, app. B, 10 CFR part 50 includes all structures, systems, and components important to safety. (I.F.1)." Page 5 of the Unistar QAPD states, "(a)dditionally, this QAPD is applied to the "important to safety" activities, except for the design and fabrication, for the packing and transport of radioactive material as delineated and allowed by 10 CFR 71.101(f), and will be classified as QA Level 1." QA Level 2 are non-safety related structure, system, and component (SSC) controls. The QAPD Introduction does not specify that it is applicable to activities important to safety other than packing and transport of radioactive material. Section B states that the "QA program provides control over activities affecting the quality of the identified structures, systems, and components to an extent consistent with their importance to safety." For consistency with the above regulation, the licensee should describe the applicability of the QAPD to activities important to safety in the description of QA Level 2 in the Introduction.

UniStar Nuclear response:

The "definition" of QA Level 2 has been clarified regarding "important to safety" in the Introduction, Section B, Quality Assurance Program, subparagraph "Identification and Application of QA Controls," and Section V, Nonsafety-Related SSC Quality Controls."

This paragraph now includes the statement that "The QA Level 2 program does not include SSCs that are otherwise classified as safety-related or important to safety."

The paragraph preceding the "definition of QA Level 2" has been restructured to clarify that it is only applicable to 10 CFR 71.

4. The UniStar Introduction, Section B, Section V, states that, for contractors, an International Organization for Standardization (ISO) 9000 series QA program may be acceptable for QA Level 2 applications provided it complies with applicable UniStar Nuclear QAPD requirements and the QAPD is reviewed and accepted by the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement. The staff does not believe that this provision meets the requirements of 10 CFR 50.34(f)(3)(ii) and should be removed from the UniStar QAPD.

UniStar Nuclear response:

UniStar Nuclear has determined that reference to ISO 9000 should be deleted.

<u>The following statements were removed:</u>

INTRODUCTION, paragraph- <u>NonSafety-Related SSC Quality Controls (QA Level 2)</u>

> "An International Organization for Standardization (ISO) 9000 series QA program may be acceptable for QA Level 2 applications provided it complies with applicable UniStar Nuclear QAPD requirements and the QAPD is reviewed and accepted by the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement."

Section B-QUALITY ASSURANCE PROGRAM-paragraph- QA LEVEL 2 REQUIREMENTS

> "An International Organization for Standardization (ISO) 9000 series QA program may be acceptable for QA Level 2 applications provided it complies with applicable UniStar Nuclear QAPD requirements and the QAPD is reviewed and accepted by the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement."

SECTION V-NONSAFETY-RELATED SSC QUALITY CONTROLS, 1st paragraph

> "An International Organization for Standardization (ISO) 9000 series QA program is acceptable for QA Level 2 applications provided it complies with UniStar Nuclear QAPD requirements and the ISO program is reviewed and approved by the UniStar Nuclear Director, Quality and Performance Improvement."

Organization

5. Page 6 of the UniStar QAPD, Revision 1, has typographical errors. Specifically, "Secion A" should be "Section A." Additionally, page 6 of the QA states that the "President, UniStar Nuclear reports to the Chief Executive Office, UniStar Nuclear;" office should be officer.

   UniStar Nuclear response:

   Correction made.

6. Draft SRP 17.5, paragraph II.A.1 states that at the most senior management level, the applicant or holder is to issue a written QAPD that establishes the quality policy and commits the organization to implement it. As such, the CEO, UniStar Nuclear, should designate the President, UniStar Nuclear, as the senior position that is responsible for overall implementation of the quality assurance program.

   UniStar Nuclear response:

   UniStar Nuclear has reviewed its organizational structure and reporting relations to its parent company. It has been determined that for the purposes of the COL, the most senior management position within the UniStar organization will be the President-UniStar Nuclear.

   The organization description and organizational charts have been revised to reflect this determination.

7. Draft SRP Section 17.5, paragraph II.A.3, states that the QAPD is to contain an organizational description that addresses the organizational structure, functional responsibilities, levels of authority, and interfaces. The organizational description is to include the onsite and offsite organizational elements that function under the cognizance

of the QA program. The NRC staff found the organizational descriptions to be difficult to follow. Specific items that need to be addressed are as follows:

a. The Design and Construction organization and functions section does not meet the intent of paragraph II.A.3 in that it does not fully describe the organization structure and levels of authority. Specifically, 1) the section does not present a clear picture of the functional responsibilities of the Executive Management Position responsible for Project Management; 2) the section does not state levels of authority for the design and construction organization; 3) the section does not address the functional responsibilities of the Executive Management position responsible for Regulatory Affairs; 4) the section states that the UniStar Nuclear QA organization will review the contractors' QA programs, however, the UniStar Nuclear QA organization does not appear on any of the organizational figures; and 5) the section does not state whether these management positions are onsite or offsite.

UniStar Nuclear response:

The Design and Construction organization was incorporated into the Corporate (Offsite) Organization
1. The functional responsibilities for the Executive Management Position responsible for Project Management have been revised.
2. The section has been revised, including the organizational charts, to provide defined levels of authority and reporting relationships
3. The responsibilities of the Executive Management position responsible for Regulatory Affairs have been defined
4. The sentence was restructured to delete the reference to the "UniStar QA organization." The UniStar Nuclear Quality and Performance Improvement (QA Organization) is now depicted on the Organizational Charts.
5. Section A, including the organization charts, have been revised to better delineate the Offsite and Onsite organizations.

b. The Corporate and Technical Support Functions section: 1) does not address the functional responsibilities of the Senior Management position responsible for Quality and Performance Improvement depicted on Figure 2; and 2) does not state whether the management positions are onsite or offsite. Additionally, for each management position described in this section, there is a statement that some of these responsibilities may be assigned to the Executive Management position responsible for Facility Operations. It is not clear how a specific site Executive Manager can be responsible for their facility operations and corporate functions.

UniStar Nuclear response:

1. The function responsibilities of the Senior Management position responsible for Quality and Performance Improvement are provided in brief under the

Corporate (Offsite) Organization and more fully under the Quality Assurance Organization.
2. Section A, including the organization charts, have been revised to better delineate the Offsite and Onsite organizations and reporting relationships.
3. The statement in question has been removed, as it added no additional value.

c. The Operating Organization and Functions section: 1) does not state whether the Executive Management position responsible for Facility Operations and the Management Position responsible for Facility Operations and Maintenance are onsite or offsite; 2) does not have the same title descriptions for Training and Engineering as depicted in Figure 3; and 3) does not specify to which corporate management position (offsite) the site management position for training functionally reports.

UniStar Nuclear response:

1. Section A, including the organization charts, have been revised to better delineate the Offsite and Onsite organizations and reporting relationships.
2. Title descriptions have been corrected.
3. The position description and organizational charts have been revised.

d. The QA Organization and Functions section: 1) does not state whether the management position, the QA organization, and the position added to the QA organization after transition to operations are onsite or offsite; 2) does not depict the QA organization on Figure 1; and 3) does not clearly indicate whether the position added to the QA organization after transition to operations is a management position.

UniStar Nuclear response:

1. Section A, including the organization charts, have been revised to better delineate the Offsite and Onsite organizations and reporting relationships.
2. The functional responsibilities of the Senior Management position responsible for Quality and Performance Improvement are provided in brief under the Corporate (Offsite) Organization and more fully under the Quality Assurance Organization.
3) The position is a management position. The description and organization chart has been revised to so indicate.

8. Draft SRP Section 17.5, paragraph II.A.3, states that, for multiple organizations, the QA program organizational description would clearly define the interface responsibilities. Section A of the QAPD states that UniStar Nuclear organization is supported by the Constellation Generation Group, Supply Chain Management. Section A also describes Information Technology responsibilities. Additionally, Figures 1, 2, and 3 present matrix relationships without further description. Section A does not clearly describe the interface between existing organizations that will perform QA activities in support of the

COL application and who also perform QA activities under existing QA programs. Identify the organizations that will perform QA activities under the UniStar Nuclear QAPD, the existing operations (Constellation) QA program, or under both QA programs.

UniStar Nuclear response:

Section A, "Organization" (text and organization charts) have been revised to define the organizational relationships of the UniStar Nuclear organizations that will be under the proposed UniStar Nuclear QAPD. It has been determined that there will not be a functional relationship to Constellation. All organizations performing QA functions will be required to implement the applicable portion of the proposed UniStar Nuclear QAPD.

9. Draft SRP Section 17.5, paragraph II.A.4, states that there should be independence between the organization performing checking functions from the organization responsible for performing the functions. In order to satisfy the Three Mile Island (TMI)-related requirement contained in 10 CFR 50.34(f)(3)(iii)(A), clarify how UniStar Nuclear will implement measures to control the independence of organizations consistent with Section 17.5, paragraph II.A.4, of the draft SRP.

UniStar Nuclear response:

The proposed UniStar Nuclear QAPD, Revision 1, Section J, "Inspection," paragraphs titled "Selecting Inspection Personnel To Perform Inspection," include the necessary information; however, given the current wording, it is not clear as to our intent. The paragraphs have been rewritten:

"All individuals who perform an inspection to verify conformance of an item to specified acceptance criteria shall be qualified to perform the assigned inspection tasks in accordance with the requirements of Section T, "Training and Qualification-Inspection and Test."...

"With the exception of receipt inspectors, inspection personnel for construction phase activities will be members of the QA organization, and therefore independent of the line performing the function. Receipt inspectors, given the nature of the receipt inspection activities are independent from those responsible for performing the function, i.e., the supplier.

During the operations phase, inspections required for modification activities will be performed by personnel from the QA organization."

10. The QA Organization and Function section states that QA Technical Support is responsible for administering the corrective action and nonconformance processes during construction. However, for operations, the management position responsible for training is responsible for managing the corrective action and nonconformance processes. Nonconformance and corrective action programs are in place to meet the requirements of Criteria XV and XVI of Appendix B to 10 CFR 50 and as such, are quality assurance

functions. Explain how the training organization is qualified to perform this function, how the training organization maintains their independence, and how the proposed management of the corrective action process by the training organization meets Appendix B.

UniStar Nuclear response:

During the operations phase, the training organization will be staffed with personnel who are responsible to administer the corrective action and nonconformance processes. This staff is independent of the training function and will be trained, and perform work, in accordance with procedures that meet this QAPD.

The responsibilities of the Management Position responsible for Training (Onsite Facility Organization), in Section A, Organization are revised to state "During the operations phase, reporting to this position are the staff responsible for the administration of the corrective action, nonconformance, self-assessment, and industry operating experience programs."

Quality Assurance Program

11. Section B of the UniStar Nuclear QAPD states that "[m]anagement is regularly informed by the UniStar Nuclear QA organization of adverse trends and lessons learned as a result of reviews conducted on audit reports, surveillance reports, corrective action reports, management assessments, etc. Corrective action is initiated as necessary." As discussed in Section A of the QAPD, the corrective action process is managed by the Training organization and not the UniStar Nuclear QA organization. Describe how the QA organization will track adverse trends and lessons learned from a process that is not under their control.

UniStar Nuclear response:

As with all QA programs and processes that are not under the direct control of the QA organization, the QA audit program is used to determine program effectiveness. Relevant excerpts from the Section R, "Audits," are:

- "The UniStar Nuclear audit program is designed to provide a comprehensive independent evaluation of activities and procedures."
- "Functional areas of the UniStar Nuclear QA program for auditing include as a minimum verification of compliance and effectiveness of implementation of internal rules, procedures (e.g., operating, design, ...corrective actions,..... "

Audits which are performed to determine "effectiveness," in addition to compliance, would require the audit team, as part of the overall audit, to discern for themselves that the corrective action program is identifying trends and that the lessons learned aspect of the corrective action program is in accordance with management expectations and procedures.

Design Control and Verification

12. Draft SRP Section 17.5, paragraph II.C.1.m, states that applicable information derived from experience, as set forth in reports or other documentation, is made available to cognizant design personnel. Page 21, Section C, of the UniStar QAPD states that "[a]pplicable information derived for experience, ..." The staff believes that "for" should be "from".

    UniStar Nuclear response:

    Correction made

13. Section C, page 22 of the UniStar QAPD, states that applicable design inputs shall be controlled by the UniStar Nuclear Engineering and Contracts Manager. This position is not depicted on any of the organizational figures provided in the QAPD or described in Section A. This position should be described in Section A and appropriately identified on an organization chart.

    UniStar Nuclear response:

    Section C revised to delete this position. The Executive Management Position for Technical Services has responsibility for design as described in Section A.

14. Section C, page 22 of the UniStar QAPD, states that design documents shall be adequate to support design, construction, and operation. Define what does adequate mean and how is this achieved.

    UniStar Nuclear response:

    In the context of design documents, adequate would mean that;

    - The design documents were prepared, reviewed, and approved in accordance with the governing procedures
    - The design document is technically correct as determined from audits by technically qualified personnel of the quality of the design documents against the criteria of the design bases.
    - Information from the corrective action system does not indicate that users are finding significant problem with the documents.
    - During the operations phase, the "Maintenance Rule" (10 CFR 50.65) program does not indicate that deficiencies are being created due to errors in design.

    This is achieved through processes and procedures that ensure:

    - Work is performed by qualified personnel in accordance with approved procedures.
    - Design documents conform to applicable requirements, including approved codes and standards.

- Design testing and/or qualified design tools are used to develop the design documents.

15. Draft SRP Section 17.5, paragraph II.C.1.n, states that the QA role in design and analysis activities is defined, and design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements. The inclusion of these criteria satisfy the TMI-related requirement contained in 10 CFR 50.34(f)(3)(iii)(H). Page 28 of the UniStar QAPD states that "[d]uring the construction phase, design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements." The staff determined that this statement does not meets the requirements of 10 CFR 50.34(f)(3)(iii)(H). Define the UniStar Nuclear QA organization role in design and analysis activities during the construction phase.

UniStar Nuclear response:

Proposed UniStar Nuclear QAPD, Revision 1, Section R, "Audits," paragraph titled "Audit Schedules" (pages 69-70) states, in part:

> "Internal or external audits shall be scheduled in a manner to provide coverage, consistency and coordination with ongoing work, and at a frequency commensurate with the status and importance of the work. Internal or external audits shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work. As a minimum,
>
> – Internal audits of organization and facility activities, conducted prior to placing a UniStar Nuclear facility in operation, shall be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter. Internal audits of activities, conducted after placing the facility in operation, shall be performed 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. **These audits [during construction and operations] include oversight of the design and analysis activities, the purpose of which will be to detect design errors." [emphasis added]**

Additionally, proposed QAPD, Section A, "Organization," paragraph titled, "QA Organization Functions." page 11, states, in part:

> "The UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement is responsible for the following activities:
>
> Oversight of the quality of design and construction"

The following statement was added to proposed QAPD Section C under "QA Role in Design and Analysis:" QA also provides oversight of the quality of design and analysis activities as described in Section R, "Audits."

16. 10 CFR 50.34(f)(3)(iii)(C) requires that QA personnel are included in the documented review and concurrence of quality-related procedures associated with design, construction, and installation. Describe how UniStar will implement measures to control the documented review and concurrence of quality-related procedures consistent with the requirements of 10 CFR 50.34(f)(3)(iii)(C).

UniStar Nuclear response:

Proposed UniStar Nuclear QAPD, Revision 1, Section F, "Document Control," paragraph titled "Preparing and Reviewing Documents" (page 34) states, in part: "During the Design and Construction phase, personnel from the QA organization shall review and concur with quality related procedures associated with design, construction and installation"

This statement has been repeated in the first descriptive paragraph of Section C.

Procurement Document Control

17. Section D, page 29 of the UniStar QAPD states that it implements "the requirements of:... Basic Requirement 4 and Supplement 4S-1 of NQA-1-1994, except for .... supplier quality assurance program requirements (subsection 2.3) which are addressed here." Provide justification of the exception to subsection 2.3 of NQA-1-1994.

UniStar Nuclear response:

Upon further review, this exception is no longer needed and has been deleted.

18. Section D, page 29 of the UniStar QAPD states, "[t]he requirements of 10 CFR 21, 'Reporting of Defects and Noncompliance,' is invoked during siting, design, construction, and testing for QA Level 1 procurement or dedication of items and services including the dedication of items or services used to satisfy the requirements of 10 CFR 50, Appendix B." 10 CFR 21 is also applicable to the fabrication of the QA Level 1 SSCs and therefore, should be included in the statement above.

UniStar Nuclear response:

Term fabrication has been added.

19. Section D, page 30 of the UniStar QAPD states, "[t]he UniStar Nuclear Executive Management position responsible for Project Management (Construction phase) or Executive Management position responsible for Technical Services (Operations phase) is responsible to establish hold points, as necessary, indicating work that cannot proceed without authorization by the applicable management." These functions should be in Section A of the QAPD with the associated position function description.

UniStar Nuclear response:

The level of detail for assignment of these functions is not necessary and has been deleted.

20. Section D, page 31 of the UniStar QAPD states, "[r]eviews of procurement documents shall be performed by personnel who have access to pertinent information and have an adequate understanding of the requirements and scope of the procurement." Draft SRP Section 17.5, paragraph II.D.3, and NQA-1-1994, subsection 3, state that the individual has an adequate understanding of the requirements and intent of the procurement documents. For consistency, replace "scope" with "intent" in the Section D sentence described above.

UniStar Nuclear response:

Correction made

21. Section D, page 31 of the UniStar QAPD, lists "work stoppage" as one of the changes in Procurement Document Change. Work stoppage was deleted as an item needed in the procurement documentation on page 30 of the QAPD. For consistency, it is recommended that "work stoppage" is also deleted from page 31.

UniStar Nuclear response:

Correction made

Document Control

22. Section F, page 35 of the UniStar QAPD, states, "[a] temporary procedure change that does not change the intent of the procedure may be made at the work location by two members of the staff knowledgeable in the areas affected by the procedures." This alternative, allowed by ANSI N18.7, is only applicable to the operational phase and should be labeled that way. Additionally, ANSI N18.7 does not specify a location where a temporary procedure change may be made. Provide a justification for allowing temporary procedure changes to be made at the work location.

UniStar Nuclear response:

The phrase "at the work location" is deleted.

The sentence is clarified by adding "During the operational phase...." and "... provided the change is approved..."

Control of Purchased Material, Equipment, and Services

23. Section G, page 38 of the UniStar QAPD, states, "[e]valuation of the supplier's technical and quality capability based on an evaluation of supplier facilities, personnel, and quality assurance program implementation" should be one method for evaluating potential suppliers. Both NQA-1-1994 and draft SRP Section 17.5, paragraph II.G.9, state that the method should be "a direct evaluation of supplier facilities,..." "Direct" should be added to the UniStar QAPD.

    UniStar Nuclear response:

    Correction made

24. Section G, page 39 of the UniStar QAPD, states, "[s]upplier quality assurance programs shall be evaluated by the QA organization before contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to these requirements. Supplier QA programs shall be accepted by the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement before the supplier starts work." If the supplier is put on the UniStar Approved Vendor List (AVL), as stated on page 37, explain why the Senior Management position responsible for Quality and Performance Improvement would need to accept the supplier's QA program if the supplier was approved prior to contract placement.

    UniStar Nuclear response:

    As part of the selection process for the performance of QA Level 1 work, an evaluation of the adequacy of a suppliers QA program is required. This evaluation is required before any contract is awarded.

    If the evaluation determines that the program is satisfactory in all aspects, the supplier is placed on the AVL with no conditions. If the overall program is found satisfactory with certain exceptions, the supplier is placed on the AVL with certain conditions that must be met prior to the start of work.

    If there are conditions that are required to be corrected prior to the start of work, UniStar Nuclear is required to obtain commitment from the supplier that the conditions will be corrected prior to the start of work.

    The Senior Management position responsible for Quality and Performance Improvement is required to determine if the conditions have been corrected prior to the supplier beginning the work.

    The situation could also occur where a supplier is listed on the AVL for one product line but have a restriction for another product line that requires corrective action.

25. Section G, pages 40 and 41 of the UniStar QAPD, adopts the alternative to procurement of commercial-grade calibration services. "Laboratory" needs to be added to the sentence following "Voluntary" in the second bullet on page 41.

UniStar Nuclear response:

Correction made

26. Draft SRP Section 17.5, paragraph II.G.6, states that the procurement of components, including spare and replacement parts, is subject to quality and technical requirements suitable for their intended service and to the purchaser's QA program requirements. Explain how this requirement is met in the UniStar QAPD.

UniStar Nuclear response:

Proposed UniStar Nuclear QAPD Revision 1, Section D, "Procurement Document Control," paragraph titled, "Procurement Document Content," states, in part:

"UniStar Nuclear procurement documents issued for QA Level 1 items or services shall include the following provisions, as applicable to the procured material, equipment or service:

- ...
- ...
- Identification of any spare and replacement parts or assemblies and the appropriate delineation of technical and quality assurance data required for ordering these parts or assemblies. ..."

27. Section G, page 43 of the UniStar QAPD, states, in part, that the "supplier shall evaluate nonconforming items according to the applicable requirements of Section O, "Nonconforming Materials, Parts, or Components," and submit a report..." Section O is part of the UniStar QAPD. Clarify whether suppliers operating under their own QA programs that have been approved by UniStar would have to follow this requirement.

UniStar Nuclear response:

The proposed QAPD has been revised to avoid any confusion regarding the relationship of proposed QAPD Section O to suppliers. The new wording states "supplier shall evaluate nonconforming items according to the applicable requirements of the purchase order and submit a report..."

Inspection

28. Section J, page 49 of the UniStar QAPD, states, "[i]nspections are performed by individuals other than those who performed the activity being inspected. Inspection personnel do not report directly to the immediate supervisors who are responsible for performing the work being inspected." As stated in draft SRP Section 17.5, paragraph

II.J.5, this alternative is only applicable to the operational phase and should be labeled as such in the UniStar QAPD.

UniStar Nuclear response:

The proposed QAPD was revised to read,

"In the operational phase, inspections are performed by individuals other than those who performed the activity being inspected. These inspection personnel do not report directly to the immediate supervisors who are responsible for performing the work being inspected."

29. Section J, page 49 of the UniStar QAPD, states, "[w]ith the exception of receipt inspectors, inspection personnel for construction phase activities and operational phase modifications will be members of the QA organization." This function does not appear in the description of the QA organization in Section A. Clarify what is meant by this statement. Specifically, are these inspectors full time members of the QA organization or temporary members for the sake of the inspection activity?

UniStar Nuclear response:

Based on our response to RAI# 9, the paragraph has been revised to clarify that, with the exception of receipt inspectors, construction phase inspectors will be members of the QA organization. In all cases, construction phase inspectors are free from the pressures of costs and schedule and are independent of the organization performing the work.

"With the exception of receipt inspectors, inspection personnel for construction phase activities will be members of the QA organization. Receipt inspectors, given the nature of the receipt inspection activities are independent from those responsible for performing the function, i.e., the supplier.

During the operations phase, inspections required for modification activities will be performed by personnel from the QA organization."

Handling, Storage, and Shipping

30. Draft SRP Section 17.5, paragraph II.M.6, states that controls for the packaging, shipping, handling and storage of items are required to be established on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Section M, page 57 of the UniStar QAPD, adopts the alternative described for the operating phase in paragraph II.M.6, but does not include the first sentence of the alternative, described above. This first sentence should be included as part of the first bullet under Controls.

UniStar Nuclear response:

A new first bullet was inserted:

"Controls for the packaging, shipping, handling and storage of items are required to be established on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage."

31. Draft SRP Section 17.5, paragraph II.M.8, states that cleanliness controls for work on safety-related and risk-significant nonsafety-related equipment are required to be established that minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. Section M, page 58 of the UniStar QAPD, states, "[c]leanliness controls for work on safety-related systems and components are required to be established ..." Section M does not adopt the phrase "risk-significant nonsafety-related equipment." This phrase needs to be included in Section M in order to adopt the approved alternative.

UniStar Nuclear response:

It was UniStar Nuclear understanding that the wording of the draft SRP was to be changed to reflect the approved alternative granted to Nuclear Management Company (NMC) in the Safety Evaluation Report (SER) dated March 24, 2005. The NMC Quality Assurance Topical Report, as approved by the SER, states "NMC establishes appropriate cleanliness controls for work on safety-related equipment to minimize introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities, including documented verification of absence of foreign materials prior to system closure," (ML050700416). "Risk-significant non-safety-related" was not part of the approved alternative that UniStar Nuclear has adopted. The proposed QAPD wording reflects the approved alternative.

Corrective Action

32. Draft SRP Section 17.5, paragraph II.P.3, states that specific responsibilities within the corrective action program may be delegated, but the applicant or holder maintains responsibility for the program's effectiveness. Section P of the UniStar QAPD does not provide measures to maintain responsibility for the program's effectiveness if specific responsibilities within the corrective action program are delegated. Clarify how UniStar will address the delegation of responsibility associated with the corrective action program consistent with Section 17.5 of the draft SRP.

UniStar Nuclear response:

This item is addressed as follows:

Proposed UniStar Nuclear QAPD Revision 1, Section A, "Organization," paragraph titled, "Delegation of Work," page 13 states, in part:

"The delegation of work between UniStar Nuclear and contractors is identified in applicable plans, contracts and implementing procedures. **If UniStar Nuclear delegates responsibility for planning, establishing, or implementing any part of the overall QA program, sufficient authority to accomplish the assigned responsibility is also delegated. The responsible manager formally evaluates the performance of delegated work by contractors.** In all cases of delegation, UniStar Nuclear retains the overall responsibility for all work performed under the direction of UniStar Nuclear." **[emphasis added]**

Audits

33. Draft SRP Section 17.5, paragraph II.R.5, states, in part, that periodic inspections of systems, software applications, and media are to be performed to ensure electronic records retrievability, integrity, and retention period. In addition, Regulatory Issue Summary 2000-18 provides guidance on storing and maintaining QA records in electronic media. Consistent with the above guidelines, describe the audit controls that will be implemented for the preservation and safekeeping of computer systems, software applications, and media.

UniStar Nuclear response:

This item is addressed in two parts as follows:

Proposed UniStar Nuclear QAPD Revision 1, Section Q, "Records," states, in part:

> "Periodic inspections of systems, software applications, and media are performed to ensure electronic records retrievability, integrity, and retention period."

Additionally, proposed QAPD, Section A, "Organization," paragraph titled, "QA Organization Functions." states, in part:

> "The UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement is responsible for the following activities:
>
> - Oversight of document and records control"

34. Draft SRP Section 17.5, paragraph II.R.7, states that audits provide a comprehensive independent evaluation of activities and procedures. Clarify how UniStar will implement audits consistent with this Section of the draft SRP.

UniStar Nuclear response:

Proposed UniStar Nuclear QAPD Revision 1, Section R, "Audits," page 69, requires these comprehensive audits as follows:

> "The UniStar Nuclear audit program is designed to provide a comprehensive independent evaluation of activities and procedures."

In the context of audits, a comprehensive audit would be one that verifies both the degree of compliance of the organization or process being audited and the effectiveness of the process. Typically, a technical specialist in the program or process being audited is used to supplement the audit team, thereby adding a higher level of competence to the team. The effectiveness aspect is most important in that, a programs or process can be in compliance but not effective. An example would be the corrective action system not identifying trends.

As another example, a design control audit could include the many facets of design control itself, i.e., review/validation of design inputs, validity of calculations, inclusion of the correct codes and standard, configuration control of the design bases, but also the impacted programs that are required to make design control effective. Some of these elements could be the training and qualification of the engineers, document control, records management, test control, specification of NDE, procurement specifications, etc. This type audit is considered a vertical slice of a process implementation. It provides management with a look at the quality of an entire process or at least the portions included in the audit scope.

35. Section R, page 72 of the UniStar QAPD, states, "[t]he results of the evaluation shall be reviewed by Supply Chain management and appropriate corrective action shall be taken be taken." Remove the last "be taken."

UniStar Nuclear response:

Correction made

Training and Qualification Criteria - Quality Assurance

36. Section S, page 75 of the UniStar QAPD, states, that the QA program and associated procedures implement the requirements of Basic Requirement 2 and Supplement 2S-2. Supplement 2S-2 contains the requirements for NDE personnel. Supplement 2S-2 should be changed to Supplement 2S-3 which contains requirements for QA audit personnel.

UniStar Nuclear response:

Correction made

37. Section S, page 75 of the UniStar QAPD, states, for qualification of auditors, that an "[o]rientation to provide a working knowledge and understanding of this NQA-1-1994 and the UniStar Nuclear procedures for implementing audits and reporting results." The staff believes that the use of NQA-1-1994 in this sentence is incorrect. Replace NQA-1-1994 with QAPD.

UniStar Nuclear response:

The sentence structure of the proposed QAPD requires correction to align with NQA-1-1994. NQA-1-1994, Supplement 2S-3, Section 2.1(a) states:

> "orientation to provide a working knowledge and understanding of this Part (Part I) [of NQA-1-1994] and the auditing organization's procedures for implementing audits and reporting results"

To align with NQA-1-1994 the word "this" before NQA-1-1994 was deleted.

As a matter of information, the requirement for training in the proposed QAPD is on the following page, which states:

"Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor:

- Knowledge and understanding of this QAPD, NQA-1-1994 and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable."

38. Section S, page 77 of the UniStar QAPD, states, "[n]on-UniStar Nuclear certified auditors may be used to perform audits provided the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement confirms and documents applicable QAPD requirements have been met and the individual has been certified in accordance with the QA procedure on auditor qualification and certification." This statement is not consistent with NQA-1-1994. Provide justification for this statement.

UniStar Nuclear response:

The paragraph is deleted as it is not necessary.

Training and Qualification - Inspection and Test

39. Section T, page 79 of the UniStar QAPD, states, "[m]anagement of the Training and Qualification - Inspection and Test is the responsibility of the Senior Management position responsible for Quality and Performance Improvement." This responsibility/function is not described in Section A of the UniStar QAPD. This responsibility/function should be listed in Section A.

UniStar Nuclear response:
Responsibility was added to those of the Senior Management position responsible for Quality and Performance Improvement in Section A. It was deleted in Section T.

40. Page 86 of the UniStar QAPD, first paragraph, add "Section" before the "G".

UniStar Nuclear response:

Correction made

Independent Review

41. Draft SRP Section 17.5, paragraph II.W.2 (Option II), states that the IRC reports to a management level above the plant manager. Section W of the UniStar QAPD states that the IRC will report to the Executive Management position responsible for Facility Operations. According to the Section A of the UniStar QAPD, the Executive Management position responsible for Facility Operations "provides day-to-day direction and management oversight of activities associated with the safe and reliable operations of a nuclear station." Based on this functional description, the IRC should report to a level above the Executive Management position responsible for Facility Operations in order to meet the requirements of Criterion XVIII of Appendix B to 10 CFR Part 50.

UniStar Nuclear response:

After a review of the onsite organizational responsibilities, it was determined that the statement regarding "provides day-to-day direction and management oversight of activities associated with the safe and reliable operations of a nuclear station" has been relocated to the responsibilities of the Management Position responsible for Facility Operations and Maintenance (plant manager). This position reports to the Executive Management position responsible for Facility Operations.

With this change, the Independent Review Committee (IRC) will report to a level above the "plant manager."

December 18, 2006

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SUBJECT: REQUEST FOR ADDITIONAL INFORMATION (RAI) REGARDING TOPICAL REPORT NO. UN-TR-06-0001, QUALITY ASSURANCE PROGRAM DESCRIPTION (QAPD), UNISTAR NUCLEAR (PROJECT NO. 746)

Dear Mr. Krich:

By letters dated July 31, August 8, and October 27, 2006 (ADAMS Accession Nos. ML062130539, ML062220296, and ML063050194, respectively), UniStar Nuclear submitted for U.S. Nuclear Regulatory Commission (NRC) staff review, the subject topical report on the QAPD. The most recent version of the topical report is Revision 1 which was submitted on October 27, 2006 (ML063050194). The staff has determined that additional information is necessary to complete its review. Ms. Joelle Starefos, the lead project manager at that time, forwarded the RAIs which are enclosed to you via electronic mail on November 28, 2006, (ML063520258). UniStar and NRC staff discussed these RAIs via teleconference on December 7, 2006. We agreed that UniStar will provide responses to the RAIs by December 29, 2006.

Please note that I have taken over the duties as lead project manager for combined license activities involving the U.S. Evolutionary Power Reactor standard design. I may be reached at (301) 415-1311 or ljb3@nrc.gov.

Sincerely,

/RA/

Larry J. Burkhart, Project Manager
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Project No. 746

Enclosure:
As stated

cc w/encl: See next page

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Enclosure:
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Letter to R. M. Krich from Larry J. Burkhart dated December 18, 2006

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION (RAI) REGARDING TOPICAL REPORT NO. UN-TR-06-0001, QUALITY ASSURANCE PROGRAM DESCRIPTION (QAPD), UNISTAR NUCLEAR (PROJECT NO. 746)

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Request for Additional Information
Regarding the UniStar Nuclear
Quality Assurance Program Description (QAPD)
Topical Report UN-TR-06-0001, Revision 1

1. Draft Standard Review Plan (SRP) 17.5, dated September 22, 2006, paragraph II.A.1 states that at the most senior management level, the applicant or holder is to issue a written QAPD that establishes the quality policy and commits the organization to implement it. Revision 1 of the UniStar QAPD is proposed to be signed by the Director of Quality and Performance Improvement. The Director of Quality and Performance Improvement is not at the most senior management level according to the UniStar QAPD. The UniStar QAPD must be signed by the Chief Executive Officer or their designee.

Introduction

2. Proposed Title 10 to the *Code of Federal Regulations* (10 CFR) Section 52.72(a)(25) will require that an application must contain a final safety analysis report that includes the following information, at a level of information sufficient to enable the Commission to reach a final conclusion on all safety matters that must be resolved by the Commission before issuance of a combined license: ... (25) A description of the quality assurance program, applied to the design, and to be applied to the fabrication, construction, and testing, of the structures, systems, and components of the facility. The Introduction states that the UniStar QAPD covers siting, design, construction (including pre-operational testing), operation (including testing), maintenance and modification of the facility. This program basis is also stated in Section B and Appendix 1 of the UniStar QAPD. Fabrication is not mentioned in the program basis. Describe how proposed 10 CFR 52.72(a)(25) will be met based on the current description of the applicability of the QAPD.

3. 10 CFR 50.34(f)(3)(ii) requires that the applicant provide sufficient information to "(e)nsure that the quality assurance (QA) list required by Criterion II, app. B, 10 CFR Part 50 includes all structures, systems, and components important to safety. (I.F.1)." Page 5 of the Unistar QAPD states, "(a)dditionally, this QAPD is applied to the "important to safety" activities, except for the design and fabrication, for the packing and transport of radioactive material as delineated and allowed by 10 CFR 71.101(f), and will be classified as QA Level 1." QA Level 2 are non-safety related structure, system, and component (SSC) controls. The QAPD Introduction does not specify that it is applicable to activities important to safety other than packing and transport of radioactive material. Section B states that the "QA program provides control over activities affecting the quality of the identified structures, systems, and components to an extent consistent with their importance to safety." For consistency with the above regulation, the licensee should describe the applicability of the QAPD to activities important to safety in the description of QA Level 2 in the Introduction.

Enclosure

4. The UniStar Introduction, Section B, Section V, states that, for contractors, an International Organization for Standardization (ISO) 9000 series QA program may be acceptable for QA Level 2 applications provided it complies with applicable UniStar Nuclear QAPD requirements and the QAPD is reviewed and accepted by the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement. The staff does not believe that this provision meets the requirements of 10 CFR 50.34(f)(3)(ii) and should be removed from the UniStar QAPD.

Organization

5. Page 6 of the UniStar QAPD, Revision 1, has typographical errors. Specifically, "Secion A" should be "Section A." Additionally, page 6 of the QA states that the "President, UniStar Nuclear reports to the Chief Executive Office, UniStar Nuclear;" office should be officer.

6. Draft SRP 17.5, paragraph II.A.1 states that at the most senior management level, the applicant or holder is to issue a written QAPD that establishes the quality policy and commits the organization to implement it. As such, the Chief Executive Officer (CEO), UniStar Nuclear, should designate the President, UniStar Nuclear, as the senior position that is responsible for overall implementation of the quality assurance program.

7. Draft SRP Section 17.5, paragraph II.A.3, states that the QAPD is to contain an organizational description that addresses the organizational structure, functional responsibilities, levels of authority, and interfaces. The organizational description is to include the onsite and offsite organizational elements that function under the cognizance of the QA program. The NRC staff found the organizational descriptions to be difficult to follow. Specific items that need to be addressed are as follows:

   a. The Design and Construction organization and functions section does not meet the intent of paragraph II.A.3 in that it does not fully describe the organization structure and levels of authority. Specifically, 1) the section does not present a clear picture of the functional responsibilities of the Executive Management Position responsible for Project Management; 2) the section does not state levels of authority for the design and construction organization; 3) the section does not address the functional responsibilities of the Executive Management position responsible for Regulatory Affairs; 4) the section states that the UniStar Nuclear QA organization will review the contractors' QA programs, however, the UniStar Nuclear QA organization does not appear on any of the organizational figures; and 5) the section does not state whether these management positions are onsite or offsite.

   b. The Corporate and Technical Support Functions section: 1) does not address the functional responsibilities of the Senior Management position responsible for Quality and Performance Improvement depicted on Figure 2; and 2) does not state whether the management positions are onsite or offsite. Additionally, for each management position described in this section, there is a statement that some of these responsibilities may be assigned to the Executive Management.

c. The Operating Organization and Functions section: 1) does not state whether the Executive Management position responsible for Facility Operations and the Management Position responsible for Facility Operations and Maintenance are onsite or offsite; 2) does not have the same title descriptions for Training and Engineering as depicted in Figure 3; and 3) does not specify to which corporate management position (offsite) the site management position for training functionally reports.

d. The QA Organization and Functions section: 1) does not state whether the management position, the QA organization, and the position added to the QA organization after transition to operations are onsite or offsite; 2) does not depict the QA organization on Figure 1; and 3) does not clearly indicate whether the position added to the QA organization after transition to operations is a management position.

8. Draft SRP Section 17.5, paragraph II.A.3, states that, for multiple organizations, the QA program organizational description would clearly define the interface responsibilities. Section A of the QAPD states that UniStar Nuclear organization is supported by the Constellation Generation Group, Supply Chain Management. Section A also describes Information Technology responsibilities. Additionally, Figures 1, 2, and 3 present matrix relationships without further description. Section A does not clearly describe the interface between existing organizations that will perform QA activities in support of the combined operating license application and who also perform QA activities under existing QA programs. Identify the organizations that will perform QA activities under the UniStar Nuclear QAPD, the existing operations (Constellation) QA program, or under both QA programs.

9. Draft SRP Section 17.5, paragraph II.A.4, states that there should be independence between the organization performing checking functions from the organization responsible for performing the functions. In order to satisfy the Three Mile Island (TMI)-related requirement contained in 10 CFR 50.34(f)(3)(iii)(A), clarify how UniStar Nuclear will implement measures to control the independence of organizations consistent with Section 17.5, paragraph II.A.4, of the draft SRP.

10. The QA Organization and Function section states that QA Technical Support is responsible for administering the corrective action and nonconformance processes during construction. However, for operations, the management position responsible for training is responsible for managing the corrective action and nonconformance processes. Nonconformance and corrective action programs are in place to meet the requirements of Criteria XV and XVI of Appendix B to 10 CFR Part 50 and as such, are QA functions. Explain how the training organization is qualified to perform this function, how the training organization maintains their independence, and how the proposed management of the corrective action process by the training organization meets Appendix B.

Quality Assurance Program

11. Section B of the UniStar Nuclear QAPD states that "[m]anagement is regularly informed by the UniStar Nuclear QA organization of adverse trends and lessons learned as a result of reviews conducted on audit reports, surveillance reports, corrective action reports, management assessments, etc. Corrective action is initiated as necessary." As discussed in Section A of the QAPD, the corrective action process is managed by the Training organization and not the UniStar Nuclear QA organization. Describe how the QA organization will track adverse trends and lessons learned from a process that is not under their control.

Design Control and Verification

12. Draft SRP Section 17.5, paragraph II.C.1.m, states that applicable information derived <u>from</u> experience, as set forth in reports or other documentation, is made available to cognizant design personnel. Page 21, Section C, of the UniStar QAPD states that "[a]pplicable information derived <u>for</u> experience, ..." The staff believes that "for" should be "from".

13. Section C, page 22 of the UniStar QAPD, states that applicable design inputs shall be controlled by the UniStar Nuclear Engineering and Contracts Manager. This position is not depicted on any of the organizational figures provided in the QAPD or described in Section A. This position should be described in Section A and appropriately identified on an organization chart.

14. Section C, page 22 of the UniStar QAPD, states that design documents shall be adequate to support design, construction, and operation. Define what does adequate mean and how is this achieved.

15. Draft SRP Section 17.5, paragraph II.C.1.n, states that the QA role in design and analysis activities is defined, and design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements. The inclusion of these criteria satisfy the TMI-related requirement contained in 10 CFR 50.34(f)(3)(iii)(H). Page 28 of the UniStar QAPD states that "[d]uring the construction phase, design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements." The staff determined that this statement does not meets the requirements of 10 CFR 50.34(f)(3)(iii)(H). Define the UniStar Nuclear QA organization role in design and analysis activities during the construction phase.

16. 10 CFR 50.34(f)(3)(iii)(c) requires that QA personnel are included in the documented review and concurrence of quality-related procedures associated with design, construction, and installation. Describe how UniStar will implement measures to control the documented review and concurrence of quality-related procedures consistent with the requirements of 10 CFR 50.34(f)(3)(iii)(c).

Procurement Document Control

17. Section D, page 29 of the UniStar QAPD states that it implements "the requirements of:... Basic Requirement 4 and Supplement 4S-1 of NQA-1-1994, except for .... supplier quality assurance program requirements (subsection 2.3) which are addressed here." Provide justification of the exception to subsection 2.3 of NQA-1-1994.

18. Section D, page 29 of the UniStar QAPD states, "[t]he requirements of 10 CFR Part 21, 'Reporting of Defects and Noncompliance,' is invoked during siting, design, construction, and testing for QA Level 1 procurement or dedication of items and services including the dedication of items or services used to satisfy the requirements of 10 CFR Part 50, Appendix B." 10 CFR Part 21 is also applicable to the fabrication of the QA Level 1 SSCs and therefore, should be included in the statement above.

19. Section D, page 30 of the UniStar QAPD states, "[t]he UniStar Nuclear Executive Management position responsible for Project Management (Construction phase) or Executive Management position responsible for Technical Services (Operations phase) is responsible to establish hold points, as necessary, indicating work that cannot proceed without authorization by the applicable management." These functions should be in Section A of the QAPD with the associated position function description.

20. Section D, page 31 of the UniStar QAPD states, "[r]eviews of procurement documents shall be performed by personnel who have access to pertinent information and have an adequate understanding of the requirements and scope of the procurement." Draft SRP Section 17.5, paragraph II.D.3, and NQA-1-1994, subsection 3, state that the individual has an adequate understanding of the requirements and intent of the procurement documents. For consistency, replace "scope" with "intent" in the Section D sentence described above.

21. Section D, page 31 of the UniStar QAPD, lists "work stoppage" as one of the changes in Procurement Document Change. Work stoppage was deleted as an item needed in the procurement documentation on page 30 of the QAPD. For consistency, it is recommended that "work stoppage" is also deleted from page 31.

Document Control

22. Section F, page 35 of the UniStar QAPD, states, "[a] temporary procedure change that does not change the intent of the procedure may be made at the work location by two members of the staff knowledgeable in the areas affected by the procedures." This alternative, allowed by American National Standards Institute (ANSI) N18.7, is only applicable to the operational phase and should be labeled that way. Additionally, ANSI N18.7 does not specify a location where a temporary procedure change may be made. Provide a justification for allowing temporary procedure changes to be made at the work location.

Control of Purchased Material, Equipment, and Services

23. Section G, page 38 of the UniStar QAPD, states, "[e]valuation of the supplier's technical and quality capability based on an evaluation of supplier facilities, personnel, and quality assurance program implementation" should be one method for evaluating potential suppliers. Both NQA-1-1994 and draft SRP Section 17.5, paragraph II.G.9, state that the method should be "a direct evaluation of supplier facilities,..." "Direct" should be added to the UniStar QAPD.

24. Section G, page 39 of the UniStar QAPD, states, "[s]upplier quality assurance programs shall be evaluated by the QA organization before contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to these requirements. Supplier QA programs shall be accepted by the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement before the supplier starts work." If the supplier is put on the UniStar Approved Vendor List (AVL), as stated on page 37, explain why the Senior Management position responsible for Quality and Performance Improvement would need to accept the supplier's QA program if the supplier was approved prior to contract placement.

25. Section G, pages 40 and 41 of the UniStar QAPD, adopts the alternative to procurement of commercial-grade calibration services. "Laboratory" needs to be added to the sentence following "Voluntary" in the second bullet on page 41.

26. Draft SRP Section 17.5, paragraph II.G.6, states that the procurement of components, including spare and replacement parts, is subject to quality and technical requirements suitable for their intended service and to the purchaser's QA program requirements. Explain how this requirement is met in the UniStar QAPD.

27. Section G, page 43 of the UniStar QAPD, states, in part, that the "supplier shall evaluate nonconforming items according to the applicable requirements of Section O, "Nonconforming Materials, Parts, or Components," and submit a report..." Section O is part of the UniStar QAPD. Clarify whether suppliers operating under their own QA programs that have been approved by UniStar would have to follow this requirement.

Inspection

28. Section J, page 49 of the UniStar QAPD, states, "[i]nspections are performed by individuals other than those who performed the activity being inspected. Inspection personnel do not report directly to the immediate supervisors who are responsible for performing the work being inspected." As stated in draft SRP Section 17.5, paragraph II.J.5, this alternative is only applicable to the operational phase and should be labeled as such in the UniStar QAPD.

29. Section J, page 49 of the UniStar QAPD, states, "[w]ith the exception of receipt inspectors, inspection personnel for construction phase activities and operational phase modifications will be members of the QA organization." This function does not appear in

the description of the QA organization in Section A. Clarify what is meant by this statement. Specifically, are these inspectors full time members of the QA organization or temporary members for the sake of the inspection activity?

Handling, Storage, and Shipping

30. Draft SRP Section 17.5, paragraph II.M.6, states that controls for the packaging, shipping, handling and storage of items are required to be established on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage. Section M, page 57 of the UniStar QAPD, adopts the alternative described for the operating phase in paragraph II.M.6, but does not include the first sentence of the alternative, described above. This first sentence should be included as part of the first bullet under Controls.

31. Draft SRP Section 17.5, paragraph II.M.8, states that cleanliness controls for work on safety-related and risk-significant nonsafety-related equipment are required to be established that minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. Section M, page 58 of the UniStar QAPD, states, "[c]leanliness controls for work on safety-related systems and components are required to be established ..." Section M does not adopt the phrase "risk-significant nonsafety-related equipment." This phrase needs to be included in Section M in order to adopt the approved alternative.

Corrective Action

32. Draft SRP Section 17.5, paragraph II.P.3, states that specific responsibilities within the corrective action program may be delegated, but the applicant or holder maintains responsibility for the program's effectiveness. Section P of the UniStar QAPD does not provide measures to maintain responsibility for the program's effectiveness if specific responsibilities within the corrective action program are delegated. Clarify how UniStar will address the delegation of responsibility associated with the corrective action program consistent with Section 17.5 of the draft SRP.

Audits

33. Draft SRP Section 17.5, paragraph II.R.5, states, in part, that periodic inspections of systems, software applications, and media are to be performed to ensure electronic records retrievability, integrity, and retention period. In addition, Regulatory Issue Summary 2000-18 provides guidance on storing and maintaining QA records in electronic media. Consistent with the above guidelines, describe the audit controls that will be implemented for the preservation and safekeeping of computer systems, software applications, and media.

34. Draft SRP Section 17.5, paragraph II.R.7, states that audits provide a comprehensive independent evaluation of activities and procedures. Clarify how UniStar will implement audits consistent with this Section of the draft SRP.

35. Section R, page 72 of the UniStar QAPD, states, "[t]he results of the evaluation shall be reviewed by Supply Chain management and appropriate corrective action shall be taken be taken." Remove the last "be taken."

Training and Qualification Criteria - Quality Assurance

36. Section S, page 75 of the UniStar QAPD, states, that the QA program and associated procedures implement the requirements of Basic Requirement 2 and Supplement 2S-2. Supplement 2S-2 contains the requirements for NDE personnel. Supplement 2S-2 should be changed to Supplement 2S-3 which contains requirements for QA audit personnel.

37. Section S, page 75 of the UniStar QAPD, states, for qualification of auditors, that an "[o]rientation to provide a working knowledge and understanding of this NQA-1-1994 and the UniStar Nuclear procedures for implementing audits and reporting results." The staff believes that the use of NQA-1-1994 in this sentence is incorrect. Replace NQA-1-1994 with QAPD.

38. Section S, page 77 of the UniStar QAPD, states, "[n]on-UniStar Nuclear certified auditors may be used to perform audits provided the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement confirms and documents applicable QAPD requirements have been met and the individual has been certified in accordance with the QA procedure on auditor qualification and certification." This statement is not consistent with NQA-1-1994. Provide justification for this statement.

Training and Qualification - Inspection and Test

39. Section T, page 79 of the UniStar QAPD, states, "[m]anagement of the Training and Qualification - Inspection and Test is the responsibility of the Senior Management position responsible for Quality and Performance Improvement." This responsibility/function is not described in Section A of the UniStar QAPD. This responsibility/function should be listed in Section A.

Nonsafety-related SSC Quality Controls

40. Page 86 of the UniStar QAPD, first paragraph, add "Section" before the "G".

Independent Review

41. Draft SRP Section 17.5, paragraph II.W.2 (Option II), states that the incident response center (IRC) reports to a management level above the plant manager. Section W of the UniStar QAPD states that the IRC will report to the Executive Management position responsible for Facility Operations. According to the Section A of the UniStar QAPD, the Executive Management position responsible for Facility Operations "provides day-to-day direction and management oversight of activities associated with the safe and

reliable operations of a nuclear station." Based on this functional description, the IRC should report to a level above the Executive Management position responsible for Facility Operations in order to meet the requirements of Criterion XVIII of Appendix B to 10 CFR Part 50.

SUMMARY OF ALTERATIONS

Revision	Summary of Revision or Change
0	Initial Issue

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INTRODUCTION

UniStar Nuclear maintains full responsibility for ensuring that the Nuclear Power Plants are sited, designed, constructed and operated in conformance with applicable regulatory requirements, specified design requirements, applicable industry standards and good engineering practices in a manner to protect the health and safety of the employees and the public. To this end, the UniStar Nuclear Quality Assurance Program conforms to the criteria established in Title 10 of the Code of Federal Regulations 10 CFR 50, Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants. UniStar Nuclear commits to implement the:

- Basic Requirements and Supplements of NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications," as described in the QAPD.
- Specific subparts of NQA-1-1994, as described in Section U.

Exceptions or alternatives to these documents that require NRC approval are documented in Table 1.

For the purpose of this QAPD, activities occurring prior to the commencement of initial fuel loading are considered "construction phase" activities. Those activities that occur once initial fuel loading has commenced are referred to "operations and/or operational phase" activities. The Operations Phase elements of the QAPD will be implemented no later than 30 days prior to the scheduled date for the initial loading of fuel.

This QAPD will be identified in FSAR Table 13.4-X, "Operational Programs Required by NRC Regulation and Program Implementation," or its equivalent.

The UniStar Nuclear QA Program described herein covers siting, design, fabrication, construction (including pre-operational testing), operation (including testing), maintenance and modification of the facility. This Quality Assurance Program Description (QAPD) describes the requirements to be applied to those safety-related structures, systems and components, (SSCs) and related activities that have been designated Quality Assurance (QA) Level 1 and to the nonsafety-related structures, systems, and components, which are determined to be QA Level 2.

These two QA Levels have been established and will apply throughout the life of the facility from licensing and siting through design, fabrication, construction, and operation. The two UniStar Nuclear Quality Assurance Program Description levels are defined as follows:

<u>Safety Related (QA Level 1)</u>

The QA Level 1 program shall conform to the criteria established in 10 CFR 50, Appendix B and the commitment to NQA-1-1994.

The QA Level 1 program shall be applied to those structures, systems, components, and administrative controls that have been determined to meet the definition of safety-related in 10 CFR 50.3, which states:

Safety-related structures, systems and components means those structures, systems and components that are relied upon to remain functional during and following design basis events to assure:

(1) The integrity of the reactor coolant pressure boundary

(2) The capability to shut down the reactor and maintain it in a safe shutdown condition; or

(3) The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures comparable to the applicable guideline exposures set forth in 10 CFR 50.34(a)(1) or 10 CFR 100.11.

The development of the SSCs classified as QA Level 1, i.e. Q-List, occurs as part of the initial design process and is maintained by the ongoing design process implemented during the operational phase.

Additionally,.this QAPD is applied to the "important to safety" activities for the packing and transport of radioactive material, except for the design and fabrication, as delineated and allowed by 10CFR71.101(f), and will be classified as QA Level 1.

NonSafety-Related SSC Quality Controls (QA Level 2)

The QA Level 2 program is an owner-defined QA program that uses the ASME NQA-1 standard as guidance. The QA Level 2 program does not include SSCs that are otherwise classified as safety related or important to safety. General QA Level 2 requirements are described in Section V, "NON-SAFETY RELATED SSC CONTROLS." These requirements are implemented by UniStar Nuclear and UniStar Nuclear contractors through the use of approved QA programs and procedures. The Owner defined QA Level 2 SSCs and their associated activities are evaluated against the requirements in Section V of this QAPD. This evaluation identifies which QA controls are needed to ensure these SSCs meet their intended functions and do not affect the function of the Safety-related SSCs. This evaluation may also include nuclear industry precedent in the application of augmented QA requirements.

For contractors, the QA Level 2 program shall be described in documents that must be approved by UniStar Nuclear. The QA Level 2 program shall be applied to Owner designated structures, systems, components, and activities.

Program Changes

The process for reviewing and approving a change to the UniStar Nuclear QAPD is described in Appendix 1.

SECTION A

ORGANIZATION

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 1, Organization, of 10 CFR 50, Appendix B; and
- Basic Requirement 1 and Supplement 1S-1 of NQA-1-1994.

UniStar Nuclear employees and contractor employees representing UniStar Nuclear have full responsibility to ensure that the facility is designed, constructed, operated, and decommissioned in a manner to protect the health and safety of the public. This responsibility begins with initial design and continues throughout the life of the facility. The UniStar Nuclear QA Program is designed to ensure that the necessary quality requirements for structures, systems, components and work activities are met. This objective is attained by ensuring that the organizational structure and the responsibility assignments are such that: (a) quality is achieved and maintained by those who have been assigned responsibility for performing work and, (b) quality achievement is verified by persons or organizations not directly responsible for performing the work.

This Section describes the UniStar Nuclear organizational structure, functional responsibilities, levels of authority and interfaces for establishing, executing, and verifying QAPD implementation. The organizational structure includes offsite and onsite functions for UniStar Nuclear. Implementing documents assign more specific responsibilities and duties, and define the organizational interfaces involved in conducting activities and duties within the scope of this QAPD. Management gives careful consideration to the timing, extent and effects of organizational structure changes.

As the owner and operator, UniStar Nuclear is responsible for siting, design, licensing, engineering, procurement, fabrication construction, startup and operation of UniStar Nuclear facilities in accordance with its QA program. There are several organizations within UniStar Nuclear that implement and support the QAPD. These organizations include, but are not limited to, Project Management, Regulatory Affairs, Technical Services, Facility Operation, and Quality Assurance. Collectively, the organization is responsible for the following activities affecting quality: preparing, reviewing, approving, and verifying designs; qualifying suppliers; preparing, reviewing, approving, and issuing instructions, procedures, schedules, and procurement documents; purchasing; verifying supplier activities; identifying and controlling acceptable and nonconforming hardware and software; manufacturing; calibrating and controlling measuring and test equipment; qualifying and controlling special processes; constructing; inspecting; testing; startup; operating; performing maintenance; performing the audit function; and controlling records.

During the design and construction phases, preparation of design and construction documents and construction itself are contracted to qualified contractors. Contractor QA Programs must be approved by the UniStar Nuclear Senior Management position responsible for Quality and

Performance Improvement before work can start as described in Section D, "Procurement Document Control," and Section G, "Control of Purchased Material, Equipment and Services." QA procedures will be developed by management to implement this QAPD in their respective areas.

The following sections describe the reporting relationships, functional responsibilities and authorities for organizations implementing and supporting the UniStar Nuclear QA Program. Organizations are responsible to develop and implement procedures to implement the Quality Assurance functions for which they are responsible.

President, UniStar Nuclear

This position is responsible for overall corporate policy, overall responsibility for the implementation of the quality assurance program and provides executive direction and guidance for the corporation as well as promulgates corporate policy through the Company's senior management staff.

The position has overall responsibility for the siting, design, fabrication, construction, and safe reliable operation of the UniStar nuclear stations, including management oversight and support of the day-to-day operations of the stations. This is the senior executive responsible for setting and implementing policies, objectives, expectations, and priorities to ensure activities are performed in accordance with the quality assurance program and other requirements.

The President is also responsible for all technical and administrative support activities provided by UniStar Nuclear and contractors. The President directs the Executive Management positions responsible for Project Management, Regulatory Affairs, Operations Support, Technical Services, Facility Operations and the Senior Management positions responsible for Quality & Performance Improvement (Quality Assurance.)

CORPORATE (OFFSITE) ORGANIZATION (Figure A-1)

Reporting to the President, UniStar Nuclear are the following positions.

Executive Management Position responsible for Project Management

This position reports to the UniStar Nuclear President and is responsible for managing the siting, fabrication, construction, startup, including pre-operational testing, procurement, and Information Technology during these phases. The siting, design, fabrication, and construction activities, preparation of design and construction documents, and construction itself are contracted to qualified contractors, which are responsible to this position.

During the Operations phase, the position will also be responsible for the implementation of large projects for the nuclear facilities. Implementation includes development of the detailed scope, estimate, schedule, cost, design, procurement, fabrication, construction, testing, and closeout of each project. Focus is on defined projects separate from ongoing routine engineering projects.

Executive Management Position responsible for Regulatory Affairs

This management position is responsible for licensing and regulatory affairs and provides organizational support and management oversight of the facilities to ensure prompt and proper disposition of regulatory issues, develops regulatory positions and advises senior management on priorities and activities affecting regulatory issues at the nuclear facilities. Other responsibilities include developing policies and standardized processes and procedures for the maintenance of the licensing basis, the preparation of submittals to the NRC and other regulatory organizations.

Executive Management Position Responsible for Operations Support

This position reports to the President, UniStar Nuclear and provides direction to the nuclear security, emergency preparedness, training, and fleet procedures departments. Responsibilities for nuclear security include facility physical security, nuclear access programs, and fitness for duty programs. Emergency preparedness responsibilities include development and maintenance of the company radiological emergency plans and coordination with off-site radiological emergency response groups for the nuclear facilities. Training ensures qualified personnel operate and support the nuclear facilities. During the operations phase the training organization will administer the fleet corrective action, self-assessment, and industry operating experience programs. During the operations phase the fleet procedures department ensures that fleet procedures are prepared in accordance with applicable regulatory requirements, industry quality standards, and this QAPD. Additionally, corporate oversight and support is provided in the areas of operations, maintenance, refueling services, radiation protection, chemistry, and work management.

Executive Management Position Responsible for Technical Services

This position reports to the President, UniStar Nuclear and provides direction to corporate (Offsite) engineering, nuclear fuel services, and probabilistic risk assessment (PRA) departments. Additionally, corporate oversight and support is provided for site engineering. This position is responsible for the engineering functions supporting design and construction activities and long-term nuclear operations, and activities related to safety and management of nuclear fuel.

Executive Management Position responsible for Facility Operations (Onsite)

This onsite position reports to the President UniStar Nuclear and is described in the Onsite Facility Organization.

Senior Management Position Responsible for Quality and Performance Improvement

This position reports to the President UniStar Nuclear and is responsible for independently planning and performing activities to verify the development and effective implementation of the UniStar Nuclear QAPD including, but not limited to, siting, design, fabrication, construction, engineering, licensing, document control, records, corrective action program, procurement, and operations. Further details of the organization and responsibilities are provided in the Quality Assurance Organization description.

ONSITE FACILITY ORGANIZATION (Figure A-2)

The onsite facility organization is responsible for operations and maintenance of the respective plant. The facility organization is responsible for operations quality inspection activities of operations on-site work as well as controlling interfaces between the operating units and any preconstruction or construction activities.

Certain positions located onsite are functionally responsible to the appropriate offsite executive management, but administratively support the Executive Management position responsible for Facility Operations.

Executive Management position responsible for Facility Operations

This position reports to the President UniStar Nuclear and is responsible for overall plant nuclear safety and implementation of the Company's quality assurance program. This position is responsible for the station's compliance with its NRC Operating License, governmental regulations, and ASME Code requirements. Areas of responsibility also include site engineering and training. The Independent Review Committee (IRC) reports to the Executive Management position responsible for Facility Operations.

Management Position responsible for Facility Operations and Maintenance

This position reports to the Executive Management position responsible for Facility Operations and is responsible for plant operations and maintenance. This position assures the safe, reliable, and efficient operation of the plant within the constraints of applicable regulatory requirements, Operating License, the quality assurance program, and provides day-to-day direction and management oversight of onsite activities. The Management Position responsible for Facility Operations and Maintenance, in carrying out the responsibility for overall safety of plant operations, is responsible for timely referral of appropriate plant matters to management and independent reviewers. Areas of responsibility also include chemistry activities, health physics/radiological protection, operations and support, work management, records management, maintenance and production planning, and related procedures and programs

Management Position responsible for Training

A site management position reports to the Executive Management position responsible for Facility Operations and functionally to the Executive Management Position responsible for Operations Support located offsite. The position is responsible for the training of personnel who operate or support the nuclear facilities. Training responsibilities include determining the need for training based on information provided by the various groups, developing performance-based training programs, implementing training programs to support employee and facility needs, and evaluating training programs. Certain functional groups may be assigned responsibility for the development and conduct of their own training programs provided these groups are not required to have a systems approach to training under 10 CFR 50.120.

During the operations phase, reporting to this position are the staff responsible for administration of the corrective action, nonconformance, self-assessment, and industry operating experience programs.

Management Position responsible for Engineering

A site management position reports to the Executive Management position responsible for Facility Operations and functionally to the Executive Management position responsible for Technical Services (offsite), and is responsible for day-to-day engineering support activities including engineering programs, equipment reliability, and system engineering.

QUALITY ASSURANCE ORGANIZATION

Senior Management Position responsible for Quality and Performance Improvement (Offsite)

The UniStar Nuclear QA organization during the design, construction, and operations phases will be headed by the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement. The staffing of the QA organization will be commensurate with its duties and functions. The UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement reports directly to the President, UniStar Nuclear. This position is:

- Vested with the authority and organizational freedom to ensure that the requirements of this QAPD are properly implemented, including the imposition of "stop work." The decision to "stop work" is not influenced by costs or schedule.
- Responsible for the overall responsibility for development, management and implementation of the UniStar Nuclear QA Program during all phases of the facility and referring appropriate matters to senior management in a timely manner.
- Responsible for performance of an annual assessment of the adequacy of the QA program's implementation.
- In the UniStar Nuclear organization such that it has effective lines of communication with persons in other senior management positions.

The UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement is responsible for the following activities:

- QA Technical Support
  - Maintain the UniStar Nuclear QAPD
  - Maintain QA procedures
  - QA technical reviews of procurement documents
  - Administer the Corrective Action and Nonconformance Processes during construction
  - Maintain the UniStar Nuclear Approved Vendors List (AVL)
  - Administer the Auditor and Lead Auditor Certification Process

- Approval of contractor QA Programs
- Oversight of contractor QA Programs Implementation
- Oversight of the quality of design and construction.
- Management of the Training and Qualification Program for Inspection and Test Personnel

- Oversight of document and records control
- QA Verification
  - Audits, surveillances and assessments
  - Contractor/supplier evaluations
  - Equipment/vendor shop inspections
  - Witness vendor acceptance testing

During the transition from construction to operations, i.e., upon commencement of the Operational phase, an onsite Management Position responsible for Quality and Performance Improvement will be added to the UniStar Nuclear QA Organization. During this transition period, as well as during operations, this additional position will report to the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement. The added position has the authority and responsibility to contact the Senior Management position responsible for Quality and Performance Improvement with any QA concerns during startup and plant operations. Additionally, the corporate functions reporting to the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement, i.e., QA Technical Support and QA Verification; with the exception of administering the corrective action and nonconformance processes during construction; will transition to the added position. During the operations phase the corrective action and nonconformance process will be managed by the Management Position responsible for Training. During the operations phase, the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement will advise the UniStar Nuclear President on quality-related matters and continue to have governance and oversight responsibilities with respect to the QA organization headed by the added position.

Management Position responsible for Quality and Performance Improvement (Onsite)

The following additional responsibilities are included to this added position for start up testing and operations:

- QA Technical Support
  - Quality Engineering support of startup organization
  - Oversight of startup activities
  - QA selected reviews and oversight of programs developed for operations including, but not limited to, the identification of QA Level 1 SSCs and any changes thereto, their performance, and verifying and maintaining the facility design basis.
  - QA selected reviews and oversight of operations, including maintenance, testing and modification procedures

- Review and concurrence of changes to the identified QA Level 1 items that could affect their function.
- QA Oversight of operations procedure implementation
- Quality Control (QC) Inspection certification process
- Applicable discipline QC inspections of modifications to QA Level 1 components

The Executive Management Position Responsible for Project Management is responsible for receipt inspections of UniStar Nuclear procured QA Level 1 SSCs.

Accordingly, during the transition from construction to operations and during the operations phase, the management of the QA organization, the QA staff, and QC receipt inspectors have the responsibility to make quality assurance decisions and have sufficient authority, access to work areas, and organizational freedom to:

- Identify quality problems
- Initiate and recommend solutions to quality problems through designated channels
- Verify implementation of solutions
- Assure that further processing, delivery, installation, or use of items is controlled until proper disposition of nonconformances, deficiencies or unsatisfactory conditions has occurred
- Have direct access to highest levels of management
- Be sufficiently independent from cost and schedule considerations and have stop-work authority.

ORGANIZATIONAL INTERFACES

The organizational interfaces between UniStar Nuclear, contractors, and project applicable regulatory agencies are identified in the appropriate plans, contracts and implementing procedures. These documents contain the appropriate protocols, applicable roles, responsibilities and approval authorities for the specific topics for which they apply. UniStar Nuclear design interfaces shall be identified and procedurally controlled. Design efforts shall be coordinated among interfacing organizations as detailed in UniStar Nuclear procedures. Interface controls shall include the assignment of responsibility and the establishment of implementing documents among interfacing design organizations for the review, approval, release, distribution and revision of documents involving design interfaces. UniStar Nuclear design information transmitted across interfaces shall be documented and procedurally controlled. UniStar Nuclear transmittals of design information and/or documents shall reflect the status of the transmitted information and documents. Incomplete designs that require further evaluation, review or approval shall be identified. When it is necessary to initially transmit the design information orally or by other informal means, design information shall be promptly confirmed through a controlled implementing document.

DELEGATION OF WORK

The delegation of work between UniStar Nuclear and contractors is identified in applicable plans, contracts and implementing procedures. If UniStar Nuclear delegates responsibility for planning, establishing, or implementing any part of the overall QA program, sufficient authority to accomplish the assigned responsibility is also delegated. The responsible manager formally evaluates the performance of delegated work by contractors. In all cases of delegation, UniStar Nuclear retains the overall responsibility for all work performed under the direction of UniStar Nuclear. All UniStar Nuclear QA Level 1 and Level 2 work activities shall meet the applicable requirements of this QAPD. Responsible managers have the authority to delegate tasks to another qualified individual within their organization provided the designated individual possesses the required qualifications and these qualifications are documented. All delegations shall be in writing. The responsible manager retains the ultimate responsibility and accountability for implementing the applicable requirements.

RESOLUTION OF DISPUTES

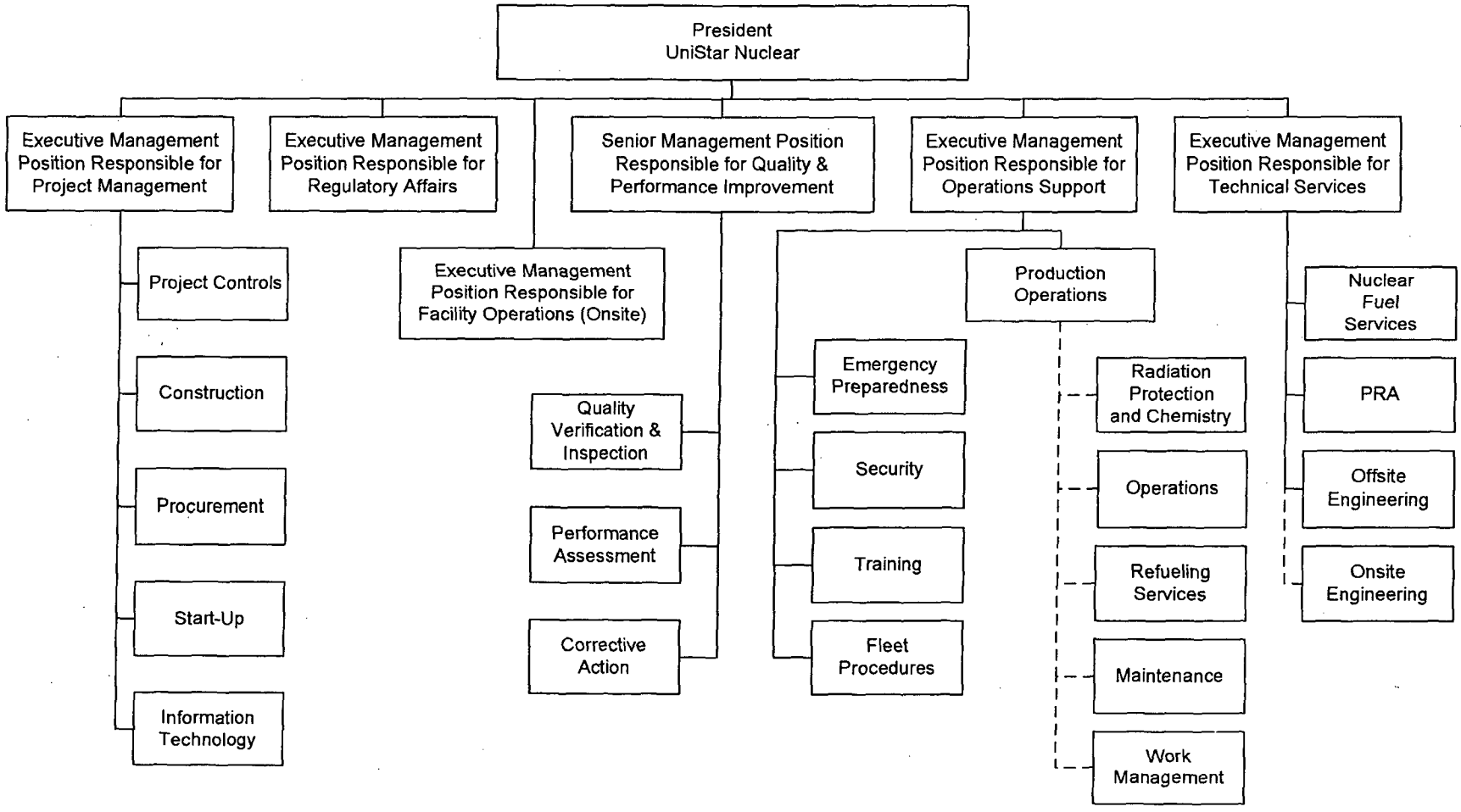
Disputes involving a difference of opinion on quality matters or issues are brought to the attention of line management, and if not resolved by the individual's manager, are elevated progressively to the Senior Management position responsible for Quality and Performance Improvement. If satisfactory resolution cannot be obtained at that level, the matter is then elevated to the UniStar Nuclear President for final resolution.

WORKER RESPONSIBILITIES

Personnel performing activities affecting quality are responsible for achieving an acceptable level of quality. Each employee has an obligation to identify concerns using the corrective action process with respect to work within their scope of responsibility whenever the health and safety of our workers, the public, or the environment is involved, or when continued work will produce results that are not in compliance with the UniStar Nuclear QA Program. Provisions are implemented to assure that personnel have the opportunity to suggest, recommend, or provide solutions to the identified concern. This process is controlled by a UniStar Nuclear procedure, which applies across the entire project/facility. The authorities and responsibilities for stopping work, the criteria and documentation required to process the stop work, and the actions required before work may resume are detailed in a UniStar Nuclear procedure. This process ensures that safety related activities are controlled until the deficiency, or unsatisfactory condition, has been resolved. Worker responsibilities are further discussed in Section P, Corrective Action.

Figure A-1

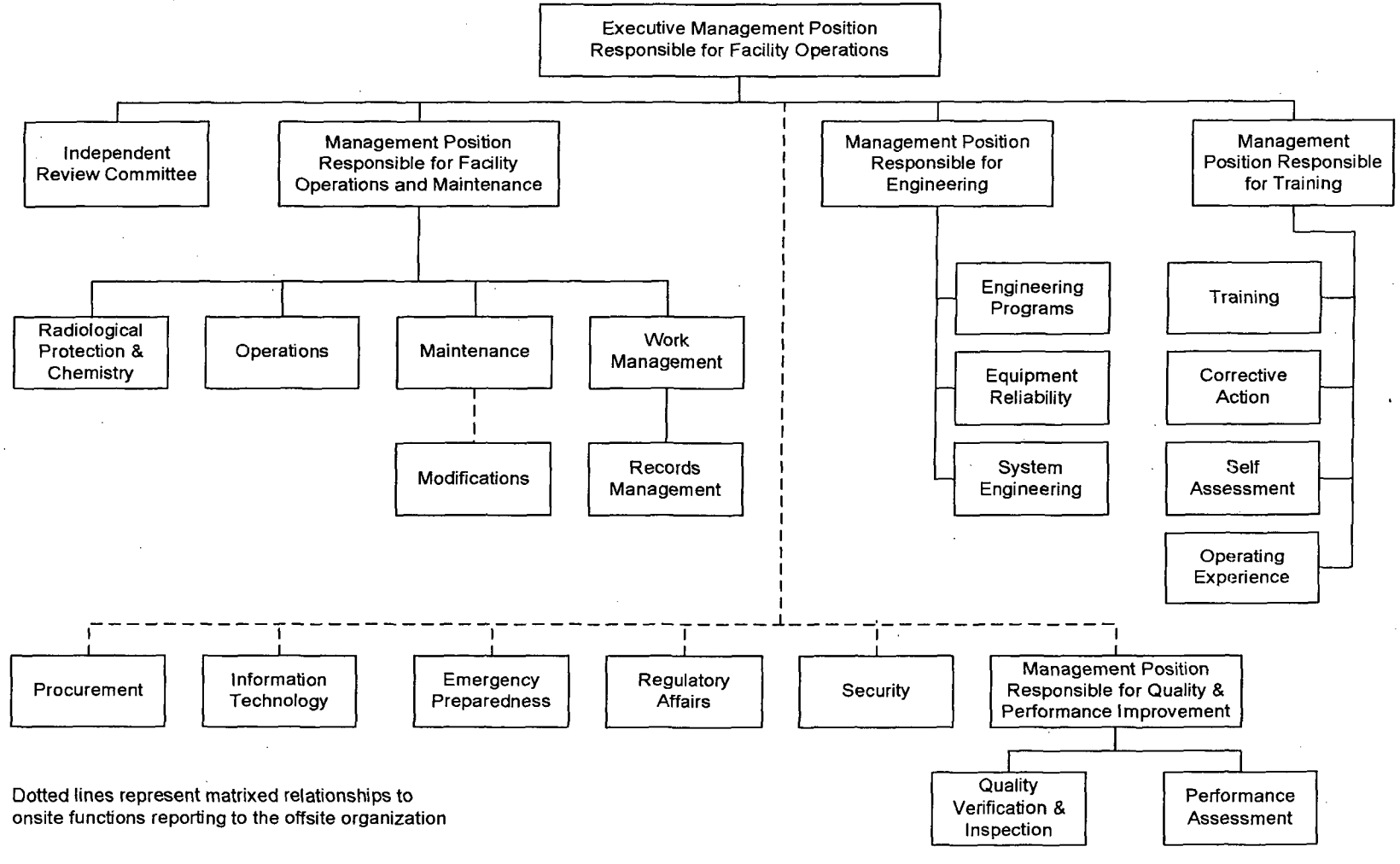
ORGANIZATION RELATIONSHIPS OF KEY MANAGEMENT
AND FUNCTIONAL GROUPS
CORPORATE (OFFSITE) ORGANIZATION



Dotted lines represent matrixed relationships
for support to the onsite organization

Figure A-2

ORGANIZATIONAL RELATIONSHIPS OF KEY MANAGEMENT
AND FUNCTIONAL GROUPS
ONSITE FACILITY ORGANIZATION



Dotted lines represent matrixed relationships to onsite functions reporting to the offsite organization

SECTION B

QUALITY ASSURANCE PROGRAM

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 2, Quality Assurance Program, of 10 CFR 50, Appendix B; and
- Basic Requirement 2 and Supplement 2S-4 of NQA-1-1994.

PROGRAM BASIS

The UniStar Nuclear Quality Assurance Program complies with 10 CFR 50, Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," and applies to all levels of the organization, including contractors, who perform QA Level 1 activities. The QA program provides control over activities affecting the quality of the identified structures, systems, and components to an extent consistent with their importance to safety. ASME NQA-1-1994 Parts I and Part II, "Quality Assurance Requirements for Nuclear Facility Applications" are used in conjunction with 10 CFR 50, Appendix B, and provide additional detailed quality assurance guidelines which are committed to in this QAPD. The UniStar Nuclear QAPD describes the UniStar Nuclear overall compliance with 10 CFR 50, Appendix B and commitments to ASME NQA-1-1994. This document states the UniStar Nuclear policies, assigns responsibilities, and specifies requirements governing implementation of the QA Program to the siting, design, fabrication, construction, and operation of the UniStar Nuclear facilities. All 18 criteria of 10 CFR 50, Appendix B have been addressed to identify the scope of the QA Program applied to UniStar Nuclear facilities. QA requirements will also apply to contractors as delineated in procurement documents controlled under Section D, "Procurement Document Control," of this QAPD. The necessary management measures to control the quality of subcontracted activities for the UniStar Nuclear design, procurement, and installation and testing of QA Level 1 components and activities have been established in this QAPD. The QAPD will be reviewed for needed revisions as described in Appendix 1, Provisions For Change.

Specific processes and controls, which implement the provisions of 10 CFR 50, Appendix B and the commitment to ASME NQA-1-1994, as specified in this QAPD, are delineated in procedures.

The QA Program provides for the planning and accomplishment of activities affecting quality under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, such as adequate cleanness, and assurance that all prerequisites for the given activity have satisfied. The UniStar Nuclear QA Program provides for special controls, processes, test equipment, tools and skills to attain the required quality and verification of quality. QA requirements contained in this QAPD are also invoked on UniStar Nuclear contractors for their contracted scope of work. When work cannot be accomplished as specified in implementing QA procedures, or accomplishment of such work would result in an adverse condition, work is stopped until proper corrective action is

taken. If procedures cannot be used as written, then the work is stopped until the procedures are changed. Requirements for stop work are further discussed in Section P, "Corrective Action."

In general a grace period of 90 days may be applied to provisions that are required to be performed on a periodic basis unless otherwise noted. Annual evaluations and audits that must be performed on a triennial basis are examples where the 90 day general grace period could be applied. The grace period does not allow the "clock" for a particular activity to be reset forward. The "clock" for an activity is reset backwards by performing the activity early.

Flowdown of QA Requirements to Contractors and Suppliers

QA requirements for QA Level 1 activities are imposed on UniStar Nuclear contractors and suppliers through the respective procurement documents for the particular scope of work being contracted. Determination of the specific QA requirements, supplier evaluations, and proposal/bid evaluations are in accordance with the requirements of Section D, "Procurement Document Control," and Section G, "Control of Purchased Material, Equipment and Services," of this document. Applicable QA Program elements required for the particular scope of work are identified in procurement documents. Potential contractors/suppliers are required to submit their QA Programs to the UniStar Nuclear QA organization for review in accordance with the request for proposal/procurement specification. Audits are performed at the contractor's/supplier's facility of their QA program and its implementation verifying that the contractor's/supplier's QA program meets the requirements established in the request for proposal/procurement specification. If the audit is acceptable then the contractor/supplier is added to the UniStar Nuclear Approved Vendors List (AVL) and a contract between UniStar Nuclear and the contractor/supplier may be issued. For procured items, UniStar Nuclear may also require that the UniStar Nuclear QA organization perform source inspections or witness tests at the supplier's facility prior to shipment, if the equipment/component warrants inspection due to its safety significance and/or complexity. Such requirements are also identified in the procurement documents and/or contract.

Construction contractors for UniStar Nuclear QA Program controlled construction activities are required to be placed on the AVL prior to contract award. Construction contractors are required to perform the QA activities required by their QA program, including audits of their own activities, as well as any required quality control (QC) inspections. The UniStar Nuclear QA organization will provide oversight of these contractors in the form of audits and surveillances, verifying that each contractor is properly implementing its QA program as approved by UniStar Nuclear QA. Contractually, contractors will be required to promptly correct UniStar Nuclear identified deficiencies and nonconformances.

IDENTIFICATION AND APPLICATION OF QA CONTROLS

QA Level 1 is applied exclusively to safety-related SSCs. All applicable sections of this QAPD are applied to QA Level 1 SSCs. Application of the QAPD requirements is part of the configuration management program used to verify and maintain the facility design basis and will be performed in accordance with documented procedures. Accordingly, as described in Section A, "Organization," the QA organization is responsible for oversight of these processes and programs.

The QA Level 2 program description is provided in Section V, "Nonsafety-related SSC Quality Controls," of this QAPD, which includes Nonsafety-Related SSCs That Perform Safety Significant Functions and Nonsafety-Related SSCs Credited for Regulated Events. These requirements are implemented by UniStar Nuclear and UniStar Nuclear contractors through the use of approved QA programs and procedures. The UniStar defined QA Level 2 SSCs and their associated activities i.e., those SSCs that are not Quality Level 1 and do not affect the functions of the safety-related or important to safety SSCs, are evaluated against the requirements in Section V of this QAPD. This evaluation identifies which QA controls are needed to ensure these SSCs meet their intended functions and do not affect the functions of the safety-related SSCs. This evaluation may also include nuclear industry precedent in the application of these augmented QA requirements.

The two QA Levels have been established and apply throughout the life of the facility from licensing and siting through design, fabrication, construction, testing, startup, operation, maintenance, and modification.

QA LEVEL 1 REQUIREMENTS

The QA Level 1 Program shall conform to the criteria established in 10 CFR 50, Appendix B, and the commitment to NQA-1-1994. The QA Level 1 program shall be applied to those structures, systems, components, and administrative controls that have been determined to be safety-related.

QA LEVEL 2 REQUIREMENTS

The QA Level 2 program is an owner-defined QA program that uses the ASME NQA-1 standard as guidance. The general QA Level 2 requirements are described in Section V, "Nonsafety-Related SSC Quality Controls." For contractors, the QA Level 2 program shall be described in documents that must be approved by UniStar Nuclear. The QA Level 2 program shall be applied to Owner designated structures, systems, components, and activities.

QUALITY ASSURANCE TRAINING

UniStar Nuclear employees who perform QA Level 1 activities receive UniStar Nuclear QA Indoctrination Training. This training includes general criteria, including introduction to applicable codes, standards, QA Procedures, QA Program elements, and job responsibilities and authorities. UniStar Nuclear personnel assigned to perform QA Level 1 activities are also required to complete training in the specific UniStar Nuclear QA procedures needed to perform their job roles and responsibilities as assigned by their supervisor. Detailed QA training is provided on the UniStar Nuclear QA Program and job specific QA procedures prior to an employee beginning QA Level 1 work. Supervision is responsible for ensuring that personnel performing work under their supervision are appropriately trained and qualified to perform assigned work. Sufficient managerial depth is provided to cover absences of incumbents. When required by code, regulation, or standard, specific qualification and selection of personnel is conducted in accordance with those requirements as established in the applicable UniStar procedures. UniStar Nuclear will also include a version of QA Indoctrination Training as part of the general employee training given to all full-time employees. The Management Position

responsible for Training is responsible for coordinating QA training activities for UniStar Nuclear personnel. This position serves as a centralized training support service for supervision in coordinating training and maintaining QA training records. This responsibility is carried out as support for line management. UniStar Nuclear supervisory personnel are responsible for determining the type and extent of the training to be provided to an individual, and ensuring that the training is properly documented for personnel performing QA Level 1 activities. 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 of Nuclear Training that implement a systematic approach to training. Retraining, when applicable, shall occur in order to maintain proficiency or when changes to work methods, technology, or job responsibilities occur. Retraining shall be documented.

MANAGEMENT ASSESSMENTS

Management of those organizations implementing the QA program, or portions thereof, shall assess the adequacy of that part of the program for which they are responsible and assure its effective implementation at least once each year or at least once during the life of the activity, which is ever shorter. During the operations phase, the period for assessing QA program implementation may be extended to once every two years.

QUALITY ASSURANCE PROGRAM STATUS REPORTING TO MANAGEMENT

Management is regularly informed by the UniStar Nuclear QA organization of adverse trends and lessons learned as a result of reviews conducted on audit reports, surveillance reports, corrective action reports, management assessments, etc. Corrective action is initiated as necessary.

SECTION C

DESIGN CONTROL AND VERIFICATION

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 3, Design Control, of 10 CFR 50, Appendix B; and
- Basic Requirements 3 and Supplements 3S-1and 11S-2 of NQA-1-1994; and
- The following Subpart from NQA-1- 1994, Part II
    - Subpart Part 2.7, Quality Assurance Requirements of Computer Software for Nuclear Facility Applications. This commitment also applies to computer software that is used to produce or manipulate data that is used directly in the design, analysis and operation of structures, systems and components relied on for safety.

Measures are established in procedures to assure that applicable requirements are correctly translated into design documents. Design control measures shall be applied to items such as the following: reactor physics, stress, thermal, hydraulic, and accident analyses; compatibility of materials; accessibility for inservice inspection, maintenance, and repair; and delineation of acceptance criteria for inspections and tests. Design inputs are specified on a timely basis to support UniStar Nuclear milestones. Controls are established for the selection and suitability of application of materials, parts, equipment and processes that are essential to the functions of structures, systems and components. Design interfaces to ensure completeness and efficiency of design are established in applicable procedures. Procedures detail the controls for design input, design process, design verification, design changes and approval. These procedures include appropriate quantitative and/or qualitative acceptance criteria for determining that activities have been satisfactorily accomplished. During the Design and Construction phase, personnel from the QA organization shall review and concur with quality related procedures associated with design, construction and installation. UniStar Nuclear design documents are prepared, reviewed and approved by qualified individuals. Applicable information derived from experience, as set forth in reports or other documentation, shall be made available to the design organization personnel.

Design is verified by one or more of the following verification methods: design reviews, alternate calculations or qualification tests. Design changes are governed by control measures commensurate with those applied to the original design. The design process and design verification practices and procedures shall be reviewed and modified, as necessary, when a significant design change is required because of an incorrect design. These and any other design deficiencies discovered during the design process on subsequent design related activities that affect the design of SSCs shall be entered into the Corrective Action Program (CAP) according to Section P, "Corrective Action." If these deficiencies cause constructed or partially constructed items (systems, structures or components) to be deficient, the affected items shall be controlled in accordance with Section O, "Nonconforming Material, Parts, or Components." Configuration management is maintained in accordance with the applicable procedures controlling changes to the various types of design documents.

DESIGN INPUT CONTROL

Applicable design inputs (such as design basis, conceptual design reports, performance requirements, regulatory requirements, codes and standards) shall be controlled according to the following requirements:

- Design inputs shall be identified and documented, and their selection reviewed and approved.
- Design inputs shall be specified and approved in a manner to support the schedule.
- Design inputs shall provide the necessary details to permit design to be carried out in a manner that provides a consistent basis for making design decisions, accomplishing design verification, and evaluating design changes.
- Changes from approved design inputs and reasons for the changes shall be identified, approved, documented and controlled.
- Design inputs based on assumptions that require re-verification shall be identified and controlled by the appropriate procedures.

DESIGN PROCESS

The UniStar Nuclear design process shall be controlled by Executive Management position responsible for Project Management (Construction phase) or Executive Management position responsible for Technical Services (Operations phase) according to the following requirements:

- UniStar Nuclear design work shall be prescribed and documented on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner and to permit verification that the design meets requirements.
- Design documents shall be adequate to support design, construction and operation.
- Appropriate quality standards shall be identified and documented, and their selection reviewed and approved.
- Changes from specified standards, including the reasons for the change, shall be identified, approved, documented and controlled.
- Design methods, materials, parts, equipment and processes that are essential to the function of the structure, system, or component shall be selected and reviewed for and suitability of application.
- Applicable information derived from experience as set forth in reports or other documentation, shall be made available to cognizant design personnel.
- Final design documents (i.e., approved design output documents and approved changes thereto) shall be sufficiently detailed as to purpose, method, assumptions, design input,

references and units such that a person technically qualified in the subject/engineering discipline can understand the documents and verify their adequacy without recourse to the originator of the design document.

- Procedural controls for identifying sub-assemblies or components on final design documents that are part of the item being designed shall be established. When a commercial-grade item is modified and/or tested to new requirements that are different from the supplier's published product description, the component part shall be traceable to documentation noting that it is different from the originally approved commercial-grade item.

- UniStar Nuclear design drawings, specifications or other design output documents shall contain appropriate inspection, examination and testing acceptance criteria.

DESIGN ANALYSIS

UniStar Nuclear design analyses shall be planned, controlled and documented. Design analysis documents shall be legible, in a form suitable for reproduction, filing and retrieval, and under configuration management control. UniStar Nuclear design calculations shall be identifiable by subject (including structure, system or component to which the calculation applies), originator, reviewer and date, or by other designators in order that approved calculations are retrievable.

Design analysis documents are required to be legible and in a form suitable for record keeping. They are sufficiently detailed as to the purpose, method, assumptions, design input, references, and units such that a person technically qualified in the subject are can review and understand the analyses and verify the adequacy of the results without recourse to the originator.

Computer software used to perform design analyses shall be developed and/or qualified, and used according to the provisions of ASME NQA-1-1994, Part II, Subpart 2.7 and Supplement 11S-2. Computer software developed and/or qualified under the UniStar Nuclear or its contractor QA programs may also be used to perform design analyses for UniStar Nuclear, provided that the UniStar Nuclear QA organization confirms these contractor QA programs meet the provisions NQA-1-1994, Part I, Supplement 11S-2 and NQA-1-1994 Part II, Subpart 2.7. Computer programs may be utilized for design analysis without individual verification of the program for each application provided:

- The computer program has been verified to show that it produces correct solutions for the encoded mathematical model within defined limits for each parameter employed; and

- The encoded mathematical model has been shown to produce a valid solution to the physical problem associated with the particular application.

Computer programs shall be controlled to assure that changes are documented and approved by authorized personnel. Where changes to previously verified computer programs are made, verification shall be required for the change, including evaluation of the effects of these changes on the above.

UniStar Nuclear design analyses documentation shall include:

- Definition of the objective of the analyses,
- Definition of design inputs and their sources,
- Results of literature searches or other applicable background data,
- Identification of assumptions and designation of those that must be verified as the design proceeds,
- Identification of any computer calculation, including computer type, computer program (e.g., name), revision identification, inputs, outputs, evidence of reference to computer program verification and the bases (or reference thereto) supporting application of the computer program to the specific physical problem,
- Review and approval.

DESIGN VERIFICATION

The following design control requirements shall be applied to verify the adequacy of UniStar Nuclear design:

- UniStar Nuclear design verification is required for design documents, and shall be performed using one or a combination of the design review, alternate calculations and/or qualification testing methods.
- The particular design verification method used shall be documented.
- Results of design verification shall be documented and shall include the identification of the verifier(s).
- Competent individuals or groups, other than those who performed the original design (but may be from the same organization), shall perform design verification. If necessary, this verification may be performed by the originator's supervisor provided that the supervisor did not specify a singular design approach or rule out certain design considerations and did not establish the design inputs used in the design; or the supervisor is the only individual in the organization competent to perform the verification.

UniStar Nuclear design verification shall be performed in a timely manner at appropriate times during the design process. Verification shall be performed before release for procurement, manufacture or construction, or release to another organization for use in other design work. In some cases (such as when insufficient data exists) it may be necessary to release unverified designs to other engineering organizations or disciplines to support schedule requirements. Unverified portions of the design shall be clearly identified and procedurally controlled. In all cases, design verification shall be completed before relying on the item or computer program to perform its function. The extent of design verification required shall be a function of the

importance to safety, complexity of design, degree of standardization, state of the art, and similarity with previously proven designs. If the design has been subjected to the verification process in accordance with ASME NQA-1-1994, it need not be duplicated for identical designs.

- UniStar Nuclear's use of previously standardized designs shall be controlled according to the following requirements:
  - The applicability of standardized or previously proven designs shall be verified with respect to meeting pertinent design inputs for each application.
  - Known problems affecting standard or previously proven designs and their effects on other features shall be considered.
  - The "Americanization" of previously proven European designs shall be documented in accordance with the applicable QA procedure.
  - The original design and associated verification measures shall be adequately documented and referenced in the files for subsequent application of the design.
  - Changes in previously verified designs shall require re-verification. Such verifications shall include the evaluation of the effects of those changes on the overall previously verified design and on any design analyses upon which the design is based.

DESIGN VERIFICATION METHODS

Acceptable verification methods include, but are not limited to, any one of the following, or a combination of the following:

- Design Reviews
- Alternate Calculations
- Qualification Testing

The design organization is required to identify and document the particular design verification method(s) that were used.

DESIGN REVIEWS

Design reviews are critical reviews to provide assurance that the final design is correct and satisfactory. The following items shall be addressed, as applicable during the review:

- Were the design inputs correctly selected and incorporated into the design?
- Are assumptions necessary to perform the design activity adequately described and reasonable? Are the assumptions adequately identified to enable subsequent reverifications after detailed design activities are completed?

- Was an appropriate design method used?
- Is the design output reasonable compared to the design inputs?
- Are the necessary design input and verification requirements for interfacing organizations specified in the design documents or in supporting procedures and instructions?

ALTERNATE CALCULATIONS

The appropriateness of assumptions, input data, and the computer program or other calculation methods used, shall be evaluated and the results shall be checked through the use of alternate calculation methods to verify the correctness of the original calculations or analyses.

QUALIFICATION TESTS

If design adequacy is to be verified by qualification testing, the tests shall be identified, procedurally controlled and documented according to the following:

- The test configuration shall be defined and documented.
- Testing shall demonstrate the adequacy of performance under conditions that simulate the most adverse design conditions. Operating modes and environmental conditions in which the item must perform satisfactorily shall be considered in determining the most adverse design conditions.
- If the tests verify only specific design features, then the other features of the design shall be verified by other means.
- Test results shall be documented and evaluated to ensure that test requirements have been met.
- If qualification testing indicates that a modification to an item is necessary to obtain acceptable performance, then the modification shall be documented and the item modified and re-tested or otherwise verified to ensure satisfactory performance.
- Scaling laws shall be established, verified and documented when tests are being performed on models or mockups.
- The results of model test work shall be subject to error analysis, where applicable, before using the results in final design work.

DESIGN CHANGE CONTROL

Design changes during the initial design phase and the operational phase shall be controlled according to the following requirements:

- Changes to final designs, field changes, modifications to the operating facility, and nonconforming items dispositioned as "use-as-is" or "repair," as described in Section O,

"Nonconforming Materials, Parts, and Components," shall have documented justification for use and are subject to the same design control measures and reviews as those applied to the original design.

- Design control measures for changes shall include provisions to ensure that the design analyses for the item are still valid.

- Changes shall be reviewed and approved by the affected groups or organizations that reviewed and approved the original design documents, with the following clarifications:

  - If the organization that originally was responsible for approving a particular design document is no longer responsible, then a new responsible organization shall be designated.

  - The designated organization shall have demonstrated competence in the specific design area of interest and have an adequate understanding of the requirements and intent of the original design.

- The interface between the design organization responsible for finalizing a design change and other organizations either involved in the review of the change, such as the QA and configuration management organizations, and those affected by the change, such as the operations and maintenance organizations, described in the next subsection, "Design Interface Control," shall be maintained.

- The design process and design verification practices and procedures shall be reviewed and modified, as necessary, when a significant design change is required because of an incorrect design. These design deficiencies shall be documented according to Section P, "Corrective Action." If these deficiencies cause constructed or partially constructed items (systems, structures or components) to be deficient, the affected items shall be controlled in accordance with Section O, "Nonconforming Materials, Parts, and Components."

- When a design change is approved other than revision to the affected design documents, field changes shall be incorporated into affected design documents when such incorporation is appropriate.

DESIGN INTERFACE CONTROL

UniStar Nuclear design interfaces shall be identified and procedurally controlled. Design efforts shall be coordinated among interfacing organizations as detailed in UniStar Nuclear procedures. Interface controls shall include the assignment of responsibility and the establishment of procedures among interfacing design organizations for the review, approval, release, distribution and revision of documents involving design interfaces. UniStar Nuclear design information transmitted across interfaces shall be documented and procedurally controlled. UniStar Nuclear transmittals of design information and/or documents shall reflect the status of the transmitted information and documents. Incomplete designs that require further evaluation, review or approval shall be identified. When it is necessary to initially transmit the design information

orally or by other informal means, design information shall be promptly confirmed through a controlled document.

During the operational phase, the Executive Management position responsible for Facility Operations is responsible for ensuring the facility complies with all applicable regulatory requirements including the requirements of this QA Program. In the discharge of these responsibilities, the Executive Management position responsible for Facility Operations directs the activities of the Engineering, Operations, Maintenance, and Training organizations through the applicable management. Procedures for controlling the interfaces and configuration management ensure that changes and modifications are properly managed and disseminated to those responsible personnel or organizations whose duties may be affected by the design change or modification and that they do not adversely impact the safe operation of the plant.

COMPUTER SOFTWARE CONTROLS

If UniStar Nuclear uses software to produce or manipulate data that is used directly in the design, analysis and operation of structures, systems, and components relied on for safety, the provisions provided in ASME NQA-1-1994 Subpart Part 2.7, Quality Assurance Requirements of Computer Software for Nuclear Facility Applications, and ASME NQA-1-1994 Supplement 11S-2, Supplementary Requirements for Computer Program Testing, shall apply. Procedures will be developed to implement these provisions as applicable.

DOCUMENTATION AND RECORDS

Design documentation which provide evidence that the design and design verification were performed in accordance with this QAPD shall be collected and maintained in accordance with the requirements of Section Q, "Records." The documentation shall include not only final design documents such as drawings, specifications and revision thereto; but also documentation, which identifies the important steps, including sources of design inputs that support the final design.

QA ROLE IN DESIGN AND ANALYSIS

During the construction phase, design documents are reviewed by individuals knowledgeable and qualified in QA to ensure the documents contain the necessary QA requirements. QA also provides oversight of the quality of design and analysis activities as described in Section R, "Audits."

SECTION D

PROCUREMENT DOCUMENT CONTROL

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 4, Procurement Document Control, of 10 CFR 50, Appendix B; and
- Basic Requirement 4 and Supplement 4S-1 of NQA-1- 1994, except for commercial-grade items which is addressed here.

UniStar Nuclear procurements shall be issued only to those suppliers that have been evaluated and qualified as acceptable for the particular scope of material, equipment and services to be procured. The material, equipment and services shall be procured from approved suppliers by procurement documents, approved by procurement management and the Senior Management position responsible for Quality and Performance Improvement or their qualified designees. Applicable design bases and other requirements necessary to assure adequate quality shall be included or referenced in documents for procurement of items and services. This program is applied to all phases of procurement including, as necessary, verification of activities of suppliers below the first tier. Procurement documents for commercial-grade items or services that will be dedicated as safety-related items or services shall contain technical and quality requirements such that the procured item or service can be appropriately dedicated. The requirements of 10 CFR 21, "Reporting of Defects and Noncompliance," is invoked during siting, design, fabrication, construction, and testing for QA Level 1 procurement or dedication of items and services including the dedication of items or services used to satisfy the requirements of 10 CFR 50, Appendix B.

During operations the requirements of 10 CFR 21 are continued for QA Level 1 procurement or dedication of items and services including the dedication of items or services used to satisfy the requirements of 10 CFR 50, Appendix B.

PROCUREMENT DOCUMENT CONTENT

UniStar Nuclear procurement documents issued for QA Level 1 items or services shall include the following provisions, as applicable to the procured material, equipment or service:

- Statement of the scope of work to be performed by the supplier.
- Technical requirements including:
    - Design bases, identified or referenced in the procurement documents.
    - Specific documents (such as drawings, codes, standards, regulations, procedures or instructions) describing the technical requirements of the material, equipment

or services to be furnished, shall be specified along with their revision level or change status.

  - Tests, inspections or acceptance requirements that UniStar Nuclear will use to monitor and evaluate the performance of the supplier shall be specified.

- Quality Assurance Program requirements including:
  - A requirement for the supplier to have a documented quality assurance program that implements the applicable requirements of 10CFR50 Appendix B and this QAPD, as appropriate to the circumstances of procurement (or the supplier may work under this QAPD). The extent of the quality assurance program shall depend on the scope, nature or complexity of the material, equipment or service to be procured. The supplier shall also incorporate the appropriate requirements into any subtier supplier issued procurement documents.

- Right of access to supplier, including subtier, facilities and records for inspection or audit by UniStar Nuclear, or other designee authorized by UniStar Nuclear.

- Provisions for establishing witness/inspection hold points beyond which work cannot proceed by the supplier without UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement authorization.

- Documentation required to be submitted to UniStar Nuclear for information, review or acceptance shall be identified along with a document submittal schedule. Record retention times, disposition requirements and record maintenance responsibilities shall be identified for documentation that will become quality assurance records.

- Requirements for the supplier to report to UniStar Nuclear in writing adverse quality conditions resulting in nonconformances. UniStar Nuclear approval of partial and full work releases and disposition of nonconformances is required.

- Identification of any spare and replacement parts or assemblies and the appropriate delineation of technical and quality assurance data required for ordering these parts or assemblies. Commercial-grade procurements shall also be identified in procurement documents.

- A requirement invoking NRC reporting requirements of 10 CFR 21 for QA Level 1 procurements.

PROCUREMENT DOCUMENT REVIEW AND APPROVAL

Procurement document reviews shall be performed and documented before issuing the procurement documents to the supplier. A review of the procurement documents and any changes thereto shall be made to verify that documents include all applicable requirements specified under Procurement Document Content above, and contain appropriate provisions to ensure that material, equipment or services will meet the governing requirements. Reviews shall be performed and documented to provide objective evidence of satisfactory accomplishment of such review prior to contract award. Changes made as a result of the bid evaluation or precontract negotiations shall be incorporated into the procurement documents. The review of such changes and their effects shall be completed prior to contract award. This review shall include the following considerations: 1) appropriate requirements specified in Procurement Document Content above, 2) a determination of any additional or modified design criteria, and 3) an analysis of exceptions or changes requested by the supplier and a determination on the impacts such changes may have on the intent of the procurement documents or quality of the item or service to be provided and shall be performed by the UniStar Nuclear organization initiating the procurement. Reviews of procurement documents shall be performed by personnel who have access to pertinent information and have an adequate understanding of the requirements and intent of the procurement.

PROCUREMENT DOCUMENT CHANGE

Changes to the scope of work, technical requirements, quality assurance program requirements, right of access, documentation requirements, nonconformance, hold points and lists of spare and replacement parts delineated in procurement documents, shall be subject to the same degree of control as used in the preparation of the original procurement document.

SECTION E

INSTRUCTIONS, PROCEDURES, AND DRAWINGS

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 5, Instructions, Procedures, and Drawings, of 10 CFR 50, Appendix B; and
- Basic Requirement 5 of NQA-1-1994

Activities affecting quality shall be prescribed by and conducted in accordance with approved procedures and other implementing documents (drawings, specifications, etc.) appropriate to the circumstances. Those procedures that delineate the responsibilities and functions of the QA organization, the QA procedures, are approved by the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement to ensure compliance with this QAPD. During the Operations phase, the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement, the Management positions responsible for Facility Operations and Maintenance, Engineering, and Training have the responsibility to review and approve the procedures that cover activities under their organizational purview that relate to the QAPD and the safe operation of the plant. Procedures approved by the Management positions responsible for Facility Operations and Maintenance, Engineering, and Training will be subject to selected review and oversight by the QA organization.

TYPES OF DOCUMENTS

The type of document to be used to perform work shall be appropriate to the nature and circumstances of the work being performed. Documents include procedures, drawings and specifications. Work controlling procedures may also utilize approved checklists, travelers or other means to assure process requirements are met, including prerequisite requirements prior to starting work. Procedures provide a consistent method for process performance and documentation of completion as well as ensure specified safety and environmental conditions are maintained.

CONTENT OF DOCUMENTS

Documents shall include or reference the following information as appropriate to the work to be performed:

- Responsibilities of the organizations affected by the document,
- Quality, technical and regulatory requirements,
- A sequential description of the work to be performed including controls for altering the sequence of required inspections, tests and other operations,
- Quantitative or qualitative acceptance criteria sufficient for determining that prescribed activities have been satisfactorily accomplished,

- Prerequisites, limits, precautions, process parameters and environmental conditions,
- Quality verification points and hold points,
- Methods for demonstrating that the work was performed as required,
- Identification of the lifetime or nonpermanent quality assurance records generated by the implementing document, and
- Identification of associated QA Levels, as appropriate.

REVIEW, APPROVAL, AND CONTROL OF DOCUMENTS

Procedures and implementing documents shall be reviewed, approved and controlled, according to the requirements of Section F, "Document Control," of this QAPD.

SECTION F

DOCUMENT CONTROL

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 6, Document Control, of 10 CFR 50, Appendix B; and
- Basic Requirement 6 and Supplement 6S-1 of NQA-1-1994.

Procedures are established which control the preparation, issuance and changes of documents that specify quality requirements or prescribe activities affecting quality. Measures are established to ensure that documents, including revisions are adequately reviewed, approved, and released for use by authorized personnel. Controlled documents are transmitted to the appropriate locations where the prescribed activity is being performed. Superseded documents are destroyed or retained only when they have been properly marked.

TYPES OF DOCUMENTS

QA procedures, other administrative procedures and implementing documents, and documents specifying quality requirements or prescribing activities affecting quality shall be controlled in accordance with this section. UniStar Nuclear documents controlled under the UniStar Nuclear QA Program will be specified by procedures and include, but are not limited to, design drawings, as-built drawings, engineering calculations, design specifications, purchase orders and related documents, vendor-supplied documents, audit and surveillance procedures, operating procedures, emergency operating procedures, technical specifications, nonconformance reports, corrective action reports, work instructions and procedures, calibration procedures, quality verification procedures, inspection and test reports, and all such documents made electronically available.

PREPARING AND REVIEWING DOCUMENTS

The document control system shall ensure that the identification of documents to be controlled and their specified distribution are proceduralized. The system shall further ensure that the responsibility for preparing, reviewing, approving and issuing documents shall be assigned by procedure to the appropriate UniStar Nuclear functional area manager. Implementing documents and documents specifying quality requirements or prescribing activities affecting quality, shall be reviewed in accordance with applicable procedures for adequacy, correctness and completeness, prior to approval and issuance. The organizational position(s) responsible for approving the document(s) for release shall be identified in the applicable procedures. During the Design and Construction phase, personnel from the QA organization shall review and concur with quality related procedures associated with design, construction and installation.

During the Operations phase, temporary procedures may be used to direct operations during testing, refueling, maintenance and modifications; to provide guidance in unusual situations not within the scope of normal procedures; and to insure orderly and uniform operations for short periods when the plant, a system, or a component of a system is performing in a manner not covered by existing detailed procedures, or has been modified or affected in such manner that

portions of existing procedures do not apply. Temporary Procedures include designation of the period of time during which they may be used.

CONTROLLING THE DISTRIBUTION AND USE OF DOCUMENTS

Documents needing to be placed under the document control system are transmitted to the Document Control organization with the distribution list for document holders. The Document Control organization shall enter the document into the Document Control electronic database and master list of controlled documents, assign document control numbers, complete transmittal forms and distribute the documents and transmittal form to the document holders. Document holders shall acknowledge receipt on the transmittal and send the acknowledgement to the Document Control organization. The up-to-date master listing of controlled documents will be made continuously available to personnel to verify that they have the current revision(s) for the performance of the activity affecting quality. The document control process will be periodically audited in accordance with the requirements of Section R, "QA Audits," to verify implementation effectiveness.

CHANGES TO DOCUMENTS

Changes to documents other than minor changes shall be reviewed for adequacy, correctness and completeness, prior to approval and issuance. Major changes shall be reviewed and approved by the same organization that performed the original review and approval unless other organizations are specifically designated. The reviewing organization shall have access to the applicable background data or information upon which to base their approval. During the operational phase, a temporary procedure change that does not change the intent of the procedure may be made provided the change is approved by two members of the staff knowledgeable in the areas affected by the procedures. The applicable procedure shall control the process, documentation and approval of the temporary changes.

MINOR CHANGES

Minor changes, such as inconsequential editorial corrections, may be made to documents without being subject to the review and approval requirements specified above. The applicable procedure shall define the organizational positions authorized and criteria acceptable for making minor changes.

PERIODIC PROCEDURE REVIEWS

Procedures used during the Operations phase will be reviewed by an individual knowledgeable in the area affected by the procedure no less frequently than every 2 years to determine if changes are necessary or desirable. Procedures are not required to be reviewed every 2 years provided that all of the following are met:

a. Applicable procedures are reviewed following any modification to a system.

b. Applicable procedures are reviewed following an unusual incident, such as an accident, significant operator error, or equipment malfunction.

c. Procedures are updated during use when discrepancies are found.

d. Procedures are reviewed prior to use if not used in the previous 2 years.

e. A QA program audit of procedures is conducted every 2 years.

PROCEDURE IMPROVEMENT

A process shall be in place to continually improve work instructions through reviews and incorporation of feedback from users.

SECTION G

CONTROL OF PURCHASED MATERIAL, EQUIPMENT AND SERVICES

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 7, Control of Purchased Material, Equipment and Services, of 10 CFR 50, Appendix B; and
- Basic Requirement 7 and Supplement 7S-1 of NQA-1-1994, except for commercial-grade items which are addressed at the end of this section.

UniStar Nuclear procurement of material, equipment and services is controlled to assure conformance with specified requirements. These controls include requirements for pre-award evaluations of suppliers' QA programs, annual evaluations, periodic audits/source inspections, and surveillances. Suppliers with a UniStar Nuclear approved QA program are placed on the UniStar Nuclear Approved Vendors List (AVL) prior to award of contract. Source inspections and surveillances, evaluation of objective evidence of quality furnished by the supplier and maintaining the AVL are the responsibility of UniStar Nuclear QA organization and are performed, as necessary, upon delivery or completion to ensure requirements specified in procurement documents are met. Inspection of received items and services is the responsibility of the procurement organization. Supplier evaluations, annual evaluations, audits, surveillances, source inspections and receipt inspections shall be documented.

PROCUREMENT PLANNING

UniStar Nuclear procurements shall be planned and documented to ensure a systematic approach to the procurement process exists and supports the schedule. Procurement planning shall:

- Identify procurement methods and organizational responsibilities, including what is to be accomplished, who is to accomplish it, how it is to be accomplished, and when it is to be accomplished.
- Identify and document the sequence of actions and milestones needed to effectively complete the procurement.
- Provide for the integration of the following activities:
    - Procurement document preparation, review and change control according to the requirements of Section D, "Procurement Document Control"
    - Selection of procurement sources, proposal/bid evaluation, and award
    - UniStar Nuclear evaluation of supplier performance
    - UniStar Nuclear verifications including any hold and witness point notifications

- Control of nonconformances
- Corrective action
- Acceptance of the material, equipment or service
- Identification of quality assurance records to be provided to UniStar Nuclear

- Be accomplished as early as possible, and no later than at the start of those procurement activities that are required to be controlled, to assure interface compatibility and a uniform approach to the procurement process.
- Be performed relative to the level of importance, complexity and quantity of the item or service being procured and the supplier's quality performance.

SOURCE EVALUATION AND SELECTION

Supplier selection shall be based on an evaluation, performed before the contract and/or purchase order is awarded, of the supplier's capability to provide the items or services in accordance with procurement document (technical and quality) requirements. The functional area needing the procurement shall request that the UniStar Nuclear QA organization evaluate the potential supplier for placement on the UniStar Nuclear AVL. Responsibilities and measures for evaluating and selecting procurement sources are detailed in the applicable QA procedure and include one or more of the following methods for evaluating potential suppliers:

- Evaluation of the supplier's history for providing an identical or similar product that performs satisfactorily in actual use. The supplier's history shall reflect current capability.
- Evaluation of supplier's current quality assurance records supported by any documented qualitative and quantitative information which can be objectively evaluated.
- Evaluation of the supplier's technical and quality capability based on a direct evaluation of supplier facilities, personnel, and quality assurance program implementation.

The results of procurement source evaluation and selection shall be documented in accordance with the applicable QA procedure.

PROPOSAL/BID EVALUATION

For proposals and bids, technically qualified personnel from the procurement organization shall perform an evaluation to determine if the proposal/bid meets procurement document requirements. As a minimum, this evaluation shall review the following subjects consistent with the importance, complexity and quantity of items or services being procured:

- Technical considerations
- QA program requirements

- Supplier personnel qualifications
- Supplier production capability and past performance
- Alternatives and exceptions

Before the contract is awarded, the procurement organization shall resolve, or obtain commitments to resolve, unacceptable quality conditions identified during the proposal/bid evaluation.

Supplier quality assurance programs shall be evaluated by the QA organization before contract placement, and any deficiencies that would affect quality shall be corrected before starting work subject to these requirements. Supplier QA programs shall be accepted by the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement before the supplier starts work.

SUPPLIER PERFORMANCE EVALUATION

The UniStar Nuclear procurement organization shall establish measures to routinely interface with the supplier and to verify supplier performance. The measures shall include:

- Establishing an understanding between UniStar Nuclear and the supplier of the requirements and specifications identified in procurement documents.
- Requiring the supplier to identify planning techniques and processes to be used in fulfilling procurement document requirements.
- Reviewing supplier documents that are prepared or processed during work performed to fulfill procurement requirements.
- Identifying and processing necessary change information.
- Establishing the method to be used to document information exchanges between UniStar Nuclear and supplier.
- Establishing the extent of source surveillance and inspection.
- Ensuring that the UniStar verification activities do not relieve the supplier of its responsibilities for verification of quality achievement.

The extent of UniStar Nuclear verifications shall be a function of the relative importance, complexity/quantity of items or services being procured and the supplier's quality performance. Verification activities shall be accomplished by qualified personnel assigned to check, inspect, audit, or witness the activities of the suppliers. UniStar Nuclear verifications shall be conducted as early as practical and shall not relieve the supplier of the responsibility for the verification of quality achievement. Verifications shall include supplier audits, surveillances or source inspections (or combinations) used as a method of evaluating the supplier's performance, and evaluation of purchaser's documentation to aid in the determination of the effectiveness of the

supplier's quality assurance program. Records, including source surveillances and inspections, audits, receiving inspections, nonconformances, dispositions, waivers, and corrective actions shall be maintained in accordance with the requirements of Section Q, "Records."

CONTROL OF SUPPLIER GENERATED DOCUMENTS

Supplier generated documents shall be controlled, processed and accepted by UniStar Nuclear in accordance with the requirements established in the applicable QA procedures. Measures shall be implemented to ensure that the submittal of supplier generated documents is accomplished in accordance with the procurement document requirements. These measures shall also provide for the acquisition, processing and recorded evaluation of technical, inspection and test data compared against the acceptance criteria. When the supplier is required to maintain specific records, the retention and disposition requirements are established.

CONTROL OF CHANGES IN ITEMS OR SERVICES

UniStar Nuclear shall establish contractual controls with suppliers to ensure that changes in procurement documents are controlled and documented in accordance with this QAPD.

ACCEPTANCE OF ITEMS OR SERVICES (other than calibration services).

Methods for accepting supplier furnished material, equipment or services shall include one or more of the following, as appropriate to the items or services being procured:

- Evaluating the supplier certificate of conformance,
- Performing either source verification, receiving inspection, post installation test, or a combination thereof,
- Technical verification of the data produced (services only),
- Surveillance or audit of the activities (services only),
- Review of objective evidence for conformance to procurement requirements (services only).

The supplier shall verify that furnished material, equipment or services comply with UniStar Nuclear procurement requirements before offering the material, equipment or services for acceptance and shall provide to UniStar Nuclear objective evidence that material, equipment or services conform to the procurement documents. Where required by code, regulations or contract provisions, documentary evidence that items conform to procurement documents shall be available at the site prior to installation or use, i.e., prior to placing reliance on the item for its intended safety function.

QUALIFICATION AND ACCEPTANCE OF CALIBRATION SERVICES

For procurement of commercial-grade calibration services for safety-related applications, laboratory accreditation programs administered by the National Institute of Standards and

Technology and by the American Association for Laboratory Accreditation, as recognized through the mutual recognition arrangement of the International Laboratory Accreditation Program (ILAC), are acceptable in lieu of a supplier audit, commercial-grade survey, or in-process surveillance provided that all of the following conditions are met:

- Accreditation is to ANSI/ISO/IEC 17025, "General Requirements for the Competence of Testing and Calibration Laboratories."
- Use of this method is limited to the National Voluntary Laboratory Accreditation Program and the American Association for Laboratory Accreditation, as recognized by ILAC signatories.
- The scope of the accreditation covers the contracted services.
- Purchase documents impose additional technical and administrative requirements to satisfy necessary QA program and technical requirements.
- 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 the domestic calibration service suppliers.
- This method is applicable to subsuppliers of calibration service suppliers, provided the above conditions are met.

CERTIFICATE OF CONFORMANCE

When a certificate of conformance is used to accept material, equipment or service:

- The certificate shall identify the purchased material, equipment or service to the specific procurement document.
- The certificate shall identify the specific procurement requirements met by the purchased material, equipment or service, such as codes, standards, pre-installation tests, and other specifications. This may be accomplished by including a list of the specific requirements or by providing, onsite, a copy of the purchase order and the procurement specifications or drawings, together with a suitable certificate.
- The procurement requirements identified shall include any approved changes, waivers or deviations applicable to the material, equipment or service.
- The certificate shall identify any procurement requirements that have not been met, together with an explanation and the means for resolving nonconformances.

- The certificate shall be signed and dated or otherwise authenticated by an individual who is responsible for the supplier's quality assurance function and whose responsibilities and position are described in the supplier's quality assurance program.

- The certification process, including the implementing documents to be followed in filling out a certificate and the administrative implementing documents for review and approval of the certificates, shall be described in the supplier's quality assurance program.

- Measures shall be identified to verify the validity of supplier certificates and the effectiveness of the certification process (such as by audit of the supplier or by an independent inspection or test of the item). Verifications shall be conducted by UniStar Nuclear at intervals commensurate with the past quality performance of the supplier.

SOURCE VERIFICATION

UniStar Nuclear may accept material, equipment or service by monitoring, witnessing or observing activities performed by the supplier. This method of acceptance is called source verification. Source verification shall be implemented consistent with the supplier's planned inspections, examinations or tests at predetermined points and performed at intervals consistent with the importance and complexity of the item. Documented evidence of acceptance of source verified material, equipment or services shall be furnished to the receiving destination of the item, to UniStar Nuclear, and to the supplier. Personnel qualified in accordance with the applicable requirements for the material, equipment or service being procured shall perform source verification.

RECEIVING INSPECTION

When receiving inspection is used to accept an item:

- The inspection shall consider any source verifications/audits and the demonstrated quality performance of the supplier.

- The inspection shall be performed in accordance with established inspection procedures.

- The inspection shall verify, as applicable, proper configuration; identification; dimensional, physical and other characteristics; freedom from shipping damage; and cleanliness.

- The inspection shall be planned and executed according to the requirements of Section J, "Inspection."

- Receiving inspection shall be coordinated with a review for adequacy and completeness of any required supplier documentation submittals.

POST-INSTALLATION TESTING

When post-installation testing is used as a method of acceptance, the UniStar Nuclear procurement organization and/or the affected/involved UniStar Nuclear organization manager

establishes post-installation test and acceptance documentation giving due consideration to supplier recommendations. The UniStar Nuclear procurement organization is ultimately responsible for ensuring appropriate test requirements and acceptance documentation are established.

CONTROL OF SUPPLIER NONCONFORMANCES

UniStar Nuclear procurement management and the supplier shall establish and document the process for disposition of items that do not meet procurement document requirements. The supplier shall evaluate nonconforming items according to the applicable requirements of the purchase order and submit a report of the nonconformance to UniStar Nuclear, including the supplier recommended disposition (for example, use-as-is or repair) and technical justification. Reports of nonconformances to procurement document requirements, or documents approved by UniStar Nuclear, shall be submitted to the UniStar Nuclear Engineering organization for approval of the recommended disposition whenever one of the following conditions exists:

- Technical or material requirements are violated.
- A requirement in supplier documents, which have been approved by UniStar Nuclear, is violated.
- The nonconformance cannot be corrected by continuation of the original manufacturing process or by re-work.
- The item does not conform to the original requirement, even though the item can be restored to a condition such that the capability of the item to function is unimpaired.

UniStar Nuclear Engineering shall disposition the supplier's recommendation and verify implementation of the disposition. UniStar Nuclear will maintain records of the supplier-submitted nonconformances.

APPROVED SUPPLIER LIST

The UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement is responsible for the development and maintenance of the UniStar Nuclear AVL. The AVL contains those suppliers with acceptable QA Programs that have been evaluated and accepted by UniStar Nuclear QA in accordance with approved procedures. The UniStar Nuclear QA organization is responsible for the procurement audit program. Satisfactory results will allow the supplier to remain on the AVL. Suppliers that have unacceptable evaluations or that have not had a procurement placed with them in three years will be removed from the AVL.

COMMERCIAL-GRADE ITEMS

Controls are imposed for the selection, determination of suitability for intended use (critical characteristics), evaluation, receipt and acceptance of commercial-grade items or services to assure they will perform satisfactorily in service in safety-related applications.

Controls for purchased commercial-grade items and services are established in procedures using 10 CFR 21 and the guidance of EPRI NP-5652, June 1988, "Guideline for the Utilization of Commercial Grade Items in Nuclear Safety-Related Applications (NCIG-07)," as modified by Generic Letter 89-02, 3/21/89, "Actions to Improve the Detection of Counterfeit and Fraudulently Marketed Products," and Generic Letter 91-05, 4/9/91, "Licensee Commercial-Grade Procurement and Dedication Programs."

For commercial-grade items, special quality verification requirements are established and described in procedures to provide the necessary assurance an item will perform satisfactory in service. Procedures address determining the critical characteristics that ensure an item is suitable for its intended use, a technical evaluation of the item, receipt requirements, and quality evaluation of the item.

Other appropriate approved regulatory means and controls will be used to support commercial-grade dedication activities. UniStar Nuclear assumes 10 CFR 21 reporting responsibility for all items that UniStar Nuclear dedicates as safety-related.

SECTION H

IDENTIFICATION AND CONTROL MATERIALS, PARTS AND COMPONENTS

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 8, Identification and Control of Materials, Parts and Components, of 10 CFR 50, Appendix B; and
- Basic Requirement 8 and Supplement 8S-1 of NQA-1-1994.

The controls necessary to ensure that only correct and accepted items (consumables, items with limited shelf life, materials, parts, and components, including partially fabricated assemblies) are used or installed will be required by the appropriate QA procedure. These identification and control measures are designed to prevent the use of incorrect or defective material, parts and components. Identification requirements for materials, parts and components are stated in design specifications, drawings, and procurement documents. Specific identification requirements are as follows.

- Items of production (batch, lot, component, part) are identified from the initial receipt and fabrication of the items up to and including installation and use. This identification relates an item to an applicable design or other pertinent specifying document.
- Physical identification is used to the maximum extent possible. Where physical identification on the item is either impractical or insufficient, physical separation, procedural control, or other appropriate means are employed.
- Identification markings, when used, are applied using materials and methods which provide a clear and legible identification and do not detrimentally affect the function or service life of the item. Markings are transferred to each part of an identified item when subdivided, and cannot be obliterated or hidden by surface treatment or coatings unless other means of identification are substituted. Sufficient precautions shall be taken to preclude identifying materials in a manner that degrades the function or quality of the item being identified.
- When required by specifications or codes and standards, that include specific identification or traceability requirements (such as identification or traceability of the item to applicable specification and grade of material; heat, batch, lot, part, or serial number; or specified inspection, test, or other records) the program shall be designed to such identification and traceability control.

Where specified, items having limited calendar or operating life or cycles shall be identified and controlled to preclude use of items whose shelf life or operating life has expired.

Provisions are made for the control of item identification consistent with the planned duration and conditions of storage, such as the following:

- Provisions for maintenance or replacement of markings and identification records from damage during handling or aging
- Protection of identifications on items subject to excessive deterioration from environmental exposure
- Provisions for updating existing plant records

SECTION I

CONTROL OF SPECIAL PROCESSES

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 9, Control of Special Processes, of 10 CFR 50, Appendix B; and
- Basic Requirement 9 and Supplement 9S-1 of NQA-1-1994.
- Supplement 2S-2 of NQA-1-1994, except for qualification of Nondestructive Examination personnel which is addressed here.

Processes affecting the quality of items or services shall be controlled by written procedures using drawings, checklists, travelers or other appropriate means. These means shall ensure that the process parameters are controlled and that specified environmental conditions are maintained. Special processes that control or verify quality, such as those used in welding, heat treating, and nondestructive examination, shall be performed by qualified personnel using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements.

SPECIAL PROCESSES

For the purpose of this section, a special process is a process, the results of which are highly dependent on the control of the process or the skill of the operators, or both, and in which the specified quality cannot be readily determined by inspection or test of the product.

Special processes that control or verify quality shall be controlled according to the requirements of this section whether or not they are covered by existing codes and standards, or whether or not the quality requirements specified for an item exceed those of existing codes or standards

PERSONNEL, IMPLEMENTING DOCUMENTS, AND EQUIPMENT QUALIFICATIONS

Implementing UniStar Nuclear documents shall be used to ensure that process parameters are controlled and that the specified environmental conditions are maintained. Each special process shall be performed in accordance with appropriate implementing documents and these implementing documents shall include or reference:

- The responsibility of the organization performing the special process to adhere to the approved procedures and processes,
- Qualification requirements for personnel, implementing documents and equipment,
- Conditions necessary for accomplishment of the special process. These conditions shall include proper equipment, controlled parameters of the process and calibration requirements, and/or

- Requirements of applicable codes and standards, including acceptance criteria for the special process.

For special processes not covered by existing codes and standards or where quality requirements specified for an item exceed those of existing codes or standards, the necessary requirements for qualifications of personnel, procedures, or equipment shall be specified or referenced in the procedures or instructions.

QUALIFICATION/CERTIFICATION OF NONDESTRUCTIVE EXAMINATION (NDE) PERSONNEL

Nondestructive Examination (NDE) personnel performing QA Level 1 activities shall be certified in accordance with specified requirements.

In lieu of Supplement 2S-2, for qualification of Nondestructive Examination personnel, certification shall be to the applicable versions of the standards referenced in Section XI of the ASME code, as permitted for use by 10 CFR Part 50.55a, for performing nondestructive examinations required by ASME Code Sections III or Section XI, or design specifications, provided that other applicable rules contained in Section XI of the ASME Code are met

DOCUMENTATION

Records shall be maintained as appropriate in accordance with Section Q, "Records," for currently qualified personnel, processes and equipment of each special process.

SECTION J

INSPECTION

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 10, Inspection, of 10 CFR 50, Appendix B; and
- Basic Requirement 10 and Supplement 10S-1 of NQA-1-1994; and
- The following Subparts from NQA-1-1994:
  - Subpart 2.4, "Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities," with the exceptions noted in Section U, and
  - Subpart 2.5, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Power Plants," with the exception noted in Section U, and
  - Subpart 2.8, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for Nuclear Power Plants"

Inspections required to verify conformance of an item or activity to specified requirements are planned and executed. Characteristics to be inspected and inspection methods to be employed are specified in procedures. Inspection results are documented. Inspection requirements and acceptance criteria shall include specified requirements contained in the applicable design documents or other pertinent technical documents approved by the responsible design organization. Inspection activities are documented and controlled by instructions, procedures, drawings, checklists, travelers or other appropriate means.

INSPECTION PLANNING

Inspection planning shall be performed, documented and include:

- Identification of each work operation where inspection is necessary to ensure quality and implementing documents that shall be used to perform the inspections;
- Identification of the characteristics to be inspected and the identification of when, during the work process, inspections are to be performed;
- Identification of inspection or process monitoring methods to be employed;
- The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements;

- Identification of the functional qualification level (category or class) of personnel performing inspections;
- Identification of acceptance criteria;
- Methods to record objective evidence of inspection results; and
- Selection and identification of the measuring and test equipment to be used to perform the inspection.

SELECTING INSPECTION PERSONNEL TO PERFORM INSPECTION

All individuals who perform an inspection to verify conformance of an item to specified acceptance criteria shall be qualified to perform the assigned inspection tasks in accordance with the requirements of Section T, "Training and Qualification-Inspection and Test." Data recorders, equipment operators or other inspection team members who are supervised by a qualified inspector shall not be required to be a qualified inspector. Verification of conformance shall be by a qualified person.

With the exception of receipt inspectors, inspection personnel for construction phase activities will be members of the QA organization. Receipt inspectors, given the nature of the receipt inspection activities are independent from those responsible for performing the function, i.e., the supplier.

During the operations phase, inspections required for modification activities will be performed by personnel from the QA organization.

In the operational phase, inspections are performed by individuals other than those who performed the activity being inspected. These inspection personnel do not report directly to the immediate supervisors who are responsible for performing the work being inspected.

INSPECTION HOLD POINTS

When mandatory hold points are used to control work that shall not proceed without the specific consent of the organization placing the hold point, the specific hold points shall be indicated in implementing documents. Consent to waive specified hold points shall be documented and approved before continuing work beyond the designated hold point.

STATISTICAL SAMPLING

When statistical sampling is used to verify the acceptability of a group of items, the statistical sampling method used shall be based on recognized standard practices and these practices shall be implemented through applicable approved procedures.

IN-PROCESS INSPECTIONS AND MONITORING

Items shall be inspected when necessary to verify quality. If inspection of processed items is impossible or disadvantageous, indirect control by monitoring of processing methods, equipment and personnel shall be provided. Inspection and process monitoring shall be conducted when

control is inadequate with only one method. A combination of inspection and process monitoring methods, when used, shall be performed in a systematic manner to ensure that the specified requirements for control of the process and the quality of the item are met throughout the duration of the process. Controls shall be established and documented for the coordination and sequencing of inspections and monitoring at established inspection points during successive stages of the process or construction.

FINAL INSPECTION

Finished items shall be inspected for completeness, markings, calibration, adjustments, protection from damage or other characteristics as required in order to verify the quality and conformance of the item to specified requirements. Documentation not previously examined shall be examined for adequacy and completeness. The final inspection shall be planned to arrive at a conclusion regarding conformance of the item to specified requirements. Final inspections shall include a review of the results and resolution of any nonconformances identified by earlier inspections. Modifications, repairs or replacements of items performed subsequent to final inspection shall require re-inspection or retest, as appropriate, to verify acceptability.

ACCEPTING ITEMS

The acceptance of an item shall be documented and approved by qualified and authorized personnel. The inspection status of an item shall be identified in accordance with Section N, "Inspection, Test and Operating Status."

INSPECTION DOCUMENTATION

Inspection documentation shall identify:

- The item inspected, date of inspection, the name of the inspector who documented, evaluated and determined acceptability;
- Name of data recorder, as applicable, and type of observation or method of inspection;
- The inspection criteria, sampling plan or reference documents (including revision levels) used to determine acceptance;
- Results or acceptability of characteristics inspected;
- Measuring and test equipment used during the inspection including the identification number and the most recent calibration date; and
- Reference to information on actions taken in connection with nonconformances, as applicable.

SECTION K

TEST CONTROL

The elements of the UniStar Nuclear QA Program described in this section and Section T, "Training And Qualification - Inspection And Test," and associated procedures implement the requirements of:

- Criterion 11, Test Control, of 10 CFR 50, Appendix B; and
- Basic Requirement 11 and Supplements 11S-1 and 11S-2 of NQA-1-1994; and
- The following Subparts of NQA-1-1994:
  - Subpart 2.4, "Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities," with the exceptions noted in Section U, and
  - Subpart 2.8, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for Nuclear Power Plants"

Tests required to verify conformance of an item or computer program to specified requirements and to demonstrate satisfactory performance for service are planned and executed. Characteristics to be tested and test methods to be employed are specified. Test results are documented and their conformance with acceptance criteria is evaluated. Tests required to collect data, such as for siting or design input, shall be planned, executed, documented and evaluated.

TEST REQUIREMENTS

Test requirements and acceptance criteria shall be provided or approved by the organization responsible for the design of the item to be tested unless otherwise designated. Required tests including, as appropriate, prototype qualification tests, production tests, proof tests prior to installation, construction tests, pre-operational tests, and operational tests are controlled. Test requirements and acceptance criteria are based upon specified requirements contained in applicable design or other pertinent technical documents.

TEST PROCEDURES

Test procedures shall include:

- Test objectives and the identification of any implementing documents to be developed to control and perform tests as appropriate
- Identification of items to be tested, test requirements and acceptance limits, including required levels of precision and accuracy;
- Identification of test methods to be employed and instructions for performing the test;

- Test prerequisites that address calibrated instrumentation, appropriate and adequate test equipment/instrumentation, trained personnel, condition of test equipment and the item to be tested, suitably controlled environmental conditions and provisions for data acquisition;

- Mandatory test hold points and methods to record data and results;

- Provisions for ensuring that prerequisites for the given test have been met;

- Selection and identification of the measuring and test equipment to be used to perform the test to ensure that the equipment is of the proper type, range, accuracy, and tolerance to accomplish the intended function; and

- Identification of the functional qualification level of personnel performing tests.

PERFORMING TESTS

Tests shall be performed in accordance with procedures that address the following requirements as applicable:

- Provisions for determining when a test is required, describing how tests are performed, and ensuring that testing is conducted by trained and appropriately qualified personnel.

- Include or reference test objectives and provisions for ensuring that prerequisites for the given test have been met, adequate calibrated instrumentation is available and used, necessary monitoring is performed and suitable environmental conditions are maintained.

- Test requirements and acceptance criteria provided or approved by the organization responsible for the design of the item to be tested, unless otherwise designated.

- Test requirements and acceptance criteria based upon specified requirements contained in applicable design or other pertinent technical documents.

- Potential sources of uncertainty and error. Test parameters affected by potential sources of uncertainty and error shall be identified and controlled.

USE OF OTHER TESTING DOCUMENTS

Other testing documents (e.g., American Society for Testing and Materials (ASTM)) specifications, supplier manuals or other related documents containing acceptance criteria may be used instead of preparing special test procedures. If used, the information shall be incorporated by reference in the approved test procedure. Implementing documents shall include adequate supplemental instructions as required to ensure the required quality of the testing work.

TEST RESULTS

Test results shall be documented and their conformance with acceptance criteria shall be evaluated by a qualified individual within the responsible organization to ensure that test requirements have been satisfied.

TEST DOCUMENTATION

Test documentation shall include:

- Item or work product tested, date of test, names of tester and data recorders, type of observation and method of testing;
- Identification of test criteria or reference documents used to determine acceptance;
- Results and acceptability of the test;
- Actions taken in connection with any nonconformances or deviations noted;
- Name of the person evaluating the test results; and
- Identification of the measuring and test equipment (M&TE) used during the test.

Training and Qualification of Test personnel shall be in accordance with Section T, "Training and Qualification - Inspection and Test."

SECTION L

CONTROL OF MEASURING AND TEST EQUIPMENT

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 12, Control of Measuring and Test Equipment, of 10 CFR 50, Appendix B; and
- Basic Requirement 12 and Supplement 12S-1 of NQA-1-1994.

This section establishes UniStar Nuclear control for tools, gages, instruments, reference and transfer standards, non destructive examination equipment, and other measuring and test equipment (M&TE) used for activities affecting quality, including design activities where applicable, construction, and operation. M&TE is controlled and at specified periods calibrated and adjusted to maintain accuracy within necessary limits. Selection of M&TE shall be controlled to ensure that such items are of proper type, range, accuracy, and tolerance to accomplish the functions of determining conformance to specified requirements.

Measuring and test equipment is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure its traceability to calibration test data.

CALIBRATION

The method and interval of calibration for each item shall be defined, based on the type of equipment stability characteristics, required accuracy, intended use, and other conditions affecting measurement control.

M&TE shall be calibrated, adjusted and maintained at prescribed intervals or, prior to use, against certified equipment having known valid relationships to nationally recognized standards. If no nationally recognized standards exist, the basis for calibration shall be documented.

For M&TE used in one-time-only applications, the calibration shall be performed both before and after use.

A calibration shall be performed when the accuracy of calibrated M&TE is suspect.

DOCUMENTING THE USE OF M&TE

The use of M&TE shall be documented. As appropriate to equipment use and its calibration schedule, the documentation shall identify the processes monitored, data collected and items inspected or tested since the last calibration.

OUT OF CALIBRATION M&TE

M&TE shall be considered to be out-of-calibration and not be used until calibrated. Out-of-calibration M&TE shall be tagged, segregated or otherwise controlled to prevent use until they have been recalibrated.

When M&TE is found out-of-calibration, the validity of results obtained using that equipment since its last valid calibration shall be evaluated to verify the acceptability of previously collected data or processes monitored for items previously inspected or tested. The evaluation shall be documented.

If any M&TE is consistently found out-of-calibration during the re-calibration process, it shall be repaired or replaced.

LOST M&TE

When M&TE is lost, the validity of results obtained using that equipment since its last valid calibration shall be evaluated to determine the acceptability of previously collected data or processes monitored for items previously inspected or tested. The evaluation shall be documented.

HANDLING AND STORAGE

M&TE shall be properly handled and stored to maintain accuracy.

COMMERCIAL DEVICES

Calibration and control shall not be required for rulers, tape measures, levels and other normal commercial equipment that provides adequate accuracy

M&TE DOCUMENTATION

Records of calibration status and the capability of measuring and test equipment to perform its intended function are maintained.

PROCUREMENT OF COMMERCIAL GRADE-CALIBRATION SERVICES

Section G, "Control Of Purchased Material, Equipment and Services," provides the details on the procurement of commercial-grade calibration services.

SECTION M

HANDLING, STORAGE, AND SHIPPING

The elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 13, Handling, Storage and Shipping, of 10 CFR 50, Appendix B; and
- Basic Requirement 13 and Supplement 13S-1 of NQA-1- 1994; and
- The following from NQA-1- 1994, (Construction Phase only)
    - Subpart 2.1, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants,"
    - Subpart 2.2, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants,"
    - Subpart 2.15, "Quality Assurance Requirements for Hoisting, Rigging, and Transporting Items for Nuclear Power Plants."

Handling, storage, cleaning, packaging, shipping and preservation of items are controlled in accordance with requirements of this section to prevent damage or loss and to minimize deterioration.

CONTROLS

Handling, storage, and shipping of items shall be conducted in accordance with established work and inspection instructions, drawings, specifications, shipment instructions, or other pertinent documents or procedures specified for use in conducting the activity.

When required for particular items, special equipment (such as containers, shock absorbers, and accelerometers) and special protective environments (such as inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified, provided, and their existence verified.

When required for critical, sensitive, perishable, or high-value articles, specific procedures for handling, storage, packaging, shipping, and preservation shall be used.

During the operations phase the following are applicable:

- Controls for the packaging, shipping, handling and storage of items are required to be established on a case-by-case basis with due regard for the item's complexity, use, and sensitivity to damage.
- Prior to installation or use, items are inspected and serviced as necessary to ensure that no damage or deterioration exists which could effect their function.

- Controls for hoisting, rigging, and transport activities are established that protect the integrity of the item involved as well as potentially affected nearby structures and components. Applicable hoisting, rigging, and transportation regulations and codes shall be followed.

- Cleanliness controls for work on safety–related and risk-significant nonsafety-related equipment are required to be established that minimize the introduction of foreign material and maintain system/component cleanliness throughout maintenance or modification activities. Procedures require documented verification of absence of foreign material prior to system closure.

SPECIAL HANDLING TOOLS AND EQUIPMENT

Special handling tools and equipment shall be used and controlled as necessary to ensure safe and adequate handling. Special handling tools and equipment shall be inspected and tested at specified time intervals and in accordance with procedures to verify that the tools and equipment are adequately maintained.

Operators of special handling and lifting equipment shall be experienced or trained in the use the equipment.

MARKING AND LABELING

Measures shall be established for marking and labeling for the packaging, shipping, handling and storage of items as necessary to adequately identify, maintain and preserve the item. Markings and labels shall indicate the presence of special environments or the need for special controls if necessary.

SECTION N

INSPECTION, TEST, AND OPERATING STATUS

During the operations phase, the elements of the UniStar Nuclear QA Program described in this section and associated procedures implement the requirements of:

- Criterion 14, Inspection, Test and Operating Status, of 10 CFR 50, Appendix B; and
- Basic Requirement 14 of NQA-1-1994.

This section establishes requirements for UniStar Nuclear to identify the status of inspection and test activities. Status is indicated either on the items or in documents traceable to the items where it is necessary to assure that required inspections and tests are performed and to assure that items which have not passed the required inspections and tests are not inadvertently installed, used or operated.

Status is maintained through indicators (i.e., physical location and tags, markings, shop travelers, stamps, inspection records or other suitable means). The authority for application and removal of tags, markings, labels and stamps are specified in procedures. Procedures require independent verifications, where appropriate, to ensure that necessary measures such as tagging equipment have been implemented correctly.

During operation, in order to ensure that equipment status is clearly evident, and to prevent inadvertent operation, the UniStar Nuclear QA Program requires structures, systems and components that are inoperable to be identified as such. This identification may be by means of tags, labels, stamps or other suitable methods. When tags, labels, or stamps are utilized for the identification of equipment status, the issuance and removal thereof is documented to ensure proper control of such identification measures.

Process control procedures, test and inspection procedures, nonconforming item control procedures, installation records and checklists are used as applicable to control the installation of structures, system and components. These documents contain hold points, activity checklists, and in many cases, step-by-step signoffs which indicate the status of fabrication, installation, inspections, and test. This system is used to prevent inadvertent use of nonconforming items or bypassing of inspections and tests and prevent inadvertent operation.

Temporary modifications, such as temporary bypass lines, electrical jumpers, lifted electrical leads, and temporary trip point settings, are controlled by approved procedures, which include a requirement for independent verification.

Changing the sequence of inspections, tests, and other activities involving safety requires the same controls as the original review and approval

SECTION O

NONCONFORMING MATERIALS, PARTS, OR COMPONENTS

The elements of the UniStar Nuclear QA Program described in this section and associated QA procedures implement the requirements of:

- Criterion 15, Nonconforming Items, of 10 CFR 50, Appendix B; and
- Basic Requirement 15 and Supplement 15S-1 of NQA-1-1994.

This section provides the process for controlling items that do not conform to specified requirements (i.e., a nonconforming item is a deficiency in characteristic, documentation, or procedure that renders the quality of an item unacceptable or indeterminate) to prevent its inadvertent test, installation, or use. For the purposes of this QAPD, items referenced to in this section means materials, parts, or components. The control of nonconforming activities and services is described in Section P, "Corrective Action." Procedures are used, as appropriate, to provide for identification, documentation, evaluation, segregation when practical, disposition of nonconforming items, and for notification to affected organizations.

DOCUMENTING AND EVALUATING NONCONFORMING ITEMS

Nonconformance documentation shall clearly identify and describe the characteristics that do not conform to specified criteria. Nonconformance documentation shall be reviewed by the responsible affected organization and recommended dispositions of nonconforming items shall be proposed in accordance with procedures. The review shall include determining the need for additional corrective actions according to the requirements of Section P, "Corrective Action." In addition, nonconformances shall be evaluated as required by 10 CFR Part 21 and/or 10 CFR 50.55(e) for reporting of defects and noncompliance. Organizations affected by the nonconformance shall be notified. Recommended dispositions shall be evaluated and approved in accordance with procedures. Personnel performing evaluations of recommended dispositions shall have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information. The responsibility and authority for reviewing, evaluating, approving the disposition and closing nonconformances shall be specified in procedures. The UniStar Nuclear procurement organization is responsible for administering the nonconformance process for external agencies, e.g., suppliers. The UniStar Nuclear Engineering organization is responsible for the internal organizations. Further processing, delivery, installation or use of a nonconforming item shall be controlled pending the evaluation and approval of the disposition by authorized personnel.

IDENTIFYING NONCONFORMING ITEMS

Employees of UniStar Nuclear and UniStar Nuclear contractors have a procedural obligation to identify and document nonconformances. Nonconforming items shall be identified by marking, tagging or other methods that do not adversely affect their end use. The identification shall be legible and easily recognizable. If the identification of a nonconforming item is not practical, the container, package or segregated storage area, as appropriate, shall be identified.

SEGREGATING NONCONFORMING ITEMS

Nonconforming items shall be segregated, when practical, by placing them in a clearly identified and designated hold area until properly dispositioned. If segregation is impractical or impossible due to physical conditions, then other precautions shall be employed to preclude inadvertent use.

DISPOSITION OF NONCONFORMING ITEMS

The disposition, such as "use-as-is," "reject," "repair," or "rework," of nonconforming items shall be identified and documented. The technical justification for the acceptability of a nonconforming item that has been dispositioned "repair" or "use-as-is" shall be documented.

Items that do not meet original design requirements that are dispositioned "use-as-is" or "repair" shall be subject to design control measures commensurate with those applied to the original design. If changes to the specifying document are required to reflect the as-built condition, the disposition shall require action to change the specifying document to reflect the accepted nonconformance. Any document or record change required by the disposition of the nonconformance shall be identified in the nonconformance documentation; and, when each document or record is changed, the justification for the change shall identify the nonconformance documentation. The disposition of an item to be reworked or repaired shall contain a requirement to reexamine (inspect, test, or nondestructive examination) the item to verify acceptability.

Reworked, repaired or replacement items shall be reexamined in accordance with applicable procedures using the original process and acceptance criteria unless the nonconforming item disposition has established alternate acceptance criteria.

SECTION P

CORRECTIVE ACTION

The elements of the UniStar Nuclear QA Program described in this section and associated QA procedures implement the requirements of:

- Criterion 16, Corrective Action, of 10 CFR 50, Appendix B, and
- Basic Requirement 16 of NQA-1-1994.

Conditions adverse to quality, including activities and services, shall be identified promptly and corrected as soon as practical. Conditions adverse to quality is an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. Conditions adverse to quality shall be documented.

UniStar Nuclear procedure(s) shall be issued to establish the Corrective Action Program (CAP), which 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.

Personnel performing evaluations to determine a corrective action/disposition have demonstrated competence in the specific area they are evaluating, have an adequate understanding of the requirements, and have access to pertinent background information.

IDENTIFYING AND CLASSIFYING CONDITIONS ADVERSE TO QUALITY

Conditions adverse to quality shall be classified in one of two categories in regard to their significance, and corrective actions shall be taken accordingly. The two categories of significance include:

- Conditions adverse to quality
- Significant conditions adverse to quality

Responsible management shall investigate and fully identify the condition and document the results. Responsible management shall then utilize investigation results to determine and document corrective action (including remedial action and if appropriate, actions to prevent recurrence). Responsible management shall complete remedial action and document completion of actions in a timely manner.

Significant condition adverse to quality is defined as

- A deficiency that would seriously impact an item, activity or service from meeting or performing its intended function or output of assuring public health and safety;
- A deficiency in design that has been approved for fabrication or construction where the design deviates extensively from design criteria and bases;
- A deficiency in the fabrication or construction of, or significant damage to, structures, systems or components that require extensive evaluation, re-design or repair in order to establish the adequacy of the structure, system or component to perform its intended function of assuring public health and safety
- A deviation from performance specifications that shall require extensive evaluation, redesign, or repair to establish the adequacy of the structure, system or component to perform its intended function;
- A significant error in a computer program used to support activities affecting quality after it has been released for use;
- A deficiency, repetitive in nature, related to an activity or item subject to the UniStar Nuclear QA Program; and
- A condition that, if left uncorrected, has the potential to have a serious negative impact on activities or items subject to the UniStar Nuclear QA Program controls.

For significant conditions adverse to quality, the cause of the condition shall be determined and corrective action taken to preclude recurrence. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management. Follow-up action shall be taken to verify implementation of the corrective action.

Significant conditions adverse to quality shall be evaluated for reportability to the NRC (when required) in accordance with 10 CFR Part 21 and/or 10 CFR 50.55(e), or other applicable reporting requirements, and reporting such conditions when warranted.

Significant conditions adverse to quality shall be evaluated for a stop work condition to determine if stopping work is warranted. If a stop work condition is identified, management shall issue stop work in accordance with the applicable procedure. Upon resolution of the related significant condition adverse to quality, management shall take appropriate action to lift and close (in part or total) the stop work order.

FOLLOW-UP ACTION

The procedure(s) establishing the CAP shall include a requirement for management to take follow-up action to verify implementation of corrective action taken to address significant conditions adverse to quality. The QA organization shall be responsible for conducting periodic assessments of these follow-up actions.

TRENDING

The procedure(s) establishing the CAP shall assign organizational responsibility for trending conditions adverse to quality and the criteria for determining adverse trends. Trend evaluation shall be performed in a manner and at a frequency that provides for prompt identification of adverse quality trends. Identified adverse trends shall be handled in accordance with the CAP described here and reported to the appropriate level of management.

SECTION Q

RECORDS

The elements of the UniStar Nuclear QA Program described in this section and associated QA procedures implement the requirements of:

- Criterion 17, Quality Assurance Records, of 10 CFR 50, Appendix B; and
- Basic Requirement 17 and Supplement 17S-1 of NQA-1- 1994, except for the storage of hard copy records (subsection 4.2(b)) which is addressed here; and
- Generic Letter 88-18, "Plant Record Storage on Optical Disks;" and
- The following Industry Standards:
    - Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guide (TG) 11-1998, "Authentication of Records and Media"
    - NIRMA TG 15-1998, "Management of Electronic Records"
    - NIRMA TG 16-1998, "Software Configuration Management and Quality Assurance"
    - NIRMA TG 21-1998, "Electronic Records Protection and Restoration"

Measures have been established that ensure that sufficient records of completed items and activities affecting quality are appropriately stored.

The records system(s) is defined, implemented, and enforced in accordance with written procedures, instructions, or other documentation. Records may be hard copy or electronic records. The term "record(s)" used throughout this section is to be interpreted as "Quality Assurance Record(s)," unless otherwise specified.

For records in electronic media, the program includes provisions for the generation, distribution, use, maintenance, storage, and disposition of electronic records. The plan provides for all acceptable media on which electronic records are created and stored. Also, the program includes provisions to verify that the media is appropriate, suitable for the capture or storage of records, and error/defect free. The UniStar Nuclear records management program implements Generic Letter 88-18, "Plant Record Storage on Optical Disks."

The records management program provide provisions for the administration, receipt, storage, preservation, safekeeping, retrieval, and disposition of all records. All electronic records are retrievable, maintained in a readable format, and safeguarded against equipment malfunction or human error. Document access controls, user privileges, and other appropriate security controls have been established. Periodic inspections of systems, software applications, and media are performed to ensure electronic records retrievability, integrity, and retention period.

Records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, materials analyses, training and qualification. Design documentation and records, which provide evidence that the design and design verification processes were properly performed are collected, stored, and maintained in accordance with documented procedures. The documentation includes not only final design documents, such as drawings and specifications, and revisions thereto but also documentation which identifies the important steps, including sources of design inputs that support the final design.

The program requires that records be examined for adequacy, legibility and completeness.

Requirements and responsibilities for record transmittal, location, distribution, retention, maintenance, and disposition have been described. Training is provided for individuals or organizations in charge of electronic records generation, data/media storage, implementation of security measures, migration/regeneration, and recovery.

The applicable design specifications, procurement documents, test procedures, operational procedures, or other documents specify the records generated, supplied, or maintained.

AUTHENTICATION

Documents are considered valid records only if stamped, initialed, authenticated, or signed and dated by authorized personnel. This authentication may take the form of a statement by the responsible individual or organization. Handwritten signatures are not required if the document is clearly identified as a statement by the reporting individual or organization. These records may be originals or reproduced copies. For electronic records, authentication is accomplished by manually affixing seal, signature, an electronic representation (user ID/password combination, digital signature) or other acceptable process control that ensures genuineness, validity, or reliability. Authorized personnel with access to electronic records and information systems should have a unique user ID/password for access. The system provides controls for users who enter or alter information in electronic records to ensure its data integrity and prevent unauthorized alteration or erasure. Transfer of authentication authority is documented and controlled in accordance with written procedures.

The records and/or indexing system(s) provides sufficient information to permit identification between the record and the item(s) or activity(ies) to which they apply. For electronic records, in addition to the minimum indexing information requirements, the software name, version, and equipment (hardware) used to produce and maintain the electronic media shall be provided.

RECORDS CLASSIFICATION

Records are classified as Lifetime or Nonpermanent. Lifetime records are those that meet one or more of the following criteria:

a. Significant value in demonstrating capability for safe operation

b. Significant value in maintaining, reworking, repairing, replacing, or modifying an item

c. Significant value in determining the cause of an accident or malfunction of an item

d. Provision of required baseline data for inservice inspections and inservice tests

Lifetime records are required to be maintained for the life of the particular item while it is installed in the plant or stored for future use.

Nonpermanent records are those required to show evidence that an activity was performed in accordance with the applicable requirements, but need not be retained for the life of the item because they do not meet the criteria for lifetime records. The retention period for nonpermanent records is established in writing.

Electronic records classified as lifetime or nonpermanent are subject to the same retention requirements prescribed for paper records/hardcopies. Retention requirements for electronic records also identify and maintain the information system (software/hardware), the documentation that describes the information system operation and use, and the record standard it produces.

ELECTRONIC RECORD MIGRATION

An electronic record migration/regeneration program is implemented for electronic records stored in media with a standard life expectancy that fails to meet the specific retention period. This program is implemented in accordance with documented procedures that provide for appropriate record authentication, quality verification of the completion, and accuracy of the data transferred.

STORAGE

Electronic media shall be stored in a dust-free environment, away from electronic devices and demagnetizing equipment. Media shall be maintained at the constant temperature of 40 to 80 degrees Fahrenheit, with a constant relative humidity of 30 to 50 percent. Magnetic and optical media shall be tested periodically to identify any loss of data, to ensure that they are free of permanent errors, and that the record system hardware/software still supports the retrieval of the records.

Non-electronic records shall be stored in facilities that minimize the risk of damage or destruction from the following:

- Natural disasters (i.e., winds, floods or fires);
- Environmental conditions (i.e., high and low temperatures and humidity);
- Infestation of insects, mold or rodents.

Originating organizations shall store records in temporary storage while active and required for use; subsequently the records shall be transmitted for permanent storage.

Temporary storage of records during processing, review or use, until turnover to the records management organization is controlled according to implementing procedures and the following requirements:

- Records shall be temporarily stored in a container or facility with a fire rating of one (1) hour. The temporary storage container or facility shall bear an Underwriters' Laboratories label (UL) (or equivalent) certifying one (1) hour fire protection, or be certified by a person competent in the technical field of fire protection.

- The maximum time limit for keeping records in temporary storage shall be specified by implementing procedures consistent with the nature or scope of work

RECORDS CORRECTION

Records are corrected in accordance with procedures which provide for appropriate review or approval by the originating organization. The correction includes the date and the identification of the person authorized to issue such correction. For records stored in electronic media, a new record is generated when substantial corrections or changes to previous electronic records are required.

RECEIPT CONTROL

The UniStar Records Management organization has been designated as the organization responsible for receiving the records. This organization is responsible for organizing and implementing a system of receipt control of records for permanent and temporary storage, and for providing protection from damage or loss during the time that the records are in his/her possession. For electronic records, in addition to the requirements described above, the organization is also responsible for organizing and implementing an inventory of system applications, record formats, and programs required to process and retrieve electronic records.

At a minimum, a receipt control system includes the following:

a. A method for designating the required records

b. A method for identifying records received

c. Procedures for receipt and inspection of incoming records

d. A method for submittal of completed records to the storage facility without unnecessary delay

Each receipt control system is structured to permit a current and accurate assessment of the status of records during the receiving process.

SECTION R

AUDITS

The elements of the UniStar Nuclear QA Program described in this section and associated QA procedures implement the requirements of:

- Criterion 18, Audits, of 10 CFR 50, Appendix B; and
- Basic Requirement 18 and Supplement 18S-1 of NQA-1-1994 Part 1.

Section S describes the Training and Qualification Criteria-Quality Assurance.

In accordance with the description of the QA organization during the various phases of design, construction, and operation provided in Section A, "Organization," the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement shall verify UniStar Nuclear compliance with all aspects of the UniStar Nuclear QA Program and determine QA Program effectiveness by ensuring that planned and scheduled audits are conducted. The UniStar Nuclear audit program is designed to provide a comprehensive independent evaluation of activities and procedures.

Elements that have been selected for audit shall be evaluated against specified requirements. An auditing function reports to the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement and has the organizational independence and authority to execute an effective audit process to meet all requirements of the QA Program. Objective evidence shall be examined to the depth necessary to determine if these elements are being implemented effectively. UniStar Nuclear audits are performed in accordance with written procedures or checklists by appropriately trained and qualified personnel who do not have direct responsibility for performing the activities being audited. Audit results are documented and provided to the appropriate management for review and corrective action as applicable. Follow-up action shall be taken to verify that corrective action is accomplished as scheduled.

AUDIT SCHEDULES

Internal or external audits shall be scheduled in a manner to provide coverage, consistency and coordination with ongoing work, and at a frequency commensurate with the status and importance of the work. Internal or external audits shall be scheduled to begin as early in the life of the work as practical and shall be scheduled to continue at intervals consistent with the schedule for accomplishing the work. As a minimum,

- Internal audits of organization and facility activities, conducted prior to placing a UniStar Nuclear facility in operation, shall be performed in such a manner as to assure that an audit of all applicable QA program elements is completed for each functional area at least once each year or at least once during the life of the activity, whichever is shorter. Internal audits of activities, conducted after placing the facility in operation, shall be performed 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. These audits include oversight of the design and analysis activities, the purpose of which will be to detect design errors.

- Internal audit frequencies of well established activities, excluding the audit of procedures, conducted after placing a UniStar Nuclear facility in operation, may be extended one year at a time beyond the above two-year interval based on the results of an annual evaluation of the applicable functional area and objective evidence that the functional area activities are being satisfactorily accomplished. The evaluation shall include a detailed performance analysis of the functional area based upon applicable internal and external source data and due consideration of the impact of any function area changes in responsibility, resources or management. However, the internal audit frequency interval shall not exceed a maximum of four years. If an adverse trend is identified in the applicable functional area, the extension of the internal audit frequency interval shall be rescinded and an audit scheduled as soon as practicable.

- Functional areas of the UniStar Nuclear QA program for auditing include as a minimum verification of compliance and effectiveness of implementation of internal rules, procedures (e.g., operating, design, procurement, maintenance, modification, refueling, surveillance, test, security, radiation control procedures, and the emergency plan), Technical Specifications, regulations and license conditions, programs for training, retraining, qualification and performance of operating staff, corrective actions, and observation of performance of operating, refueling, maintenance and modification activities, including associated record keeping.

- Regularly scheduled internal audits shall be supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness.

An audit schedule shall be developed annually and revised as necessary to ensure that coverage is maintained current. When any work carried out under the requirements of the QA program is delegated to others, the QA audit program shall assess the work.

PROCUREMENT AUDITS

Procurement audits are accomplished as follows:

- Audits are not necessary for procuring the following items:
    - Those that are relatively simple and standard in design, manufacturing, and testing
    - Those that are adaptable to standard or automated inspections or tests of the end product to verify quality characteristics after delivery
- Audits are conducted as follows for procurement of items not covered by the exceptions listed above:

- The supplier's QA program is audited on a triennial basis.
- The triennial period begins when the first audit is performed.
- An audit is initially performed after the supplier has completed sufficient work to demonstrate that its organization is implementing a QA program.
- If a subsequent contract or a contract modification significantly enlarges the scope of or changes the methods or controls for activities performed by the same supplier, an audit of the modified requirements is conducted, thus starting a new triennial period.
- If the supplier is implementing the same QA program for other customers that is proposed for use on the auditing party's contract, the preaward survey may serve as the first triennial audit. Therefore, when such preaward surveys are employed as the first triennial audits, they must satisfy the same audit elements and criteria as those used on other triennial audits.
- If more than one purchaser buys from a single supplier, a purchaser may either perform or arrange for an audit of the supplier on behalf of itself and other purchasers to reduce the number of external audits of the supplier. The scope of this audit should satisfy the needs of all of the purchasers, and the audit report should be distributed to all the purchasers for whom the audit was conducted. When UniStar Nuclear relies on the results of an audit performed on behalf of several purchasers, UniStar Nuclear remains individually responsible for the adequacy of the audit.

Evaluations of suppliers are documented and take into account the following, where applicable:

- Receipt inspection, operating experience, and supplier evaluation programs are reviewed on an ongoing basis as the information becomes available. The results of the review are promptly considered for effect on a supplier's continued qualification and adjustments made as necessary (including corrective actions, adjustments of supplier audit plans, and input to third party auditing entities, as warranted).
- Additionally, results are reviewed periodically to determine if, as a whole, they constitute a significant condition adverse to quality requiring additional action.
- If there is no ongoing receipt inspection or operating experience with which to analyze the supplier for a period of twelve months, an annual evaluation shall be performed as follows:
  - Review of supplier-furnished documents and records such as certificates of conformance, nonconformance notices, and corrective actions
  - Results of previous source verifications, audits, and receiving inspections
  - Operating experience of identical or similar products furnished by the same supplier

- Results of audits from other sources (e.g., customer, NUPIC, ASME, or NRC audits)

The results of the evaluation shall be reviewed by procurement management and appropriate corrective action shall be taken. Adverse findings resulting from these evaluations shall be periodically reviewed in order to determine if, as a whole, they result in a significant condition adverse to quality and to provide input to the supplier audit program. Adverse findings shall be documented in accordance with Section P, "Corrective Action."

AUDIT PLANS

A documented audit plan shall be developed for each audit. This plan shall identify the audit scope, requirements for performing the audit, type of audit personnel needed, work to be audited, organizations to be notified, applicable documents, audit schedule, and implementing documents or checklists to be used.

AUDIT TEAMS

The UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement shall select and assign auditors who are independent of any direct responsibility for performing the work being audited. Audit personnel shall have sufficient authority and organizational freedom to make the audit process meaningful and effective. The audit team shall include one or more auditors comprised of representatives from the UniStar Nuclear QA organization and any applicable technical organizations. A lead auditor shall be appointed to supervise the team, organize and direct the audit, prepare and coordinate issuance of the audit report and evaluate responses. Technical specialists may be used to assist in assessing the adequacy of technical processes. Before commencing the audit, the lead auditor shall ensure the personnel assigned to the audit team are prepared and collectively have experience and/or training commensurate with the scope, complexity or special nature of the work to be audited. Lead auditors, auditors and technical specialists shall be trained and qualified according to the requirements of Section S, "Training and Qualification Criteria-Quality Assurance."

PERFORMING AUDITS

The UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement shall provide written notification of a planned audit to the affected organizations at a reasonable time before the audit is to be performed. The notification shall include all relevant information pertaining to the audit, such as schedule, scope and names of audit lead and team members, if known. In addition, the audit team leader shall ensure the following is performed:

- The audit team shall be adequately prepared before starting the audit.
- Audits shall be performed in accordance with written procedures or checklists.
- Elements that have been selected for the audit shall be evaluated against specified requirements.

- Objective evidence shall be examined to the depth necessary to determine if the selected elements are being implemented effectively.

- Audit results shall be documented by auditing personnel, and reported to/reviewed by management having responsibility for the area audited. Conditions requiring prompt corrective action shall be reported immediately to management of the audited organization.

- Identified audit findings shall be documented and the audited organization shall correct the findings according to the requirements of Section P, "Corrective Action." Minor audit findings can be corrected during the conduct of the audit.

REPORTING AUDIT RESULTS

The audit report shall be prepared and signed by the audit team leader and issued to the management of the audited organization in a timely manner after completion of the audit. The audit report shall include the following information:

- A description of the audit scope.

- Identification of the auditors.

- Identification of persons contacted during the audit.

- A summary of audit results and the documents reviewed, persons interviewed and the specific results of the reviews and interviews (i.e., a summary of the checklist contents).

- Statement as to the effectiveness of the implementation of the QA Program elements audited.

- A description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.

- A requested date for response by the audited organization.

RESPONDING TO AUDITS

Management of the audited organization or activity shall:

- Investigate adverse audit findings in a timely manner;

- Determine and schedule corrective action, including measures to prevent recurrence;

- Prior to or by the requested response date, notify the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement in writing of the actions taken or scheduled.

EVALUATING AUDIT RESPONSES

The UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement or designee is responsible for evaluating audit responses.

FOLLOW-UP ACTION

Follow-up action shall be taken by the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement to verify that corrective actions are completed as scheduled according to the requirements of Section P, "Corrective Action."

RECORDS

- Audit records include audit plans and audit reports.
- Written replies and the record of completion of any required corrective actions.

These documents are QA records and shall be submitted as delineated in Section Q, "Records."

SECTION S

TRAINING AND QUALIFICATION CRITERIA - QUALITY ASSURANCE

The elements of the UniStar Nuclear QA Program described in this section and associated QA procedures implement the requirements of:

- Criterion 2, Quality Assurance Program, of 10 CFR 50, Appendix B; and
- Basic Requirement 2 and Supplement 2S-3 of NQA-1-1994, except for qualification of lead auditors (subsection 3.3) which is addressed here.

Management of the Training and Qualification-Quality Assurance is the responsibility of the Senior Management position responsible for Quality and Performance Improvement.

QUALIFICATION OF AUDITORS

The Senior Management position responsible for Quality and Performance Improvement shall establish the audit personnel qualifications and the requirements for the use of technical specialists to accomplish the auditing of quality assurance programs. Personnel selected for quality assurance auditing assignments shall have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Auditors shall have, or be given, appropriate training or orientation to develop their competence for performing required audits. Competence of personnel for performance of the various auditing functions shall be developed by one or more of the following methods:

- Orientation to provide a working knowledge and understanding of NQA-1-1994 and the UniStar Nuclear procedures for implementing audits and reporting results.
- Training programs to provide general and specialized training in audit performance. General training shall include fundamentals, objectives, characteristics, organization, performance, and results of quality auditing. Specialized training shall include methods of examining, questioning, evaluating, and documenting specific audit items and methods of closing out audit findings.
- On-the-job training, guidance, and counseling under the direct supervision of a Lead Auditor. Such training shall include planning, performing, reporting, and follow-up action involved in conducting audits.

The prospective Lead Auditor shall have the capability to communicate effectively, both in writing and orally. These skills shall be attested to in writing by the Senior Management position responsible for Quality and Performance Improvement.

Prospective Lead Auditors shall have training to the extent necessary to assure their competence in auditing skills. Training in the following areas shall be given based upon management evaluation of the particular needs of each prospective Lead Auditor:

- Knowledge and understanding of this QAPD, NQA-1-1994 and other nuclear-related codes, standards, regulations, and regulatory guides, as applicable.
- General structure of quality assurance programs as a whole and applicable elements as defined in NQA-1-1994.
- Auditing techniques of examining, questioning, evaluating, and reporting; methods of identifying and following up on corrective action items; and closing out audit findings.
- Audit planning in the quality-related functions for the following activities: siting, designing, purchasing, fabricating, handling, shipping, receiving, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, modifying, and decommissioning of nuclear facilities or associated components, and safety aspects of the nuclear facility.
- On-the-job training to include applicable elements of the audit program.

The prospective lead auditor shall have participated in a minimum of five QA audits within a period of time not to exceed 3 years prior to the date of qualification, one audit of which is a nuclear QA audit within the year prior to qualification or for individuals with related industry experience, demonstrated ability to properly implement the audit process, to effectively organize and report results, including participation in at least one nuclear audit within the year preceding the date of qualification.

The prospective Lead Auditor shall pass an examination which shall evaluate his comprehension of and ability to apply the body of knowledge identified above. The examination may be oral, written, practical, or any combination of the three types. The development and administration of the examination shall be the responsibility of UniStar Nuclear. UniStar Nuclear may delegate this activity to an independent certifying agency, but shall retain responsibility for conformance of the examination and its administration to NQA-1-1994. Integrity of the examination shall be maintained by UniStar Nuclear or certifying agency through appropriate confidentiality of files and, where applicable, proctoring of examinations. Copies of the objective evidence regarding the type(s) and content of the examination(s) shall be retained by UniStar Nuclear in accordance with the requirements of Section Q, "Records."

Lead Auditors who fail to maintain their proficiency for a period of 2 years or more shall require requalification. Requalification shall include retraining in accordance with the above requirements, including reexamination, and participation as an Auditor in at least one nuclear quality assurance audit.

Each Lead Auditor shall be certified by the Senior Management position responsible for Quality and Performance Improvement as being qualified to lead audits. This certification shall, as a minimum, document the following:

- Employer's name
- Lead Auditor's name

- Date of certification or recertification;
- Basis of qualification (i.e., education, experience, communication skills, training, examination, etc.);
- Signature of the Senior Management position responsible for Quality and Performance Improvement

Records of personnel qualifications for Auditors and Lead Auditors performing audits shall be established and maintained. Records for each Lead Auditor shall be maintained and updated annually.

Qualification- Other QA Personnel

The UniStar Nuclear management positions responsible for management of the implementation of the QA program shall be qualified as follows:

- Education: baccalaureate in engineering or related science; and
- Minimum experience for the position: 4 years of related experience (3 of the 4 years must include 2 years of nuclear power plant experience and 1 year of supervisory or management experience); and
- Special Requirements: management and supervisory skills and experience or training, including leadership, interpersonal communication, management responsibilities, motivation of personnel, problem analysis and decision making, and administrative policies and procedures; and
- 1 year of experience performing quality verification activities

Individuals who do not possess these formal education and minimum experience requirements shall not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by the incumbent's management.

Other individuals responsible for planning, implementing, and maintaining the QA plan shall be qualified as follows:

- Education: high school diploma
- Minimum experience: 1 year related experience

Individuals who do not possess these formal education and minimum experience requirements shall not be eliminated automatically when other factors provide sufficient demonstration of their abilities. These other factors are evaluated on a case-by-case basis and approved and documented by the incumbent's management.

SECTION T

TRAINING AND QUALIFICATION – INSPECTION AND TEST

The elements of the UniStar Nuclear QA Program described in this section and associated QA procedures implement the requirements of:

- Criterion 2, Quality Assurance Program, of 10 CFR 50, Appendix B; and
- Basic Requirement 2 and Supplements 2S-1 of NQA-1-1994.

Qualification/Certification of Inspection and Test Personnel

Inspection and test personnel initial qualification requirements are based on education, training, experience and demonstration of capability in performing the type of inspection or test commensurate with the job.

Inspection and test personnel performing QA Level 1 activities shall be certified in accordance with NQA-1-1994 Supplement 2S-1, Supplementary Requirements for the Qualification of Inspection and Test Personnel. Written procedures are established for the qualification of inspection and test personnel, and for the assurance that only those personnel who perform inspection and test activities are required to be established.

The job performance of inspection and test personnel shall be reevaluated at periodic intervals not to exceed 3 years.

Any person who has not performed inspection or testing activities in his/her qualified area for a period of 1 year shall be reevaluated prior to performing inspection or test activities.

Inspections by persons during on-the-job training for qualification are performed under the direct observation and supervision of a qualified person and verification of the conformance is by the qualified person until certification is achieved.

TRAINING AND CERTIFICATION RECORDS

Training and certification records for inspection and test personnel shall be maintained as follows:

- Employer's name
- Identification of person being certified
- Activities certified to perform
- Basis used for certification which includes such factors as education, experience, indoctrination, and training test results, where applicable
- Results of periodic evaluation

- Results of physical examinations, when required
- Signature of employer's designated representative who is responsible for such certification
- Examination results
- Date of certification or recertification and date of certification expiration
- Results of capability demonstration

SECTION U

QA PROGRAM COMMITMENTS

Through this QAPD, UniStar Nuclear commits to compliance with the regulatory guidance and industry standards governing quality assurance as described below along with any exceptions or alternatives described within this QAPD.

Regulatory Guides (RG)

a. RG 1.26, Revision 3, "Quality Group Classifications and Standards for Water-, Steam-, and Radioactive-Waste-Containing Components of Nuclear Power Plants"

b. RG 1.29, Revision 3, "Seismic Design Classification"

c. GL 89-02, 3/21/89, "Actions to Improve the Detection of Counterfeit and Fraudulently Marked Products"

d. GL 91-05, 4/9/91, "Licensee Commercial-Grade Dedication Programs"

Standards

a. Subpart 2.1, "Quality Assurance Requirements for Cleaning of Fluid Systems and Associated Components for Nuclear Power Plants," ASME, NQA-1-1994, "Quality Assurance Requirements for Nuclear Facility Applications" – UniStar Nuclear commits to implement this subpart during the Construction Phase.

b. Subpart 2.2, "Quality Assurance Requirements for Packaging, Shipping, Receiving, Storage, and Handling of Items for Nuclear Power Plants," ASME NQA-1-1994 – UniStar Nuclear commits to implement this subpart during the Construction Phase.

c. Subpart 2.4, "Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities," ASME NQA-1-1994 – UniStar Nuclear commits to this subpart as addressed in Sections J and K of this QAPD, with the alternatives as identified in Table 1, Exception #2

d. Subpart 2.5, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Power Plants," ASME NQA-1-1994 – UniStar Nuclear commits to implementing this subpart with the alternative identified in Table 1, Exception #3

e. Subpart 2.7, "Quality Assurance Requirements of Computer Software for Nuclear Facility Applications," ASME NQA-1-1994 – UniStar Nuclear commits to this subpart as addressed in Section C of this QAPD.

f. Subpart 2.8, "Quality Assurance Requirements for Installation, Inspection, and Testing of Mechanical Equipment and Systems for Nuclear Power Plants," ASME NQA-1-1994 – UniStar Nuclear commits to this subpart as addressed in Sections J and K of this QAPD.

g. Subpart 2.15, "Quality Assurance Requirements for Hoisting, Rigging, and Transporting Items for Nuclear Power Plants," ASME NQA-1-1994 – UniStar Nuclear commits to implement this subpart during the Construction Phase.

h. Subpart 2.20, "Quality Assurance Requirements for Subsurface Investigations for Nuclear Power Plants," ASME NQA-1-1994 – UniStar Nuclear commits to this subpart for subsurface investigation activities.

i. Nuclear Information and Records Management Association, Inc. (NIRMA) Technical Guide (TG) 11-1998, "Authentication of Records and Media" – UniStar Nuclear commits to this TG as addressed in Section Q of this QAPD.

j. NIRMA TG 15-1998, "Management of Electronic Records" – UniStar Nuclear commits to this TG as addressed in Section Q of this QAPD.

k. NIRMA TG 16-1998, "Software Configuration Management and Quality Assurance" – UniStar Nuclear commits to this TG as addressed in Section Q of this QAPD

l. NIRMA TG 21-1998, "Electronic Records Protection and Restoration" – UniStar Nuclear commits to this TG as addressed in Section Q of this QAPD

m. Section 4, "Storage, Preservation, and Safekeeping," of Supplement 17S-1, "Supplementary Requirements for Quality Assurance Records," NQA-1-1994 Edition – UniStar Nuclear commits to this Section as addressed in Section Q of this QAPD.

SECTION V

NONSAFETY-RELATED SSC QUALITY CONTROLS

This section outlines the owner defined Quality Assurance Program for QA Level 2 activities, including, Nonsafety-Related SSCs Credited for Regulated Events. For contractors, the QA Level 2 program shall be described in documents that must be approved by UniStar Nuclear. The QA Level 2 program shall be applied to owner designated structures, systems, components, and activities. Requirements for QA Level 2 are defined below. QA Level 2 requirements shall not be applied to safety-related SSCs, items that may affect the functions of the safety-related SSCs, or items important to safety.

A. Nonsafety-related SSCs that are significant contributors to plant safety

The quality control criteria under subsection B apply to the Quality Assurance Program requirements for SSCs that are not safety related and are significant contributors to plant safety.

B. Nonsafety-Related SSCs Credited for Regulated Events

- UniStar Nuclear commits to implement quality requirements to the fire protection system in accordance with Regulatory Position 1.7, "Quality Assurance," in RG 1.189, April 2001, "Fire Protection for Operating Nuclear Power Plants,"

- UniStar Nuclear commits to implement the quality requirements to anticipated transients without scram (ATWS) equipment in accordance with Generic Letter 85-06, April 1985, "Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related."

- UniStar Nuclear commits to implement 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 RG 1.155, August 1988, "Station Blackout."

The following criteria apply to Quality Assurance Program requirements for non safety-related SSCs that perform safety significant functions or are credited for regulated events. This Quality Assurance program provides assurance that these nonsafety-related SSCs are designed, fabricated, erected, tested, maintained, and operated so that they will function as intended. Those SSCs that are safety-related shall be controlled in accordance with QAPD Sections A through U and W, including Appendix 1 and Table 1.

Organization

The organization structure and related responsibilities described in Section B, "Organization," of the UniStar QAPD apply.

Quality Assurance Program

The QA program shall be under the management control of the UniStar Nuclear Senior Management position responsible for Quality and Performance Improvement. This control

consists of (1) formulating and/or verifying that the QA program incorporates suitable requirements and is acceptable to the management responsible for these programs and (2) verifying the effectiveness of the QA program through review, surveillance, and audits.

Performance of other QA program functions may be performed by personnel outside of the QA organization.

The Quality Assurance Program requirements for fire protection, anticipated transients without scram (ATWS), station blackout (SBO) and SSCs that are not safety-related shall meet specified criteria. These criteria apply to items within the scope of the fire protection, e.g., such as fire protection systems and features, emergency lighting, communication and self-contained breathing apparatus, as well as the fire protection requirements of applicable equipment important to safety.

Design and Procurement Document Control

Measures shall be established to include these requirements in design and procurement documents and that deviations therefrom are controlled such that:

a. Design and procurement document changes, including field changes and design deviations, are subject to the same level of controls, reviews, and approvals that were applicable to the original document.

b. Quality standards are specified in the design documents, such as appropriate fire protection, ATWS, and SBO codes and standards, and deviations and changes from these quality standards are controlled

c. New designs and plant modifications, including fire protection systems, ATWS systems, and SBO systems are reviewed by qualified personnel to ensure inclusion of appropriate requirements. These reviews should include items such as:

    - Design reviews to verify adequacy of wiring isolation and cable separation criteria.

    - Design reviews to verify appropriate requirements for room isolation (sealing penetrations, floors, and other fire barriers).

    - Design related guidelines used in complying with 10 CFR 50.63 are included in design and procurement documents.

    - Design requirements of 10 CFR 50.62 shall be translated into design and procurement documents.

d. A review and approval of the adequacy of fire protection, ATWS, and SBO requirements and quality requirements stated in procurement documents are performed and documented by qualified personnel. This review shall determine that fire protection ATWS, and SBO requirements and quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and the

procurement document has been prepared, reviewed, and approved in accordance with applicable QA program requirements.

Instructions, Procedures, and Drawings

Section E, "Instructions, Procedures, and Drawings," of the UniStar QAPD shall be used to provide the overall program for instructions, procedures, and drawings.

Specific requirements that apply to fire protection, ATWS, and SBO activities are:

- Fire Protection: Inspections, tests, administrative controls, fire drills, and training that govern the fire protection program shall be prescribed by documented instructions, procedures, or drawings and shall be accomplished in accordance with these documents such that:

  i. Indoctrination and training programs for fire prevention and fire fighting are implemented in accordance with documented procedures.

  ii. Activities such as design, installation, inspection, test, maintenance, and modification of fire protection systems are prescribed and accomplished in accordance with documented instructions, procedures, and drawings.

  iii. Instructions and procedures for design, installation, inspection, test, maintenance, modification, and administrative controls are reviewed to ensure that the proper fire protection requirements are addressed, such as control of ignition sources and combustibles, provisions for backup fire protection capability, disabling a fire protection system, and the restriction on material substitution unless specifically evaluated.

  iv. The installation or application of penetration seals, fire barrier systems, and fire retardant coatings is performed by trained personnel using approved procedures.

- ATWS – Maintenance on the equipment shall be based on the appropriate use of vendor information. Any departure from the vendor guidance shall be based on a documented evaluation conducted by the Engineering Organization.

- SBO –Inspections, tests, administrative controls, and training shall be in compliance with 10 CFR 50.63

Document Control

Section F, "Document Control," of the UniStar QAPD shall be used to provide the overall program for document control.

Control of Purchased Material, Equipment, and Services

Section G, "Control of Purchased Material, Equipment, and Services," of the UniStar QAPD shall be used to provide the overall program for control of purchased material, equipment, and

services. These measures are established to ensure that purchased material, equipment, and services conform to the procurement documents. These measures should include: 1) Provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor, inspections at suppliers, or receipt inspections. 2) Source or receipt inspection, as a minimum, for those items whose quality cannot be verified after installation.

Identification and Control of Purchased Items

Section H, "Identification and Control of Materials, Parts, and Components," of the UniStar Nuclear QAPD shall be used to provide the overall program for identification and control of materials, parts, and components. These controls include storage of environmentally sensitive equipment or material and the storage of material that has a limited shelf-life.

Special Processes

Section I, "Special Processes," of the UniStar Nuclear QAPD shall be used to provide the overall program for special processes.

Inspection

Section J, "Inspection," of the UniStar Nuclear QAPD shall be used to provide the overall program for inspection activities. Personnel conducting these inspections are independent from the individuals performing the activity being inspected and are knowledgeable of the requirements.

This program shall include:

a. Inspections of:

    - Installation, maintenance, and modification of fire protection systems or features.
    - Emergency lighting and communication equipment to ensure conformance to design and installation requirements.

b. Inspection of penetration seals, fire barriers, and fire retardant coating installations to verify the activity is satisfactorily completed.

c. Inspections of cable routing to verify conformance with design requirements.

d. Inspections to verify that appropriate requirements for room isolation (sealing penetrations, floors, and other fire barriers) are accomplished during construction.

e. Inspection procedures, instructions, and check lists that provide for:

    - Identification of characteristics and activities to be inspected.
    - Identification of the individuals or groups responsible for performing the inspection operation.

- Acceptance and rejection criteria.
- A description of the method of inspection.
- Recording evidence of completing and verifying a manufacturing, inspection, or test operation.
- Recording inspector or data recorder and the results of the inspection operation.

f. Periodic inspections of fire protection systems, emergency breathing and auxiliary equipment, emergency lighting, and communication equipment to ensure the acceptable condition of these items.

g. Periodic inspection of materials subject to degradation such as fire barriers, stops, seals, and fire retardant coatings to ensure these items have not deteriorated or been damaged.

Test and Test Control

Section K, "Test Control," of the UniStar QAPD shall be used to provide the overall program for test and test control activities.

A test program shall be established and implemented to ensure that testing is performed and verified by inspection and audit to demonstrate conformance with design and system readiness requirements. The tests shall be performed in accordance with written test procedures; test results shall be properly evaluated and acted on. This test program shall include:

a. Installation Testing- following construction, modification, repair or replacement, sufficient testing should be performed to demonstrate that fire protection systems, emergency lighting, and communication equipment will perform satisfactorily in service and that design criteria are met. Written test procedures for installation tests incorporate the requirements and acceptance limits contained in applicable design documents.

b. Periodic testing- the schedules and methods for periodic testing are developed and documented. Fire protection equipment, emergency lighting, and communication equipment are tested periodically to ensure that the equipment will function properly and continue to meet the design criteria.

c. Programs are established for QA/QC to verify testing of fire protection systems and features and to verify that test personnel are effectively trained.

d. Test results are documented, evaluated, and their acceptability determined by a qualified responsible individual or group.

e. ATWS SSCs are tested, as appropriate, prior to installation and operation and periodically.

Control of Measuring and Test Equipment

Measuring and test equipment (M&TE) control measures include provisions to control, calibrate, and adjust M&TE at specified intervals.

Handling, Storage, and Shipping

The handling, storage, and shipping of items shall include provisions for handling, storage, shipping, cleaning, packaging, and preservation in accordance with practices established by UniStar Nuclear and the manufacture's recommendations.

Inspection, Test, and Operating Status

Section N, "Inspection, Test, and Operating Status," of the UniStar Nuclear QAPD shall be used to provide the overall program for Inspection, Test, and Operating Status. This program includes measures for the 1) documentation or identification of items that have satisfactorily passed required tests and inspections, and 2) The identification by means of tags, labels, or similar temporary markings to indicate completion of required inspections and tests and operating status.

Nonconforming Items

Section O, "Nonconforming Materials, Parts, and Components," of the UniStar Nuclear QAPD shall be used to provide the overall program for the control of nonconforming materials, parts, and components.

This program ensures that nonconforming material, parts or components are controlled to prevent inadvertent use or installation. These measures include provisions to ensure that:

a. Nonconforming, inoperative, or malfunctioning fire protection systems, emergency lighting, and communication equipment are appropriately tagged or labeled.

b. The identification, documentation, segregation, review disposition, and notification to the affected organization of nonconforming materials, parts, components, or services are procedurally controlled.

c. Documentation identifies the nonconforming item, describes the nonconformance and the disposition of the nonconforming item and includes signature approval of the disposition.

d. Provisions are established to identify those individuals or groups delegated the responsibility and authority for the disposition and approval of nonconforming items.

Corrective Action

Section P, "Corrective Action," of the UniStar Nuclear QAPD shall be used to ensure that conditions adverse to quality such as failures, malfunctions, deficiencies, deviations, and uncontrolled combustible materials are promptly identified, reported, and corrected. These measures ensure that:

a. Procedures are established for evaluation of conditions adverse to fire protection (such as nonconformance, failures, malfunctions, deficiencies, deviations, and defective material and equipment) to determine the necessary corrective action.

b. In the case of significant or repetitive conditions adverse to AWTS, SBO, and fire protection, including fire incidents, the cause of the conditions is determined and analyzed, and prompt corrective actions are taken to preclude recurrence. The cause of the condition and the corrective action taken are promptly reported to cognizant levels of management for review and assessment.

Records

Section Q, "Records," of the UniStar Nuclear QAPD shall be used to ensure that required records are maintained and controlled. This program includes processes that ensure the following:

a. Records are identifiable and retrievable and shall demonstrate conformance to fire protection requirements. The records include results of inspections, tests, reviews, and audits; non-conformance and corrective action reports; construction, maintenance, and modification records; and certified manufacturers' data.

b. Record retention requirements are established.

c. ATWS records delineated in 49 FR 26036 (pages 26042-26043) shall be maintained and controlled.

Audits

In lieu of independent audits, line management may periodically review and document the adequacy of the quality controls and take any necessary corrective action. Line management is responsible for determining whether reviews conduced by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities.

Audits shall be conducted and documented in accordance with Section R, "Audits," of the UniStar Nuclear QAPD to verify compliance with the fire protection program such that:

- Audits are performed to verify compliance with the administrative controls and implementation of quality assurance criteria, including design and procurement documents, instructions, procedures, drawings, and inspection and test activities as they apply to fire protection features and safe shutdown capability.

b. Additionally, fire protection audits shall be performed by a qualified audit team. The team shall include at least a lead auditor from the licensee's QA organization, a systems engineer, and a fire protection engineer. The lead auditor shall be qualified, for example, per ASME NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities." The systems engineer shall be knowledgeable in safety systems, operating

procedures, and emergency procedures. The fire protection engineers (or engineering consultant) shall meet the qualifications for membership in the Society of Fire Protection Engineers at the grade of member. The fire protection engineer can be a licensee employee who is not directly responsible for the site fire protection program for two of three years, but shall be an outside independent fire protection consultant every third year. This audit team approach will ensure that the technical requirements as well as the QA requirements are adequately assessed.

c. Insurance company inspections shall not be used to satisfy any of the fire protection audit requirement. However, if the insurance company develops an inspection that has the proper scope and the inspection team includes a person knowledgeable in nuclear safety, an insurance company may perform these audits in conjunction with a lead auditor from the licensee's QA organization.

Two distinct fire protection audits are specified below:

1. **24 months (maximum interval of) Fire Protection Audit**. UniStar Nuclear has developed performance based schedule for fire protection. This program requires periodic performance reviews. The audit frequency shall not exceed 24 months.

   The elements that are incorporated in the 24-month audit are:

   a. Purpose – The purpose of the 24-month audit of the fire protection program and implementing procedures is to ensure that the requirements for design, procurement, fabrication, installation, testing, maintenance, and administrative controls for the respective programs continue to be included in the plant QA program for fire protection and meet the criteria of the QA/QC program established by the UniStar Nuclear. The 24-month audit shall be performed by qualified UniStar Nuclear personnel who are not directly responsible for the site fire protection program or by an outside independent fire protection consultant. These audits shall normally encompass an evaluation of existing programmatic documents to verify continued adherence to NRC requirements.

   b. Scope – Each audit shall verify that the commitments of the Safety Analysis Report (SAR) and that the requirements of the Technical Specifications and license conditions have been met and that modifications to systems and structures or changes in operating procedures have not decreased the level of safety in the plant. The audit shall include inspection of all plant areas for which fire protection is provided and, in particular, examination of fire barriers, fire detection systems, and fire extinguishing systems provided for equipment important to safety. The audit shall verify that:

      - The installed fire protection systems and barriers are appropriate for the objects protected by comparing them to NRC guidelines and SER-approved alternatives and noting any deviations.

      - The fire hazard in each fire area has not increased above that which was specified in the SAR.

- Regularly scheduled maintenance is performed on plant fire protection systems.

- Identified deficiencies have been promptly and adequately corrected.

- Special permit procedures (hot work, valve positioning) are being followed.

- Plant personnel are receiving appropriate training in fire prevention and firefighting procedures and the training program is consistent with approved standards. (The audit team should witness a typical training session.)

- Plant response to fire emergencies is adequate by analyzing incident records and witnessing an unplanned fire drill.

- Administrative controls are limiting transient combustibles in areas important to safety.

- Problem areas identified in previous audits have been corrected.

- The audit shall analyze all problem areas identified by the audit and recommend appropriate fire protection measures to provide a level of safety consistent with NRC guidelines.

2. **Triennial Fire Protection Audit**. The triennial audit is basically the same as the 24-month fire protection audit; the difference lies in the source of the auditors. The triennial audit shall be performed by an outside independent fire protection consultant. These audits shall normally encompass an evaluation of existing documents (other than those addressed under the 24-month audit) plus an inspection of fire protection system operability, inspection of the integrity of fire barriers, and witnessing the performance of procedures to verify that the fire protection program has been fully implemented and is adequate for the objects protected. Duplicate audits are not required.

SECTION W

INDEPENDENT REVIEW

During the Operation phase, an Independent Review Committee (IRC), reporting to the Executive Management position responsible for Facility Operations will perform the following:

- Reviews proposed changes to the facility as described in the SAR. The IRC review verifies that such changes do not adversely effect safety and if a technical specification change or NRC review is required.

- Reviews proposed tests and experiments not described in the SAR. These tests and experiments are reviewed prior to implementation. The IRC also verifies that tests or experiments do not require a technical specification change or NRC review.

- Reviews proposed technical specification changes and license amendments relating to nuclear safety prior to implementation, except in those cases where the change is identical to a previously approved change.

- Reviews violations, deviations, and reportable events that are required to be reported to the NRC in writing within 24 hours. This review includes the results of investigations and recommendations resulting from such investigations to prevent or reduce the probability of recurrence of the event.

- Reviews any matter related to nuclear safety that is requested by the President, UniStar Nuclear, Executive Management position responsible for Facility Operations, Management Position Responsible for Facility Operations and Maintenance, or any IRC member,

- Reviews corrective actions for significant conditions adverse to quality.

- Auditing the adequacy of the audit program every two years.

The IRC serves in an advisory capacity to the Executive Management position responsible for Facility Operations on all matters related to nuclear safety for their assigned UniStar Nuclear facilities.

Composition

The IRC shall be composed of a minimum of five members. No more than a minority of members are from the onsite operating organization. A minimum of the chairman or alternative chairman and 2 members must be present for all meetings. The Executive Management position responsible for Facility Operation shall appoint, in writing, the members of IRC, including the IRC Chairperson and the Vice Chairperson drawn from the IRC members.

Consultants and contractors shall be used for the review of complex problems beyond the expertise of the IRC.

Alternates

Alternate members shall be appointed in writing by the IRC Chairperson to serve on a temporary basis. Each alternate shall meet the minimum qualifications described above for IRC, and shall have the same area of expertise as the member being replaced.

Meeting Frequency

The IRC shall meet at least once per calendar quarter until 30 days of continuous full power operation is achieved. Afterwards meetings are conducted no less than twice a year. Meetings may also be convened by the IRC Chairperson.

Persons on the IRC are qualified as follows:

- Supervisor or Chairman of the IRC
  - Education: baccalaureate in engineering or related science.
  - Minimum experience: 6 years combined managerial and technical support.
- IRC members
  - Education:

    Baccalaureate in engineering or related science for those IRC review personnel who are required to review problems in nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, nondestructive testing, instrumentation and control, radiological safety, mechanical engineering, and electrical engineering.

    High school diploma for those independent review personnel who are required to review problems in administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment.
  - Minimum experience: 5 years experience in their own area of responsibility (nuclear power plant operations, nuclear engineering, chemistry and radiochemistry, metallurgy, nondestructive testing, instrumentation and control, radiological safety, mechanical engineering, and electrical engineering, administrative control and quality assurance practices, training, and emergency plans and related procedures and equipment)

Records

Results of the meeting are documented and recorded.

APPENDIX

APPENDIX 1

PROVISIONS FOR CHANGE

This QAPD is reviewed and revised as necessary to reflect any changes that occur during the siting, fabrication, design, construction, operation, including maintenance and modifications. In addition, this QAPD is revised when corrective actions, regulatory, organizational, or work scope changes warrant changes to the UniStar Nuclear QA Program. The UniStar Nuclear QAPD is maintained current through design, construction, and operation. The UniStar Nuclear QAPD is kept current as the design, construction, and operation activities progress, and appropriate changes are made based on any of the following:

- UniStar Nuclear lessons learned from audit and assessment findings,
- Program improvements identified from analysis of trends, and
- Changes due to regulations, commitments, reorganizations, revised project schedule, or program improvements from continuous review of assessment results and process improvement initiatives.

Any changes that reduce commitments in the approved QAPD, including those commitments that affect the QA Level requirements in this QAPD, will be submitted to the NRC for review and approval prior to implementation as required by 10 CFR 50.54(a)(3) and 10 CFR 50.55(f)(3). Changes that do not reduce commitments will be submitted in accordance with 10 CFR 50.54 and 10 CFR 50.55(f)(3), as applicable.

For the purposes of 10 CFR 50.54(a)(3) and 10 CFR 50.55(f)(3) the following are not considered a reduction in commitment.

- Quality assurance program changes involving administrative improvements and clarifications, spelling corrections, punctuation, or editorial items,
- The use of a QA standard approved by the NRC which is more recent than the QA standard in the licensee's current QA program at the time of the change;
- The use of a quality assurance alternative or exception approved by an NRC safety evaluation, provided that the bases of the NRC approval are applicable to the licensee's facility;
- The use of generic organizational position titles that clearly denote the position function, supplemented as necessary by descriptive text, rather than specific titles;
- The use of generic organizational charts to indicate functional relationships, authorities, and responsibilities, or, alternately, the use of descriptive text;
- The elimination of quality assurance program information that duplicates language in quality assurance regulatory guides and quality assurance standards to which the licensee is committed; and

- Organizational revisions that ensure that persons and organizations performing quality assurance functions continue to have the requisite authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations.

TABLE

Table 1 UniStar Nuclear Exceptions/Alternatives with Basis

	UNISTAR NUCLEAR EXCEPTIONS/ALTERNATIVES	SOURCE/BASIS FOR ACCEPTANCE
1	In lieu of the applicable requirements of NQA-1-1994 Basic Requirement 4, Supplement 4S-1 and Supplement 7S-1, controls for the procurement of commercial-grade items shall be based on the requirements of 10 CFR 21 and the guidance of EPRI NP-5652, June 1988, as modified by Generic Letter 89-02, March 21, 1989, and Generic Letter 91-05, April 9, 1991.	NQA-1-1994 does not adequately address the process for procurement of commercial-grade items and services, and has not been endorsed by the NRC staff for that purpose. Generic Letter 89-02 conditionally endorses EPRI NP-5652 for evaluating commercial grade products for suitability for use in safety-rated applications. Generic Letter 91-05 reaffirms the conditional endorsement of EPRI NP-5652. 10 CFR 21 was amended effective October 19, 1995 to revise the terms Basic Component, Commercial Grade Item, and Dedication, and add the terms Critical Characteristics and Dedication Entity. This alternative is acceptable for UniStar Nuclear to assure the quality of procured supplier products since this requirement and guidance is the latest issued and endorsed by the NRC staff for procurement of commercial-grade items.
2	Section U – NQA-1-1994, Subpart 2.4, "Installation, Inspection, and Testing Requirements for Power, Instrumentation, and Control Equipment at Nuclear Facilities" (ANSI/IEEE Std. 336-1985), will be implemented with the following alternatives:	These alternatives are consistent with the provisions approved by the NRC in Safety Evaluation of Proposed Changes to the Quality Assurance Program, Quality Assurance Program Consolidation for Dominion Nuclear Connecticut, Inc. and Virginia Electric and Power Company, dated September 9, 2005.
	• All references to ANSI/ASME NQA-1, ANSI/ASME NQA-2, and ANSI/ANS-3.2 are changed to refer to the appropriate sections of ANSI/ASME NQA-1-1994 and this QAPD	This alternative is acceptable because it provides consistency with this QAPD to implement UniStar Nuclear's commitment to 10 CFR 50, Appendix B.
	• With regard to subsection 3.3, "Procedures and	This alternative is acceptable because it allow for a consistent method of preparing procedures and

Table 1 UniStar Nuclear Exceptions/Alternatives with Basis

	UNISTAR NUCLEAR EXCEPTIONS/ALTERNATIVES	SOURCE/BASIS FOR ACCEPTANCE
	Instructions," as an alternative to the 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.	instructions in accordance with company administrative controls.
	• Instrumentation and control devices installed in operating facilities are not required to be labeled as described in subsection 7.2.1, provided the information is maintained in suitable documentation traceable to the device.	This alternative is acceptable based on providing an equivalent level of control over information related to the calibration of these devices.
3	Section U – NQA-1-1994, Subpart 2.5, "Quality Assurance Requirements for Installation, Inspection, and Testing of Structural Concrete, Structural Steel, Soils, and Foundations for Nuclear Power Plants," will be implemented with the following alternative:	This alternative is consistent with the provisions approved by the NRC in Safety Evaluation of Proposed Changes to the Quality Assurance Program, Quality Assurance Program Consolidation for Dominion Nuclear Connecticut, Inc. and Virginia Electric and Power Company, dated September 9, 2005.
	• With regard to subsection 7.7, "Curing," ASTM C 1315 is added to the first paragraph as another applicable standard for test methods for curing compounds.	This alternative is acceptable based on a later approved standard that is comparable for meeting the requirements of subsection 7.7.