

From: Joelle Starefos
To: Krich, Rod
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Subject: RAI: UniStar QAPD UN-TR-06-001 Revision 1

Rod,

Per our discussion today, and consistent with our revised schedule to provide the Staff's request for additional information by November 29, 2006, I am attaching a file with 41 questions for UniStar's response. Please review the attachment and let me know if there are any questions that require further clarification with the Staff — I will facilitate that dialogue. Please also let me know if you will not be able to respond to the RAI with 30 days of the November 29th date, as previously discussed.

Thank you, Joelle

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**Request for Additional Information
Regarding the UniStar Nuclear
Quality Assurance Program Description
Topical Report TR-UN-06-001 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 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.

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.
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.

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 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 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.

- 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 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.
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 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.

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 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".
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 meet 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 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.
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 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 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.