March 25, 2003

Mr. Rod Krich
Exelon Generation Company
4300 Winfield Road
Warrenville, IL 60555

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION ON THE LOUISIANA ENERGY SERVICES QUALITY ASSURANCE PROGRAM DESCRIPTION, REVISION 0, DATED NOVEMBER 26, 2002

Dear Mr. Krich:

We have completed the initial technical review of the Louisiana Energy Services (LES) Quality Assurance Program Description (QAPD), dated November 26, 2002, transmitted by letter dated December 3, 2002. We note that your advance submittal of the QAPD is in support of your planned license application for the Gas Centrifuge Enrichment Plant in Hartsville, Tennessee. It is our understanding that the submitted QAPD is intended to address all design, procurement, fabrication, construction, startup testing, and operations activities for the design, construction, operation, and decommissioning of that facility.

Our technical review of the QAPD has identified additional information or clarification that is needed to determine its acceptability for the proposed activities. These issues were identified in our March 5 and 6, 2003, telephone discussions, and are in the enclosed Request for Additional Information (RAI). During our review, we are primarily using NUREG-1520, "Standard Review Plan (SRP) for the Review of a License Application for a Fuel Cycle Facility," published March 2002. If the additional information, specified in the RAI, results in a revision of the QAPD, LES should submit the revised QAPD to the U.S. Nuclear Regulatory Commission (NRC) for review. LES may respond separately to information requested in the enclosure.

The acceptability of the scope and quality assurance (QA) element descriptions in the QAPD cannot be determined for the full scope of proposed activities until the Integrated Safety Analysis Summary and the description and commitments to the interfacing management measures have been submitted in the facility license application and reviewed by the NRC. An NRC staff in-office review of the QAPD implementation and supporting QA procedures may also be scheduled as a part of the review process.

If you have any questions regarding these actions, I can be reached at (301) 415-7299.

Sincerely,

/RA/

Timothy C. Johnson
Special Projects Section
Special Projects and Inspection Branch
Division of Fuel Cycle Safety
and Safeguards
Office of Nuclear Material Safety
and Safeguards

Docket: 70-3103

Enclosure: Request for Additional Information
LES Quality Assurance Program Description

cc: William Szymanski/DOE
George Dials/LES
James Curtiss/W&S
Jerry Clift/Trousdale
Mario Robles/USEC
E. Nanney/State of Tennessee
Michael Marriotte/NIRS

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Request for Additional Information
LES Quality Assurance Program Description, Dated November 26, 2002
Docket: 70-3103

Quality Assurance Program Description (QAPD) Introduction, Sections 1 and 2

1. 10 CFR 70.64, Requirements for New Facilities or New Processes at Existing Facilities, (a) Baseline Design Criteria, and (1) Quality Standards and Records, requires that the design must be developed and implemented in accordance with management measures, to provide adequate assurance that Items Relied on for Safety (IROFS) will be available and reliable to perform their function when needed.

   The QAPD Introduction states that the Louisiana Energy Services (LES) Quality Assurance Program conforms to the criteria in 10 CFR Part 50, Appendix B, which are "implemented following the quidelines of the American Society of Mechanical Engineers (ASME) quality assurance (QA) standard NQA-1-1994, "Quality Assurance Program Requirements for Nuclear Facilities," as revised by the ASME NQA-1a 1995 Addenda" (NQA-1). However, the QAPD does not identify specific commitments to the NQA-1 Part I Basic Requirements and most of the Supplementary Requirements. The QAPD also does not include or address many of the supplementary requirements, nor does it state exceptions to them.

   Please identify the specific LES QAPD commitments or exceptions to the 18 Basic and Supplementary Requirements of NQA-1 for IROFS. Also, explain the QAPD references to NQA-1 as guidelines, not commitments.

2. Standard review Plan (SRP) NUREG-1520, Section 11.4.3.8, "Other QA Elements," states that the review criteria should include that "the applicant describes the attributes of QA elements including the (a) organizational structure, (b) functional responsibilities, and (c) charts of the lines, interrelationships, and areas of responsibility and authority for all organizations performing activities relied on for safety, including the organization of the applicant and, as applicable, its principal contractors architect/engineer, constructor, construction manager, and operator. Persons or organizations responsible for ensuring that appropriate QA has been established and for verifying that activities affecting quality have been correctly performed have sufficient authority, access to work areas, and organizational independence to carry out their responsibilities."

   The QAPD requires clarification to clearly show the organization, various functions, responsibilities, and internal and external interfaces, for design, construction, and operation, including all team members and major subcontracted functions. The QAPD Policy, Introduction, Section 1.0, "Organization," and Section 2, "QA Program," do not fully describe the organizational structure, functional responsibilities and activities to which the QA program applies.

   a) Describe clearly how the design engineering, construction, safety, and QA functions and organizations report and interface within LES, and how activities are controlled by the QAPD.

b) Explain the LES organization, its external interfaces, including major subcontractors or delegated responsibilities, and to whom the various QA functions report during construction, startup testing and operations, including design control/configuration management, inspection, quality control, procurement, receipt inspection, and document and records control. Since construction, startup testing and operations may be concurrent as the facility is completed in phases, this should include how the controls are applied.

c) Clearly identify the responsibilities, functions, and interfaces of the QA Director and the QA Manager and, on Page A5, the "QA Managers".

d) Explain what is, and who is in charge of, the "QA organization," and clarify the requirements of the various QAPD sections that refer to the QA Director, QA Manager and QA organization.

e) Please clarify how the appropriate authority, access to work areas, and organizational independence of the QA organization and QA management is assured through all facility phases under the proposed LES organization.

f) Identify and explain the functions and responsibilities of the QA organization responsible for review and oversight of the Integrated Safety Analysis process, the structures, systems, and component (SSC) IROFS Quality Levels categorization process and determinations, for establishing the QA controls to provide adequate assurance of IROFS performance, and for verification of the design bases.

3. SRP NUREG-1520, Section 11.1, "Management Measures, Purpose of Review", states that the applicant's descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable the reviewer to understand the capability of the measure to be implemented at the facility.

QAPD Introduction and Section 2, "QA Program," presents QA Levels and Requirements for SSCs and the graded application of QA controls, however, it does not adequately define or describe the process for determining the QA Level and the process, criteria, and approach for applying QA Level 1 requirements to IROFS.

a) Clarify the process, criteria and methods for determining QA Levels for all SSCs and for application of QA controls to IROFS.

b) Also, describe the QA controls that assure that QA Level 2 or 3 SSCs do not affect the functions of IROFS.

c) Please explain how the QAPD elements or Quality Level requirements would be applied to SSCs that serve other regulatory or safety functions, such as radiation monitors and criticality alarms, which may not be categorized as IROFS.

d) Explain how the categorical statement in the QAPD Introduction section that a QA program meeting International Standards Organization (ISO) 9000 "is acceptable for QA Level 1 applications" is appropriate for activities, suppliers, or services that have not yet

been selected or had their QA programs audited or evaluated. These consensus standards may be appropriate for a particular activity or procurement, however, this should be based on an appropriate evaluation of the supplier's programs for the scope and the activity, product, or service. The specific ISO 9000 standard(s) intended should be identified also.

QAPD Section 3, Design Control

4. SRP NUREG-1520, Section 11.4.3.8.3, states that the review guidance criteria should include the applicant's description of the design control function that is established to include design inputs, process, analyses, verification, interfaces, changes, and design documentation and records.

a) Clarify that the QAPD design control commitments include Basic Requirement 1 and Supplement 1S-1 of NQA-1.

b) Clarify that the QAPD, Section 3, Design Control, fourth paragraph commitments for computer programs that are design output includes NQA-1, Part II, Subpart 2.7, "QA Requirements for Computer Software For Nuclear Facility Applications." Please also clarify that the QAPD commitments include NQA-1, Part II, Subpart 2.7, for all computer software that is used to produce or manipulate data that is used directly in the design, analysis and operation of SSCs relied on for safety.

c) Confirm that all deficiencies that are discovered, during the design process or subsequent design-related activities that affect the design of SSCs are also included in the controls identified in the QAPD, Section 15, "Nonconforming Materials, Parts, or Components," and Section 16, "Corrective Action," or address the adequacy of exceptions or other specific controls.

e) Describe the measures to be provided during the facility operational phase to ensure responsible personnel are made aware of design changes and modifications that may affect the performance of their duties. This description should include appropriate references to the design, configuration management, QA, maintenance, and operations organizational entities.

QAPD Section 4, "Procurement Document Control," and Section 7, "Control of Purchased Material, Equipment, and Services"

5. The requirements of 10 CFR Part 21 are applicable to organizations receiving a 10 CFR Part 70 license.

a) Delete the statement regarding services or materials which cannot meet the 10 CFR 21 reporting requirements, since this is a regulatory requirement for the entity that dedicates the item or service for nuclear application.

b) Delete reference to the Electric Power Research Institute and Nuclear Construction Issues Group, "Guidelines for Utilization of Commercial Grade Items in Nuclear Safety Related Application."

c) Identify a commitment to apply the 10 CFR Part 21 requirements for dedication of items or services for 10 CFR 50 applications or describe the LES alternate commitments including controls to provide assurance of the relied upon functions of the IROFS and any basic component for the facility.

6. SRP NUREG-1520, Section 11.1, “Management Measures, Purpose of Review,” states that the applicant’s descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable the reviewer to understand the capability of the measure to be implemented at the facility.

a) In QAPD Section 4.0, “Procurement Document Control,” and Section 7.0, “Control of Purchased Material, Equipment, and Services,” as well as Section 1.0, “ Organization,” clarify the project and QA management responsibilities for preparing and controlling an approved suppliers list, supplier selection, procurement document preparation and approval, bid evaluation, review of supplier-generated documents, acceptability of items in-work, delivered items and services (activities), resolution of supplier nonconformance and procurement and supplier records.

b) Also, describe QA, design engineering, and procurement organization interfaces and interactions for controlling these activities, particularly the processes for controlling changes, supplier-generated nonconformance, and for assuring that items under Quality Level 2 and 3 requirements do not affect IROFS.

QAPD Section 5, Instructions, Procedures, and Drawings

7. SRP NUREG-1520, Section 11.1, “Management Measures, Purpose of Review,” states that the applicant’s descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable the reviewer to understand the capability of the measure to be implemented at the facility.

QAPD Section 5, “Instructions, Procedures, and Drawings,” states that procedures are reviewed by knowledgeable personnel. Please identify the scope and function of the QA organization in this area. Clarify whether the QA organization does review or approve all QA implementing procedures, and procedures affecting IROFS or quality-affecting activities, and identify the basis and process for procedure review.

QAPD Section 6, Document Control

8. SRP NUREG-1520, Section 11.1, “Management Measures, Purpose of Review,” states that the applicant’s descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable the reviewer to understand the capability of the measure to be implemented at the facility. SRP NUREG-1520, Sections 11.4.3.8.5 and 11.4.3.8.6 state that the review guidance criteria should include the applicant’s description of the QA elements to control instruction, procedures, drawings, and documents.

a) QAPD Section 6.0, “Document Control,” does not address the requirements of NQA-1, supplement 6S-1, nor identify the types of documents controlled, and the LES document control methods and system are not described. Please clarify and address the commitments and requirements for document control, including types of documents controlled, responsibilities, and document review and change controls.

b) Describe the LES document control system or features, such as a master list or equivalent. Clarify whether a master list or equivalent, updated and distributed to predetermined personnel in a timely manner, has been established to identify the current revision of instructions, procedures, specifications, drawings, and procurement documents.

QAPD Section 9, Control of Special Processes

9. SRP NUREG-1520, Section 11.1, “Management Measures, Purpose of Review,” states that the applicant’s descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable the reviewer to understand the capability of the measure to be implemented at the facility.

Please address commitments to NQA-1, Supplement 9S-1, requirements in Section 2 for process control, Sections 3.1.1 and 3.2.2 for equipment qualification and controls, Section 3.3 for records, and Section 3.4 for special processes not covered by existing codes and standards.

QAPD Section 10, Inspection

10. SRP NUREG-1520, Section 11.1, “Management Measures, Purpose of Review,” states that the applicant’s descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable the reviewer to understand the capability of the measure to be implemented at the facility.

a) Clarify that inspection personnel do not report directly to the immediate supervisors, who are responsible for performing the work being inspected, as stated in NQA-1 Supplement 10S-1, Section 3.1.

b) Specify a commitment that, where sampling is used to verify acceptability of a group of items, the sampling procedure shall be based on recognized standard practices, as stated in NQA-1, Supplement 10S-1, Section 5.2, or provide alternate bases with justification.

QAPD Section 11, Test Control

11. SRP NUREG-1520, Section 11.1, “Management Measures, Purpose of Review,” states that the applicant’s descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable

the reviewer to understand the capability of the measure to be implemented at the facility.

a) QAPD Section 11, "Test Control," does not address requirements for computer program testing, nor does it contain, or commit to, the requirements of Supplement 11S-2. Please identify the LES QAPD commitments and requirements for computer software that is used to produce or manipulate data that is used directly in the determination, categorization, design, analysis, and operation of IROFS.

b) Please clarify the Section 11 requirements for LES engineering and QA personnel for monitoring or oversight of supplier tests, and identify organizational responsibilities and the procedural controls to assure the test adequacy.

QAPD Section 12, Control of Measuring and Test Equipment

12. SRP NUREG-1520, Section 11.1, "Management Measures, Purpose of Review," states that the applicant's descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable the reviewer to understand the capability of the measure to be implemented at the facility.

a) Please clarify that control of measuring and test equipment is a commitment for design activities, where applicable, and the construction phase.

b) Clarify that the QAPD controls assure verification of the acceptability of items previously inspected or tested when equipment is found to be out of calibration.

QAPD Section 13, Handling, Storage, and Shipping

13. SRP NUREG-1520, Section 11.1, "Management Measures, Purpose of Review," states that the applicant's descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable the reviewer to understand the capability of the measure to be implemented at the facility.

NQA-1 Basic Requirement 13 and Supplement 13S-1 has specific requirements that are not specifically committed to or addressed by the QAPD. Please clarify that the QAPD commitments to the NQA 1 requirements including 13S-1, Sections 3.3 and 3.4, for special handling and lifting tools and equipment.

QAPD Section 15, Nonconforming Materials, Parts, or Components

14. SRP NUREG-1520, Section 11.1, "Management Measures, Purpose of Review," states that the applicant's descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable the reviewer to understand the capability of the measure to be implemented at the facility.

a) State that the requirements of Section 15 apply to activities and services as well as materials, parts, or components, or identify alternative methods or controls.

b) Identify the QAPD commitment, or exceptions, to all of the requirements of NQA-1, Supplement 15S-1, Sections 4.4 and 4.5, for disposition and rework activities.

c) Clarify the responsibilities for nonconforming items, including the QA organization responsibilities and involvement, and explain the following Section 15 statements:

1. "LES or its representative had the responsibility for resolutions and approval of the ultimate disposition of nonconforming item reports....."

2. "The QA Director or QA Manager is responsible for assuring that the proper organizations are assigned responsibility for resolution."

3. "All organizational groups within their areas have authority to disposition nonconforming items."

QAPD Section 16, Corrective Action

15. SRP NUREG-1520, Section 11.1, "Management Measures, Purpose of Review," states that the applicant's descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable the reviewer to understand the capability of the measure to be implemented at the facility.

NQA-1 Basic Requirement 16, "Corrective Action," states that "Conditions adverse to quality shall be identified promptly and corrected as soon as practical." These NQA-1 commitments are not explicitly addressed in the LES QAPD. Please confirm the QAPD commitment to these requirements or address the basis for other QAPD corrective action commitments.

QAPD Section 17. QA Records

16. SRP NUREG-1520, Section 11.1, "Management Measures, Purpose of Review," states that the applicant's descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable the reviewer to understand the capability of the measure to be implemented at the facility. Management measures guidance for records management are detailed in NUREG-1520, Sections 11.3.7, 11.4.3.7, 11.5.2.7, and 11.6.7.

QAPD Section 17, "Quality Records," has a brief description of the LES QA Program, but does not describe a records management system and does not discuss, identify or present the relationship or integration or interface with the management measures. A commitment to construct, locate, and secure record storage facilities in accordance with NQA-1 is identified, but it does not address the requirements of, or identify that this includes NQA-1, Supplement 17S-1. Please clarify the requirements for retention,

receipt, storage, retrieval, and disposition of records, including records administration, a records system, generation of records, record validation, distribution, identification, and classification. This clarification should include the commitments to Supplement 17S-1 and identify any exceptions or alternative approaches to that supplement.

QAPD Section 18. Audits

17. SRP NUREG-1520, Section 11.1, "Management Measures, Purpose of Review," states that the applicant's descriptions of management measures should address in sufficient detail how the measure is designed, organized, and conducted to enable the reviewer to understand the capability of the measure to be implemented at the facility.

a) Clarify the basis and criteria for determining the audit scope and frequency in selecting and scheduling internal and supplier audit activities for the various QA, safety and management activities, for suppliers and for construction, testing and operation of IROFS.

b) Please identify the qualification requirements for auditor and lead auditor training and qualifications.

c) Identify the QAPD commitments to the requirements of NQA-1, Supplement 18-S1, and identify any exceptions or alternative approaches..

QAPD Section 19 Provisions for Changes

18. SRP NUREG-1520, Section 11.4.3.8.19, identifies guidance criteria for the applicant's provisions for review and updates based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA changes.

Please clarify QAPD Section 19, "Provisions for Changes," to clearly identify the provisions for continuing QA, including notification of the NRC of changes in the implementation of the QA program from that described in the QAPD. The QAPD should include appropriate provisions for the resubmittal of the QAPD, based on reorganizations, revised activities, lessons learned, changes to applicable regulations, and other QA changes, both prior to approval of a license and after. Clarification is particularly needed for changes in the QAPD commitments that address 10 CFR Part 70.61 through 70.64 requirements, including QA Level requirements, and SSC/IROFS classification.