"Designated Original"

71-0950

ZIONSOLUTIONS LLC
An EnergySolutions Company

10 CFR 72.140(d)

February 23, 2011 ZS-2011-0166

U.S. Nuclear Regulatory Commission
ATTN: Director, Office of Nuclear Material Safety and Safeguards
Washington, DC 20555-0001

Zion Nuclear Power Station, Units 1 and 2
Facility Operating License Nos. DPR-39 and DPR-48
NRC Docket Nos. 50-295 and 50-304

Subject: Quality Assurance Program for the Independent Spent Fuel Storage Installation

On September 1, 2010, the NRC issued License Amendment 185 for the Zion Nuclear Power Station, Unit 1 and License Amendment 172 for the Zion Nuclear Power Station, Unit 2 (Ref. 1). These amendments implemented the May 4, 2009 NRC Order approving the License Transfer of the Zion Nuclear Power Station (ZNPS) from Exelon Generation Company, LLC (Exelon) to Zion*Solutions*, LLC (ZS) (Ref. 2).

ZS assumed authority and responsibility for the functions necessary to fulfill the quality assurance requirements of the Permanently Defueled Technical Specifications and the requirements specified in Appendix A, Section 2.6 of the Exelon Quality Assurance Topical Report (QATR) Revision 84. Exelon transferred all of the functions of the Quality Assurance organization to ZS.

Concurrent with the license transfer, the ZS Quality Assurance Project Plan (QAPP) was revised to reflect the change in ZNPS ownership and operation including the new ZS organization and management positions. The QAPP, Revision 1, was implemented on September 1, 2010 in accordance with 10 CFR 50.54(a)(3) with no decrease in the level of commitment provided by the previously established Exelon QATR program.

The QAPP is designed to meet the requirements of 10 CFR 50, Appendix B, 10 CFR 71, Subpart H, and 10 CFR 72, Subpart G, and ANSI/ASME NQA-1-1994. The ZS QAPP incorporates the applicable portions of the Energy*Solutions* corporate Quality Assurance Program (QAP) Rev. 0, and the Exelon QATR Revision 84, Appendix A, Section 2.6, Augmented Quality Requirements for Zion Station. The Energy*Solutions* QAP was submitted to the NRC on Docket No. 71-0935 on December 29, 2006 and approved by the NRC on November 14, 2007. The Exelon QATR was submitted to the NRC on ZNPS Docket Nos. 50-295 and 50-304 on November 13, 2007 and approved by the NRC on February 24, 2009.

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NMSS01

Pursuant to 10 CFR 72.140(d), this letter notifies the NRC of our intent to apply the QAPP to all activities associated with the design, fabrication, installation, and operation of an Independent Spent Fuel Storage Installation (ISFSI) at ZNPS. The ZS QAPP Revision 2, effective February 10, 2011, is provided in Enclosure (1) for your review.

Additionally, in order to facilitate the detailed design and engineering schedule for the ISFSI, ZS requests the NRC issue the security orders for additional security measures and access authorization pertaining to an ISFSI at your earliest convenience. This information will ensure that the ZNPS ISFSI is designed and built to meet the current NRC ISFSI security requirements.

If you have any questions regarding this submittal, please contact me at (224) 789-4041.

Respectfully,

Patrick S. Thurman, Esq.
Vice President Regulatory Affairs

References:

1) John B. Hickman (U.S. Nuclear Regulatory Commission) Letter to John A. Christian, President, ZionSolutions, LLC, "Issuance of Conforming Amendments Relating to the Transfer of Licenses for Zion Nuclear Power Station, Units 1 and 2", dated September 1, 2010
2) John B. Hickman (U.S. Nuclear Regulatory Commission) Letter to John A. Christian, President, ZionSolutions, LLC, "Order Approving Transfer of Licenses and Conforming Amendments Relating to Zion Nuclear Power Station, Units 1 and 2", dated May 4, 2009

Enclosure: (1) ZionSolutions, LLC Quality Assurance Project Plan, Revision 2

cc: Regional Administrator, Region III, U.S. NRC
John Hickman, U.S. NRC Senior Project Manager
Eric Benner, U.S. NRC Branch Chief, Licensing Branch, Division of Spent Fuel Storage and Transportation
Service List

Zion Nuclear Power Station, Unit 1 and 2 License Transfer Service List

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ZION SOLUTIONS LLC
An EnergySolutions Company

Quality Assurance Project Plan

ZS-QA-10

Zion*Solutions* LLC

Zion Station Restoration Project

Revision 2

Author Approval:	Edward L. Martin Acting Quality Assurance Manager	9-01-10 Date
RA/QA Approval:	Tom R. Tramm Tom R. Tramm, Director Director, Regulatory Affairs and QA	9/1/10 Date
VP EHSQS Approval:	Richard E. Campbell Richard E. Campbell, Energy*Solutions* VP EHSQS Commercial Group	9/1/10 Date
Senior VP Approval:	Patrick Daly Patrick Daly Senior VP & General Manager	9/1/2010 Date

ZION*SOLUTIONS* LLC
ZION STATION RESTORATION PROJECT

STATEMENT OF QUALITY ASSURANCE POLICY

This Quality Assurance Project Plan (QAPP) defines the Zion*Solutions* LLC Quality Assurance Program to be implemented during the Zion Station Restoration and Dry Cask Storage (DCS) Project at the Zion Nuclear Power Station (ZNPS) site. This QAPP is designed to meet the requirements of Title 10 of the Code of Federal Regulations, Part 50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," ANSI/ASME NQA-1-1994, Part 71, Subpart H, "Quality Assurance Requirements for Packaging and Transportation of Radioactive Waste" and Part 72, Subpart G, "Quality Assurance Requirements for the Independent Storage of Spent Nuclear Fuel, High Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste."

The QAPP incorporates the applicable portions of the current Energy*Solutions* Quality Assurance Program (QAP) Revision 0, effective date May 31, 2007, and the existing Exelon Quality Assurance Topical Report (QATR) Revision 84, Appendix A, Section 2.6, Augmented Quality requirements for Zion Station. Augmented Quality requirements are addressed in the appropriate subsections of Section 4.0, Quality Assurance Requirements, and are implemented in a graded approach.

Implementation of the QAPP will include initial training to ensure employees are aware of their personal responsibility to consistently deliver quality products and services that meet regulatory, and industry requirements while ensuring the health and safety of their fellow workers, the public, and the environment.

This QAPP applies to all activities associated with the design, fabrication, installation, and operation of an Independent Spent Fuel Storage Installation (ISFSI), safe storage of spent nuclear fuel, and all related plant modifications and other site activities as designated by the General Manager. Design and fabrication of the Dry Fuel Storage System (DFSS) portion of the DCS project will not be performed under this QAPP; however, selection, qualification, and performance-based overview of the selected DFSS designer and DFSS fabrication will be conducted in accordance with this QAPP.

Sep. 1, 2010
President, Zion*Solutions* LLC

Chief Executive Officer, Zion*Solutions* LLC

TABLE OF CONTENTS

TABLE OF CONTENTS

FIGURES

APPENDICES

1.0 Introduction

The Zion Nuclear Power Station (ZNPS) located in Zion, Illinois is currently being maintained in a SAFSTOR condition by its owner, Exelon Corporation. The Exelon Quality Assurance Topical Report (QATR) is designed to meet the requirements of 10 CFR 50, Appendix B, and ANSI/ASME NQA-1-1994, and reflects the direction of applicable regulatory guides and industry standards thereby assuring that the health and safety of the public is not caused undue risk.

Energy*Solutions* has entered into an agreement with Exelon under which Zion*Solutions*, a wholly-owned subsidiary of Energy*Solutions*, assumes ownership of the facility, takes possession of the licenses, and undertakes decommissioning activities, to be conducted by Energy*Solutions* and affiliated companies.

The nuclear fuel stored in the Spent Fuel Pool (SFP) will be placed in Dry Cask Storage (DCS) casks and stored in an ISFSI, a secured storage pad on the ZNPS site. In addition, greater than Class C (GTCC) waste also will be stored at the ISFSI location.

This Quality Assurance Project Plan (QAPP) defines the methodology that the Zion*Solutions* Project Team will utilize to meet the quality assurance requirements of 10 CFR 50 Appendix B, ANSI/ASME NQA-1-1994, 10 CFR 71 Subpart H, and 10 CFR 72 Subpart G as applicable to these tasks.

1.1 Project Quality Assurance Program

This QAPP defines the Quality Assurance (QA) program requirements applicable to the Zion*Solutions* restoration and DCS project including activities such as: existing plant operations, licensing, site design, procurement, vendor selection, fabrication, shipping, receiving, storing, cleaning, erecting, site installation, inspecting, testing, cask loading, cask sealing, cask handling, preparation for an ISFSI operation, waste handling, packaging and transportation, and associated plant modification activities. The QAPP also may be utilized for other site activities as designated by the General Manager. Quality Assurance, as defined herein, encompasses all those planned and systematic actions related to the control of the physical characteristics and quality of the material or components to predetermined requirements necessary to provide adequate confidence that a component, structure, or system will perform satisfactorily in service. Quality is recognized as an interdisciplinary function and not the sole responsibility of the Quality Assurance Department. The QAPP utilizes the existing 10 CFR 50 Appendix B, NRC approved, Exelon QATR as the initial basis of the program. In addition, the QAPP incorporates the Energy*Solutions* NRC approved 10 CFR 71 Subpart H QAP requirements.

QA programmatic requirements within this QAPP are based on, and meet, all applicable quality assurance requirements stipulated in 10 CFR 50 Appendix B, 10 CFR 71 Subpart H, and 10 CFR 72 Subpart G. In addition, the applicable requirements of

ANSI/ASME NQA-1-1994 Basic Requirements have been incorporated. It should be noted that the Energy*Solutions* QAP commits to the requirements of 10 CFR 50 Appendix B, 10CFR71 Subpart H, 10CFR72 Subpart G, and ANSI/ASME NQA-1.

The project's quality program as defined in this QAPP primarily consists of the current Exelon QATR, Energy*Solutions* QAP, and applicable existing ZNPS and Zion*Solutions'* implementing procedures and instructions. Additionally, project unique procedures and processes, and Subcontractor QA programs define various aspects of the quality program controls that are applicable to the DCS project and other site activities as designated by the General Manager, and supplement this QAPP. The project unique procedures and process documents address applicable elements of ASME NQA-1-1994 Supplementary Requirements.

Supplier and subcontractor quality activities associated with the DCS will be performed in accordance with a QA program that meets the requirements of this QAPP as specified in written Zion*Solutions* contract documents. Activities will not be subcontracted without documented permission of the Zion*Solutions* Senior Vice President & General Manager (GM) and Zion*Solutions* Quality Assurance Manager (QAM). Suppliers and subcontractors will perform their activities in accordance with their QA programs, procedures, and specific project procedures, which shall be reviewed and accepted by Zion*Solutions* QA prior to use. Subsequent to Zion*Solutions* acceptance, all major changes to supplier and subcontractor programs, procedures, instructions and processes applicable to the project shall be reviewed and accepted by Zion*Solutions* prior to use.

The Zion Restoration and DCS project includes activities that temporarily maintain existing SSCs in operation, decommissioning of SSCs that are no longer required, design and construction of an ISFSI and transferring fuel from the existing SFP to the ISFSI, and releasing the remainder of the site for unrestricted use. The QAPP is written to invoke the quality assurance requirements that apply to these activities based on their function and importance to safety. As such, varying degrees of QA criteria are applied.

1.2 Scope

This QAPP applies to project activities performed by the Zion*Solutions* project team and its suppliers and subcontractors for the duration of the DCS project activities associated with the operation and decommissioning of SSCs classified as Important to Defueled Condition (ITDC), and other site activities as designated by the GM. The DCS portion of the project is defined as beginning with the project conceptual design including ZNPS modifications required to accommodate the DFSS and continuing through the final placement of the last DFSS canister on the ISFSI pad and ending with the completion of the clean-out of the fuel pool. Operation of the ISFSI will be performed under this QAPP. The Restoration portion of the project includes activities that release the site for unrestricted use except for the ISFSI.

A Graded Approach To Quality shall be applied to the DCS project activities and other selected site activities as designated by the GM and will be defined through classification of tasks delineated in Section 3.0.

The Graded Approach to Quality involves both technical and quality oversight requirements for project activities, including subcontractors, and typically consists of a balanced review of technical and quality capabilities with a focus on technical acceptability of the activity, product and service.

The Augmented Quality requirements that were established by Exelon for existing SSC's designated as ITDC will continue to be applied in a graded approach as defined in the applicable subsections of Section 4.0, Quality Assurance Requirements.

See Section 3.0 for project task classification, Section 4.0 for QA requirements and Section 5.0 for QA oversight.

2.0 QUALITY RESPONSIBILITIES

This section defines the responsibilities of key project members accountable for implementation of the QAPP. Functions and actions can be delegated; however, the responsibility remains with the designated individual. Implementation and management oversight of the QAPP is the responsibility of the following key individuals:

Note: Minor variations may occur between the titles contained herein and those used in practice. Specific position descriptions may be contained in other approved company documents. Certain functions may be named differently within the Energy*Solutions* and Zion*Solutions* organizations.

2.1 Senior Vice President & General Manager (GM)

This project executive provides direct oversight of the project, and other selected tasks, to ensure the project is properly planned, staffed and executed. The General Manager has overall authority and responsibility for the establishment and effective implementation of the Zion*Solutions* quality assurance program. The General Manager has periodic meetings with the management team to review plans and progress and to address stakeholder, quality, and project management issues. The GM delegates to the Management Team the day-to-day responsibilities for the DCS project, plant operation and decommissioning such as, but not limited to, safe conduct of work, procedure reviews, test and experiment reviews, personnel qualification, and other selected tasks.

2.2 Senior Vice President & General Manager, Commercial Services Operations (SVP)

This executive manages the operation of all Energy*Solutions* projects at commercial facilities. He reports directly to the President of Zion*Solutions*. The SVP assures that the Zion*Solutions* project receives timely and effective support from Energy*Solutions* corporate groups. He meets periodically with the General Manager and other key managers to review plans and progress and to address project management and quality issues.

2.3 Management Team

The Management Team consist of those VP's, Directors and Managers who are the senior person in each department/functional area. They report directly to the GM on all DCS project, plant operations and decommissioning activities and are responsible for the implementation of the QAPP for the duration of the project and other site activities as designated by the General Manager. Management Team members have full authority and accountability for successful project planning and execution, including effective implementation of this QAPP. They are responsible for assuring that project personnel are properly indoctrinated, trained, and qualified to all applicable project quality and technical requirements. They also are responsible for

satisfactory resolution of nonconforming conditions and effective implementation of corrective action commitments. They are responsible for contract management and development of contract deliverables in accordance with quality requirements defined in this QAPP. They are also responsible for ensuring that applicable project quality and technical requirements are transmitted to, addressed by, and acceptably implemented by the project's Subcontractors.

2.4 Director Regulatory Affairs and Quality Assurance (DRA/QA)

The DRA/QA reports directly to the GM on licensing and quality assurance issues. The DRA/QA is responsible for the day-to-day licensing activities, interfaces with the Nuclear Regulatory Commission and Exelon, and is the Single Point of Contact for licensing and regulatory matters and concerns. The DRA/QA has management overview responsibility for quality assurance requirements and staffing. The Director is a member of the Zion*Solutions* Quality Council and, in the absence of the Quality Assurance Manager, chairs the Council.

2.5 Quality Assurance Manager (QAM)

The QAM reports to the DRA/QA, and has access to the GM and Energy*Solutions* Corporate Director, QA for quality matters. The QAM also has a functional relationship with the Management Team Members and Project Support Personnel (PSP). The QAM is responsible for establishing and maintaining the QAPP, monitoring the project's quality objectives through overview activities, and providing feedback to management on the effectiveness of the QAPP. The QAM evaluates, accepts, and performs oversight of supplier and subcontractor Quality Assurance programs.

The QAM formulates and assures execution of overview/acceptance plan for suppliers and subcontractors that lack acceptable Quality Assurance programs to ensure their full compliance with applicable requirements of this QAPP. The QAM is the custodian of this QAPP and, as such, is responsible for initiating necessary changes and revisions and obtaining necessary reviews and approvals of technical changes. The QAM and the Training Manager, with assistance from Quality Assurance personnel, provide orientation and training on applicable quality requirements to the project team. The QAM also is responsible for identification and execution of quality HOLD points, QC inspections, and QA/QC personnel qualification. The QAM chairs the Zion*Solutions* Quality Council and periodically provides reports on project quality activities to the GM, DRA/QA, and the management team.

2.6 Human Resources/Training/Labor Relations Manager (HRTLRM)

The HRTLRM reports directly to the GM in a number of capacities. For purposes of this QAPP, the Manager is responsible for overview and management of the project

training program. The Manager shall periodically evaluate and report the status of the training program and effectiveness of the training process to the GM.

2.7 Zion*Solutions* Project Review and Advisory Board (PRAB)

The Project Review and Advisory Board provide independent oversight of the project to ensure compliance with licenses and regulations and to provide guidance on where improvements are needed and how they can be made. The PRAB has access to audit and management assessment reports and provides feedback to the GM and input to the Quality Council. The PRAB reports to the President, Zion*Solutions*.

2.8 Quality Assurance Personnel

The QA personnel report directly to the QAM and have a functional relation with management and support personnel. The QA personnel perform project overview activities such as oversight, auditing, and inspecting to verify that activities affecting the functions that are important to safety have been correctly performed. In addition, they support the supplier and subcontractor Quality Program evaluation process.

2.9 Support Personnel (SP)

The Project Team consists of a number of support personnel that are responsible for performing their activities in accordance with this QAPP. Support personnel activities include, but are not limited to, safety, ALARA/RP, engineering, licensing, operations, security, maintenance, document control/records, fire protection, reactor engineering, emergency planning, training, and procurement.

2.10 Supplier/Subcontractor Project Managers

Supplier/Subcontractor Project Managers are responsible for assuring their personnel are properly indoctrinated, trained, and qualified to all applicable project and Subcontractor quality program requirements. They are also responsible for assuring acceptable implementation of technical and quality requirements, and for ensuring when nonconforming conditions are identified, they are satisfactorily resolved.

2.11 Supplier/Subcontractor Quality Assurance Managers

The Managers are responsible for assuring their quality program and procedures are effectively implemented in accordance with the Supplier's QA program (reviewed and accepted by Zion*Solutions*) and this QAPP. Each Manager is responsible for providing proposed Quality Assurance program revisions to the QAM for review and acceptance prior to implementation on the DCS project. Each Quality Assurance Manager of major suppliers/subcontractors may be a member of the Quality Council as determined by the GM and QAM.

3.0 CLASSIFICATION OF PROJECT TASKS

The DCS project involves activities that include design, procurement, fabrication, construction, assembly, inspection, testing, repair, modification, and data collection that are subject to 10 CFR 50, 10 CFR 71, and/or 10 CFR 72 regulatory requirements. The Quality Assurance requirements of these activities are classified based on their function and importance to safety, and are described in Section 4.

The extent of the quality assurance criteria applicable to tasks associated with the Systems, Structures and Components (SSCs) will, as a minimum, be based on their quality classification. The level of quality rigor applicable to a task is directly proportional to the task's importance to safety. The quality classification dictates the quality requirements and overview applicable to a task.

Assignment of quality classification is a two-step process consisting of:

(i) Determination of EITHER important to safety OR not important to safety, and

(ii) Categorization of SSCs determined to be important to safety.

DCS SSCs are classified as Important to Safety or Not-Important to Safety based on their function and the definition of Important to Safety provided in Table 3.1, "DCS Quality Assurance Classification Category Descriptions." Guidance provided in NUREG-1536, NUREG-1567, and NUREG-1617 Standard Review Plans also is utilized when making the determination of task classifications.

Importance to Safety relates to the basic ISFSI nuclear safety criteria, as follows:

- Maintain subcriticality
- Maintain confinement
- Ensure that radiation dose rates and doses for workers and public do not exceed acceptable levels (and remain ALARA)
- Maintain retrievability of the fuel by normal means
- Heat removal (as necessary to meet the above criteria)

Once a SSC is determined to be Important To Safety it is further categorized into one of three quality assurance classification categories (A, B, or C) based on the descriptions given in Table 3.1. The ISFSI quality assurance classification categories given in Table 3.1 are consistent with the NRC guidance given in NUREG/CR-6407 and Regulatory Guide 7.10.

Table 3.1 – DCS Quality Classification Category Descriptions

Classification Category	Importance to Safety	Description
A	**CRITICAL** TO SAFE OPERATION	Any structure, system or component whose failure could directly result in a condition adversely affecting public health and safety. The failure of a single item could cause loss of primary containment leading to release of radioactive material, loss of shielding, or unsafe geometry compromising criticality control.
B	**MAJOR** IMPACT ON SAFETY	Any structure, system or component whose failure or malfunction could indirectly result in a condition adversely affecting public health and safety. The failure of a category B item, in conjunction with a failure of an additional item, could result in an unsafe condition.
C	**MINOR** IMPACT ON SAFETY	Any structure, system or component whose failure or malfunction would not significantly reduce the packaging effectiveness and would not be likely to create a situation adversely affecting public health and safety.
NITS	**Not Important To Safety**	Any structure, system or component whose failure or malfunction would not reduce the packaging effectiveness or would not create a situation adversely affecting public health or safety.

4.0 QUALITY ASSURANCE REQUIREMENTS

Quality procedures, instructions, processes, and systems will be utilized to manage, supervise and perform work for the duration of the Zion Restoration and DCS project. The approach to achieving effective quality assurance and control throughout the project involves the effective execution of this QAPP, the DFSS Designer, the Design Authority, and other supplier/subcontractor quality programs and associated procedures, instructions, processes, and systems. A Design Authority (DA) is a selected Architect-Engineering firm, crane designer, or the selected Dry Cask Storage System (DCSS) Designer for the DCS project. Each is the Design Authority within its assigned scope of responsibility.

4.1 Organization

The Zion Restoration and DCS Project organization, authority, duties, responsibilities, and interface requirements are addressed in QAPP Section 2.0, Quality Responsibilities. These activities include performing activities affecting the functions of structures, systems, and components which are important to safety, those associated with attaining quality objectives, and the QA functions. The primary Zion Restoration and DCS Project organizations are Zion*Solutions*, Energy*Solutions*, DFSS Designer, DFSS Prime Fabricator(s), and Design Authorities.

The QAM position shall be responsible for verifying the proper establishment and effective execution of the QAPP and shall have no assigned responsibilities that would preclude appropriate attention to Quality Assurance matters.

Quality Assurance staff shall have sufficient independence from cost and schedule considerations and shall have the access to work areas and organizational freedom to effectively identify quality problems, initiate, recommend or provide solution to quality problems through designated channels, verify implementation of solutions; and assure that further processing, delivery, installation, and use are controlled until proper disposition of a nonconformance, deficiency, or unsatisfactory condition has occurred. The QAM has the authority to stop work when significant conditions adverse to quality warrant such action.

In the case where differences of opinion involving the QAPP requirements exist, they shall be brought to the attention of the GM for resolution. If necessary, the QAM also has the ability to elevate the item to the Corporate Director, QA for resolution.

The responsibility for achieving and maintaining quality resides with those performing the work. Personnel or organizations not directly responsible for performance of the work can verify quality achievement of that work.

4.2 QA Program

The Zion*Solutions* Quality Assurance Project Plan (QAPP) consists of those planned and systematic actions necessary to assure that activities will be conducted in a satisfactory manner and that equipment and material will perform satisfactorily in service. The system is based on the concept that work performance is a process that can be planned, executed, assessed, and improved. Management is responsible for these ongoing activities. Since all work is accomplished using people, equipment, and procedures as directed by management, management is responsible for fostering an attitude of support and encouraging personnel to complete their work in a quality manner. All employees are responsible for identifying non-compliant work or areas for improvement. Management is responsible for identifying (both internal and external) project needs and expectations. Meeting these needs and expectations is a measure of quality and success.

4.2.1 QAPP Application

Procedures describe how Zion*Solutions* implements the requirements of the QAPP. These procedures document methods for planning, reviewing, implementing, controlling, and verifying activities affecting quality.

The QAPP shall apply to all activities that are important-to-safety or DCS operations and require compliance with applicable sections of the documents listed below:

- 10CFR50, Appendix B
- 10CFR71, Subpart H
- 10CFR72, Subpart G
- ANSI/ASME NQA-1-1994

The applicability of the QAPP takes into consideration the regulatory requirements for important-to-safety and DCS operations items and activities, as well as their complexity and impact on safety, the need for special controls, demonstration of compliance through inspection and test, and the degree of standardization of the item. The requirements of the QAPP are implemented using a graded approach allowing control over items and activities to be commensurate with their importance and level of risk and are not reductions in quality requirements. Measures are established for identifying the components, systems, and structures to be covered by the QAPP. During the planning of an activity or design of an item the QAPP requirements will be implemented through procedures.

4.2.2 Quality Achievement, Management, and Verification

The achievement of quality is the responsibility of all employees and is led by management. The QAPP provides for a systematic approach at various levels for oversight and assessment to assure the adequacy and effectiveness of implementation of the QAPP and implementing procedures. A tiered approach to verification and assessment includes self-checking by the individuals performing the work, supervision and oversight by management, independent inspection, and surveillance and verification to confirm adequacy and effectiveness of results. Managers are required to assess the effectiveness of their own operations and implementation of their portion of the QAPP. QA personnel perform independent audits, surveillances, and inspections to verify the effectiveness of the QAPP.

The management team provides systematic planning to establish the scope of work, analyze hazards, and confirm the appropriateness of methods to be used and controls to be applied. Work performed is then monitored to confirm performance within the established controls and to provide feedback to achieve continuous improvement as an integral process of assuring effectiveness of the quality and safety systems.

The management team members within each group periodically perform effectiveness reviews of activities that affect quality, safety, and regulatory requirements. The management team is comprised of representatives from Engineering, Operations, Quality Assurance, Safety, Radiation Safety, and other areas as needed.

On an annual basis, the Director, Regulatory Affairs and QA, will provide the GM an assessment on the effectiveness of the QAPP. This assessment is based on the performance and review of audits, independent assessments, inspections, surveillances, and trending.

4.2.3 Personnel Qualification and Certification

4.2.3.1 Training and Indoctrination

The requirements and responsibilities established for the project Team ensure that management assess their organizations' training needs and assure that all personnel performing activities affecting quality are indoctrinated, trained, and qualified according to their level of responsibility and assigned functions. This includes training on appropriate procedures, processes and policies and any special skill training required for the performance of job activities. Qualification is completed prior to

performing work, unless qualification is based upon demonstration of job skills under the supervision of a qualified person. The extent of such training is commensurate with the scope, nature, and complexity of the activity, as well as the education, experience, and abilities of the individual. Training scopes, objectives, and methods of implementation are included in approved procedures.

All activities affecting quality are accomplished under suitably controlled conditions. Controlled conditions include the use of appropriate equipment, suitable environmental conditions for accomplishing the activity, and assurance that prerequisites for the given activity have been satisfied. Management provides for any special control, processes, test equipment, tools, and skills to attain the required quality and for verification of quality.

Indoctrination and training are conducted as necessary to assure suitable proficiency is achieved and maintained. Project personnel shall be trained in the applicable procedures and project-specific documents.

The QAM shall monitor suppliers/subcontractors, as necessary, for implementation of these requirements.

4.2.3.2 Inspection and Test Personnel

Inspection and test personnel have experience commensurate with the scope of work and the complexity of the activity and are selected and trained in accordance with approved procedures. The job performance of inspection and test personnel is reevaluated at periodic intervals not to exceed three (3) years. Certification or qualifications that are revoked for deficient job performance will result in the reevaluation of items inspected or tested by the individual.

Personnel performing nondestructive examinations are qualified in accordance with the American Society of Nondestructive Testing recommended practice, or as otherwise commensurate with the NDE requirements.

Certification documentation shall be maintained in accordance with approved procedures.

4.2.3.3 Lead Auditors and Inspectors

Quality Assurance (QA) Lead Auditors are qualified and certified by Zion*Solutions* or by approved suppliers. Lead Auditors are qualified in accordance with established procedures, and records are maintained. Training methods, minimum experience requirements, and certification practices are in accordance with NQA-1, Supplement 2S-3, 1994. Proficiency evaluations are performed annually and documented for individuals performing audit activities and appropriate certification renewal or re-qualification actions are taken.

Personnel performing inspection activities are qualified and certified in accordance with established procedures that comply with ANSI N45.2.6, 1978 or NQA-1, Supplement 2S-1, 1994.

Auditor and Inspector certification documentation shall be maintained in accordance with approved procedures.

4.3 Design Control

Design Control procedures ensure that the design meets applicable regulatory requirements, and that design activities are carried out in a planned and controlled manner. Procedures describe responsibilities for design interface, control, verification, and change. Approved procedures govern translation of applicable project and regulatory requirements and design bases into design, procurement, and procedural documents, as well as controlling the design documents and design document distribution.

ITDC Design Control requirements are addressed via a graded approach.

Design controls shall be applied to: criticality physics, radiation shielding, stress, thermal, hydraulic, accident analysis, compatibility of materials, accessibility for in-service inspection, maintenance and repair, features to facilitate decontamination, and delineation of acceptance criteria for inspections and tests.

4.3.1 Design Input

The engineering organization is responsible for identifying and documenting design input. Design inputs include:

- Design basis;
- Performance requirements;
- Regulatory requirements;

- Equipment specifications;
- Industry codes and standards; and
- Technical requirements.

The input used in each design is documented, reviewed, and approved in a timely manner by the responsible design organization. Documented design inputs provide the necessary level of detail to ensure the design activity can be carried out correctly and provides a consistent basis for making decisions, accomplishing design verification, and for evaluating changes. Changes from approved design inputs, including the reason for the changes, are documented, approved, and controlled.

Design inputs including appropriate quality standards shall be specified in a timely basis and translated into applicable design documents. Deviations from the quality standards shall be controlled. Design measures shall include review for suitability of application for materials, parts, equipment and processes that are important to safety.

4.3.2 Design Process

Zion*Solutions* describes and controls the design process through approved procedures. Appropriate design documents are developed to support the design, construction/manufacture, and operation. Quality standards are identified, documented, and approved by cognizant personnel. In addition, measures are established for selection and review for suitability of application of materials, parts, equipment, and processes. Design activities result in design output documents that meet the design input requirements. Design documents contain the identification of assemblies and/or components that are part of the item being designed. These measures include provisions to assure quality standards are specified and included in design documents. Any deviations from these standards are documented, reviewed, and approved.

4.3.3 Design Analysis

Design analysis is performed and documented in accordance with approved procedures. Design analysis reports provide the following details as applicable:

- The objective of the analysis;
- Design inputs and their sources;
- Literature research and background data;

- Assumptions and designation of those that must be verified as design proceeds;
- Calculation methodology and calculations;
- Summary of results and compliance with requirements;
- Identification of computer calculations, including computer hardware and software; and
- Review and approval as specified in engineering procedures.

The Project team shall develop a standardized approach for the project to initiate, perform, document, check, approve, revise, and retain engineering calculations. This process will be utilized by project personnel performing design calculation activities including internal design review, validation, and verification activities on design information and design products produced.

4.3.4 Design Verification

Design verification is performed to ensure that appropriate requirements and project needs are translated to the design documents. Design verification is performed in accordance with approved procedures that define responsibilities, methods, and documentation requirements. Independent personnel who have qualifications equal to those of the original design personnel perform design verification. This could include an engineering supervisor who initiated the design provided he/she did not specify a singular design approach or rule out certain design considerations. No individual is ever the verifier for his/her own work or input.

Design verification methods include, but are not limited to, formal design reviews, alternative calculations, and qualification testing. The level of design verification applied complies with identified requirements.

Design verification is usually performed and discrepancy resolution is complete prior to the release of the design output document for production uses or process implementation. An exception would be cases where insufficient data exists to finalize the design at a point in the project where material procurement or preliminary facility construction must begin. In such cases, unverified portions of the design are identified and controlled. Final design verification is completed prior to reliance on the item or process to perform its function. Engineering Management shall document completion of design verification.

The design documents and records that provide evidence that a design analysis was accomplished in accordance with this QAPP shall be accumulated, maintained, and stored at the site for the duration of the project.

4.3.5 Design Review

Management is responsible for ensuring design reviews are performed at appropriate phases of the design process. Design review performance requirements, methods, and responsibilities are included in approved procedures.

The design is evaluated for the adequacy of the incorporated design inputs and the design methods used. Responsibilities for action items are assigned, verified completed, and the results are incorporated into the final design.

Individuals or multi-disciplined design review teams perform independent reviews on important-to-safety and DCS operations items. These reviews are performed by competent personnel and address the following as applicable:

- Design input selection;
- Design output compared to design input and verification requirements from interfacing organizations;
- Design methods;
- Design inputs correctly incorporated into the design;
- Adequately described, reasonable, and identified assumptions; and
- Assignment of quality levels.

QA may review design drawings, specifications, calculations, and procurement documents via a performance-based overview process (generally not as an in-line review responsibility).

4.3.6 Alternative Calculation

The requirements for verification by alternative calculations are described in procedures that include the review of appropriateness of assumptions, input data, and computer program or other calculation methods used.

4.3.7 Qualification Tests

Qualification testing (synonymous with design validation) provides the assurance that products conform to defined user needs and requirements. Qualification tests of important-to-safety and DCS operations items validate and demonstrate the adequacy of performance under conditions that simulate the most severe design conditions in accordance with written test procedures and test specifications. Test specifications are reviewed and approved by the responsible engineering organization. The engineering group responsible for the design approves results of the qualification tests. For tests performed on models or mockups, scaling laws are established and verified. Test results obtained for model or mockup test work are subject to error analysis, where applicable, prior to use in final design work. Information regarding verification that is incomplete, including incomplete qualification tests, is available prior to installation of equipment.

4.3.8 Design Changes

Changes to final design, field changes, and modifications are justified and subject to design control measures commensurate with those applied to the original design. These measures shall include assurance that the design analyses for the items are still valid. Where changes to previously verified designs have been made, the initial design verification shall be reviewed for the impact of the changes to the original design and the need for any supplementary design verification shall be determined. Changes are approved by the same, or equivalent, group organization responsible for review and approval of the original design documents.

4.3.9 Interface Control

Formal design interfaces are established when multiple organizations (internal or external) participate in the design process. Procedures are written that establish and document responsibility and authority for transmittal, review, approval, release, distribution, and revision of design inputs and design output documents. Transmittals shall indicate the status of design information or of documentation submitted, including any incomplete items that require further actions.

4.3.10 Computer Programs

Computer programs (whether generated, transferred, or purchased) used to calculate or develop important-to-safety and DCS operations data shall be subjected to documented verifications or validations, including evaluation of program changes. Computer programs may be used 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.

4.4 Procurement Document Control

Controls for procured items and services are established in approved programs and procedures. These programs and procedures require the technical, quality, regulatory, and administrative requirements applicable to the procurement to be specified in procurement documents. To the extent necessary, procurement documents require suppliers to adequately implement a quality program consistent with the type and use of the item or service being purchased.

ITDC Procurement Document Control requirements are addressed via a graded approach.

Management is responsible for supplying personnel to perform the procurement process and ensuring that project-specific requirements for procurement documents are documented.

Procurement documents generated under the controls of this section involve project contracts placed with supplier/subcontractor team members or other supplier/subcontractors performing specific DCS tasks, and other tasks designated by the GM.

4.4.1 Content of the Procurement Document

Procurement documents shall include the following as applicable: the scope of work; technical and regulatory requirements; quality criteria for items and services; quality requirements for suppliers and sub-tier suppliers; documentation requirements; quality record maintenance and retention; right of access for audit or inspection; requirements for reporting and approving supplier generated nonconformance's; and identification of spare and replacement parts.

4.4.2 Procurement Document Review

Technical, safety, and quality personnel who have an understanding of the requirements and intent of the procurement, shall review the procurement documents. Procurement documents are reviewed, approved, and documented prior to award.

QA shall review all Important to Safety (ITS) procurements for the appropriate Quality Assurance requirements prior to issuance.

4.4.3 Procurement Document Changes

Changes to procurement documents receive the same level of review and approval as the original.

4.5 Instructions, Procedures and Drawings

Management is responsible for ensuring that important-to-safety and DCS operations activities are described in instructions, procedures, or drawings, which are prepared and approved prior to commencing activities. All project personnel are responsible to perform their activities in accordance with the requirements of these documents. These documents include appropriate quantitative and qualitative acceptance criteria to verify that the activity has been satisfactorily accomplished.

ITDC instructions, procedures and drawings requirements are addressed via a graded approach.

Management is responsible for maintaining these documents current to reflect actual work practice. Instructions, procedures, work instructions and drawings are prepared, reviewed, issued, and controlled in accordance with approved procedures.

Procedures shall be reviewed periodically for adequacy and effectiveness.

4.6 Document Control

Documents that prescribe or affect quality are controlled to ensure that the proper revisions are used. Controlled documents include documentation for important-to-safety and DCS operations activities such as procedures, work instructions, and drawings.

ITDC Document Control requirements are addressed via a graded approach.

The Document Control System ensures that all documents are properly identified, distributed, and retained as specified in approved procedures.

Documents are reviewed for adequacy and approved for release by authorized personnel prior to issuance. Documents are issued to and used at the location where the activity is performed as specified in project procedures. Document changes are reviewed and approved in accordance with project procedures. Project documents, including changes, shall be identified, prepared, reviewed, approved, maintained, revised, and controlled in accordance with the requirements of this QAPP.

Documents will be controlled based upon their revision date and specific project distribution lists. Management is responsible for assigning personnel to originate and process project documents, for review and approval, and assure that correct documents are being used.

4.6.1 Document Preparation, Review, Approval, and Issuance

Management is responsible for identifying documents to be controlled and for their distribution. Controls are established in approved procedures that define responsibility, authority, issue, use, and revision of controlled documents. Management ensures that documents are reviewed for adequacy, completeness, and correctness prior to issue.

4.6.2 Document Changes

Document changes are reviewed and approved in accordance with project procedures. Minor changes such as inconsequential editorial corrections do not require the same review cycle as the original document. Approved procedures define the types of changes considered minor and the persons who are permitted to make these changes.

4.7 Control of Purchased Materials, Equipment and Services

Zion*Solutions* procurement controls establish measures to ensure those procured items and services for important-to-safety and DCS operations applications are clearly and adequately specified in procurement documents. Items and services are provided by suppliers and subcontractors who are capable of producing items and furnishing services that conform to procurement document requirements. These procurement methods are controlled by procedures for supplier evaluation, review of procurement requirements, and audit/surveillance of supplier's facilities.

ITDC Control of Purchased Items and Services requirements are addressed via a graded approach.

Commercial grade items may be procured and dedicated for important-to-safety and DCS operations applications. Qualified project personnel shall identify the

critical characteristics and the method(s) (e.g., special tests and inspections, commercial supplier survey, source verification, and/or acceptable supplier/item performance record) to be used to dedicate commercial grade items. Dedication of commercial grade items shall be accomplished in accordance with approved procedures.

4.7.1 Supplier Evaluation

Project technical, procurement, and QA personnel participate, as appropriate, in evaluation of potential procurement sources performed by Energy*Solutions'* Corporate Quality Assurance Department or Zion*Solutions* QA staff. Zion*Solutions'* QA Department shall perform a third party review of Energy*Solutions'* audits to ensure they are acceptable to Zion*Solutions'*. Zion*Solutions'* recommendations of procurement sources are based on these evaluations. Results of supplier evaluations performed prior to contract award are documented and retained. The evaluations cover review of capabilities and facilities for technical, manufacturing, and quality performance, and include any or all of the following, as appropriate:

- Historical performance data, particularly in product quality and delivery.
- Review of supplier's QA Program, including current quality records.
- Inspections, audits, or surveillances to verify supplier's QA Program implementation.
- Source qualification programs.

Supplier evaluations include elements of the QA Program applicable to the purchased item or services.

Engineering and QA will identify supplier qualification requirements and documentation in accordance with procedures.

4.7.2 Procurement Requirements

Requirements to be met by the supplier are detailed in the procurement documents, which may include procurement specifications. Procurement specifications detail the supplier QA requirements such as inspection reports, provisions for inspection, equipment calibration prior to use, and provisions for inspection after component repair. The procurement specification also may require the supplier to submit the following for Zion*Solutions*'s review:

- Special process procedures for performing welding, heat treatment, and nondestructive examination.
- Recommended inspection point program.
- Appropriate documentation as required by applicable codes, standards, and procurement documents.
- Notices of nonconformance and their disposition.
- Test procedures in accordance with applicable codes and standards.

4.7.3 Supplier Surveillance

QA is responsible for conducting and documenting supplier surveillance activities. Surveillance activities may include:

- Witnessing tests, inspections, nondestructive examinations, and various special process operations.
- Monitoring heat treatment, welding, cleaning, preserving, and packaging activities.

QA also is responsible for verifying supplier conformance with established procedures such as:

- Use of Zion*Solutions* accepted drawings and procedures.
- Document change control.
- Material identification and traceability control.
- Control of repairs.
- Control and calibration of measuring and test equipment.

Documentation packages for purchased items, if required, are reviewed by QA or their qualified designee prior to release of the items for use. This documentation may include material test reports, inspection and test reports, NDE reports, and applicable code data reports.

4.7.4 Receiving Inspection

Receiving inspection shall be performed for purchased items that are important-to-safety or DCS operations related (including spare or replacement parts) to ensure that:

- Items are properly identified and correspond to the receiving documentation.
- Inspection records and certificates of conformance attesting to the acceptance of the items are available.
- Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work.
- Physical attributes comply with specified requirements.

Records of such inspections and documentary evidence that material, equipment, and services conform to procurement specifications and documents shall be retained or be available prior to installation or use of the item, material, equipment or service, for the life of the package, and for the life of the ISFSI as applicable. Nonconforming conditions or discrepancies identified during a receipt inspection shall be documented on Condition Report (CR). ZS will keep all fuel records and ISFSI component records and turn them over to Exelon upon transfer of the 10CFR50 licenses.

4.7.5 Post Installation Testing

When used, post installation test requirements and acceptance criteria shall be established with input from the supplier, if appropriate.

4.7.6 Vendor Evaluation

A documented evaluation is required annually for suppliers maintained on the supplier list. Supplier audits, when required, shall be conducted at least once every thirty-six (36) months in accordance with the audit section of this document. A third party review of an audit performed or accepted by Energy*Solutions* may be performed to add the supplier to the list. This review shall be documented.

The controls used for procuring items or services include the requirement that the suppliers/subcontractors are required to implement their QA Program for the requested item or service for ITS category A and B. Applicable subcontractors are subject to technical and quality assurance reviews for acceptance. Suppliers/ subcontractors performing activities that affect quality will conduct the activities in accordance with a Quality Assurance program that meets the applicable requirements of this QAPP. Supplier/subcontractor QA programs must be reviewed and accepted by Zion*Solutions* QA prior to use including technical and quality assurance program changes that result from bid evaluations or negotiations. Subcontractors will be evaluated to pre-established technical and quality assurance requirements.

Supplier/subcontractor qualifications and capabilities will be determined based upon evaluation, previous quality services provided, surveillance/audit and/or Zion*Solutions* or Energy*Solutions* recommendations. In addition to an initial evaluation of the supplier/subcontractor QA program, QA will perform periodic independent oversight (audit, surveillance or assessment) at intervals consistent with the importance, complexity and quantity of the product or service to ensure performance as required by the applicable Zion*Solutions* procurement document.

4.8 Identification and Control of Materials, Parts and Components

Controls are established in approved procedures to assure that only correct and accepted items are used or installed. Identification is maintained either on the items or in documents traceable to the item. When such controls are required, the following methods of identification and control will be utilized.

4.8.1 Identification

Identification such as batch, lot, serial number, or part number is maintained from initial receipt up to and including installation. The identification relates the item to the applicable design or other specification document when appropriate. Zion*Solutions* utilizes physical identification when possible. Other means, including separation or procedural control, are used when physical identification is not possible.

4.8.2 Markings

Markings are applied using materials and methods that are clear, legible, 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. Markings are not obliterated or hidden by surface treatments or coatings unless other identification methods are established.

4.8.3 Traceability

Project procedures specify methods for identification of items when codes, standards, or specifications require identification or traceability of an item. Procedures describe how to maintain traceability to a specification, grade of material, heat, batch, lot, part or serial number, or inspection, test, or other records.

The identification and control of material, parts, and components will include the use of heat numbers when applicable to assure the maintenance of identification and traceability throughout all stages of the project and to prevent the use of incorrect or defective material, parts or components.

4.8.4 Shelf/Operating Life

Items having limited calendar or operating life are controlled to preclude use after the shelf life or operating life has expired.

4.8.5 Maintaining Identification in Storage

Provisions are made in project procedures for maintenance or replacement of markings and identification due to damage from handling or aging, excessive deterioration due to environmental exposure, and for updating records while in storage.

4.9 Control of Special Processes

Processes are planned and performed under controlled conditions that ensure conformance to project requirements, quality system requirements, and applicable codes, standards, and regulations. Inspection, audit, assessment, surveillance, and non-destructive examination procedures are used to perform such verifications. Management is responsible for ensuring that only properly trained and qualified personnel are assigned to accomplish work activities and that they are provided adequate facilities, equipment, tools, and information to perform their work in compliance with requirements. Managers monitor the quality of activities through the results of in-process checks described in implementing procedures. These checks may be performed by co-workers or supervisory personnel independent of the work and provide a method of tracking and trending events that affect the quality, safety, or regulatory status of operations, products, and services.

4.9.1 General Processes

Instructions, procedures, drawings, checklists, process control documents, or other appropriate methods are used to control processes affecting the quality of items and services. When required, process parameters and environmental conditions are specified and maintained.

4.9.2 Special Processes

Special processes that control or verify quality are performed by qualified personnel using qualified procedures. Personnel, equipment, and procedures used to perform special processes are qualified in accordance with specified requirements. Qualified procedures for special processes include required conditions such as proper equipment, controlled parameters, and calibration requirements. Documentation of personnel,

equipment, and process qualifications is maintained in accordance with procedures.

4.10 Inspection

Quality Assurance, engineering, and technical support personnel are responsible for ensuring that inspections required to verify conformance of an item or activity to specified requirements are planned, executed, and documented by qualified personnel according to approved procedures.

ITDC Inspection requirements are addressed via a graded approach.

Equipment modifications, repairs, and replacement are inspected in accordance with the original design and inspection requirements unless an approved alternative exists.

4.10.1 Personnel

Inspection personnel are independent of those who performed the work being inspected. Personnel who verify conformance of work for acceptance are qualified to perform the inspection in accordance with approved procedures. Personnel in training for qualification as an inspector by on-the-job training are directly supervised by a qualified person who verifies the inspection results until qualification is achieved.

4.10.2 Inspection Hold Points

Responsibilities for identifying and specifying hold points are established in approved procedures. Quality Assurance, Engineering, and technical support representatives are responsible for identifying inspection hold points in appropriate documents to ensure that no further work is performed until a certain inspection has been completed. Work does not proceed beyond hold points without consent from the organization that established them. This consent is recorded prior to continuation of work.

4.10.3 Inspection Planning

Inspection procedures, instructions, or checklists identify the characteristics and activities to be inspected:

- acceptance criteria;
- responsible organization for performing inspection;
- and, provide for recording objective evidence of inspection results.

Planning also includes identification of hold or witness points;

- approval of data by supervisors to ensure that all inspection prerequisites and requirements have been satisfied, including operator and equipment qualifications;
- and, if applicable, establishment of sampling methods based on recognized standard practices, in accordance with approved procedures or project plans.

4.10.4 In-Process Inspection

Inspections are performed, as necessary, to verify conformance to requirements. Indirect control by monitoring may be utilized when direct inspection is impractical. Both inspection and monitoring are performed when control is inadequate without both. A combination of inspection and process monitoring is performed in a systematic manner to assure quality is achieved throughout the duration of the process.

4.10.5 Final Inspection

Final inspection includes a record review of the results of inspection and resolution of nonconformance's identified in previous inspections. Items are inspected for completeness, markings, calibration, adjustments, and protection from damage. The acceptance of the item will be documented and approved by authorized personnel. Modification, repair, or replacement requires re-inspection or retest to verify acceptability, as appropriate.

4.10.6 In-Service Inspection

In-service inspection methods are established to verify that the characteristics of an item continue to stay within the specified limits. Inspection methods include routine evaluation of emergency and safety systems, and verification of calibration or integrity of instruments or systems and their maintenance, as appropriate.

4.10.7 Inspection Records

Inspection records contain, at a minimum, identification of the item inspected, date of inspection, inspector name, type of observation, acceptance and rejection criteria, results or acceptability, and reference to nonconformance's.

4.11 Test Control

Testing to verify conformance of processes, equipment, and products to specified requirements and to demonstrate satisfactory performance is planned and

performed by qualified personnel in accordance with approved procedures. Tests required to collect data are planned, executed, documented, and evaluated.

ITDC Test Control requirements are addressed via a graded approach.

DCS tests will be performed in accordance with written test procedures that incorporate the requirements and acceptance criteria contained in the DCS System Safety Evaluation Report and Certificate of Compliance.

4.11.1 Test Requirements

Engineering and technical support representatives are responsible to ensure that test requirements and acceptance criteria are developed and incorporated into appropriate test plans, procedures, or checklists. The test methods and acceptance criteria are based on specified requirements contained in design or other technical documents. As appropriate, test plans are established, procedures developed, and results documented on checklists or other suitable records.

4.11.2 Test Procedures

Test procedures include or reference characteristics to be tested and test objectives and prerequisites. Prerequisites such as calibrated instrumentation, equipment and its condition, personnel qualification, environmental conditions, and collection and recording of data are taken into consideration during development of test procedures. Test procedures are reviewed and approved by cognizant technical, quality, and management personnel. Changes to test procedures are required to be reviewed and approved by the same, or equivalent, organization(s) as the original procedure.

4.11.3 Test Results

Test results are documented and evaluated by a responsible authority to assure the test requirements were satisfied. Records include as a minimum the item tested, date of test, name of the tester, environmental conditions, observations, acceptance and rejection criteria, results and acceptability, action taken for deviations noted, and name of the person evaluating results.

4.11.4 Testing after Modifications

Modification, repairs, or replacements shall be in accordance with the original design and test requirements or acceptable alternatives approved in the same, or equivalent, manner as the original.

4.11.5 Computer Program Testing

Testing of computer programs is performed in accordance with written procedures that address test requirements, verification methods, in-use tests, test results, and records requirements. Additional requirements regulating computer program testing are contained in Section 3 of this QAPP.

4.12 Control of Measuring and Test Equipment

Measuring and Test Equipment (M&TE) used for important-to-safety and DCS operations activities is controlled in accordance with approved procedures to ensure accuracy. The calibration process assures that all measuring instruments used in the acceptance of material, equipment, and assemblies are calibrated and properly adjusted at specified intervals to maintain accuracy within pre-determined limits. These procedures identify the responsible organizations, the devices to be controlled, the controlling and calibration methods, and calibration intervals to maintain accuracy within the necessary limits.

ITDC Control of Measuring and Test Equipment requirements are addressed via a graded approach.

Management is responsible for selecting the appropriate type, range, accuracy, and tolerance of M&TE to verify conformance to specified requirements.

M&TE is calibrated, adjusted, and maintained at scheduled intervals against certified equipment or standards having known valid relationships to nationally recognized standards, derived from accepted values for natural physical constants or by the ratio type of self-calibration. If no national standard exits, the basis of calibration is documented. The method and interval of calibration for each item is based on the type of device, stability characteristics, required accuracy, purpose, frequency of usage, and environment where it will be used.

Calibration methods are documented and performed by competent personnel in an environment that does not adversely affect the calibration. Special controls for usage, handling, and storage are documented and applied when they are required for environmental conditions such as temperature, humidity, cleanliness, or radiation to maintain accuracy or operating characteristics of the device.

When a M&TE device is found out of calibration, previous test results back to the previous acceptable calibration date are validated. Out-of-calibration devices are tagged or segregated until repaired and recalibrated or replaced.

Record of calibration history is maintained and equipment is marked to indicate calibration status. Documentation includes the equipment identification number, next calibration due date, the inspector's or calibrator's signature or initials attesting to the accuracy and validity of the calibration, and the location or work/test activity where the equipment has been used for acceptance.

4.13 Handling, Storage and Shipping

Materials considered critical, sensitive, perishable, or QA designated are handled, cleaned, stored, packaged, and shipped in accordance with controls identified in codes, standards, regulations, engineering specifications, or project requirements to prevent damage or loss and to minimize deterioration.

4.13.1 Instruction

Handling, storage, and shipping processes are conducted in accordance with written procedures, inspection instructions, drawings, specifications, vendor recommendations, or other documents, as appropriate. Information pertaining to shelf life, environment, packaging, temperature, cleaning, preservation, etc., is included, as required, to meet design, regulatory, and project requirements.

4.13.2 Requirements

When necessary for particular products, special protective environments, such as inert gas atmosphere, and specific moisture content and temperature levels, are specified and provided in applicable documents.

The use of special handling equipment or techniques is addressed in procedures. Special tools and equipment are inspected and tested in accordance with approved procedures that describe the inspection and test methods, time intervals, maintenance methods, and personnel qualifications and training requirements.

4.13.3 Marking

Suitable marking or labeling to identify, maintain, and preserve the item is provided during packaging, shipment, handling, and storage.

4.13.4 USNRC-Licensed Packages

ZionSolutions shall meet the requirements of 10CFR71, Subpart H and 10CFR72, Subpart G and DOT 49 CFR for restrictions concerning handling, storage, and shipping of NRC Licensed packages.

Transportation cask handling and operation shall conform to the handling and operating procedure for each licensed cask.

Prior to the shipment of a transport cask, conditions of the NRC's Certificate of Compliance (specifications, tests, and inspections) shall be satisfied. Required shipping papers shall be prepared and shall accompany the shipment in accordance with regulatory requirements and approved procedures.

Established safety restrictions concerning handling, storage, and shipping shall be included in the handling and operating procedures for storage and transport casks.

4.14 Inspection, Test, and Operating Status

Methods to indicate the status of inspections, tests, and operating status of systems for DCS, ISFSI, or spent fuel cask items and other selected tasks also include stamps, tags, or routing cards. Methods used will assure that required inspections and tests are performed and to assure that items which have not passed the required inspections or tests are not inadvertently installed, used or operated and to prevent inadvertent operation of systems. These methods provide for identification of items which have satisfactorily passed the required inspections and tests.

The status of items can be determined at any point throughout an operational process to prevent inadvertent use, installation, or operation of nonconforming or defective items. Status indicators are required to the extent possible to prevent operation of items that are removed from service for test, calibration, maintenance, or repair, and to ensure that required inspections and tests have been performed.

Status is identified by the use of tags, markings, stamps, or travelers. The authority for application and removal of status indicators is identified in approved procedures. Quality Assurance personnel routinely monitor project activities to assure status indicators are used and removed, as appropriate, in accordance with approved procedures.

4.15 Nonconforming Materials, Parts or Components

Items that do not conform to specified requirements are controlled to prevent inadvertent installation or use in accordance with approved procedures. Procedures include controls that provide for reporting, identifying, documenting, evaluating, segregating (when feasible), dispositioning nonconforming items, and notifying affected organizations.

ITDC Control of Nonconforming Conditions requirements are addressed via a graded approach.

Management is responsible for establishing an environment for identifying potential conditions adverse to quality. Management shall conduct analysis, as appropriate, to systematically determine significance of these conditions and actions appropriate to the conditions.

All project personnel are responsible for reporting nonconforming conditions. Management, at all levels, fosters a "no fault" attitude toward the identification of conditions that are adverse to quality, such as failures, malfunctions, nonconformances, and out-of-control processes including the failure to follow procedures. Nonconforming items are identified by using marking, tagging, or other means that do not adversely affect their end use.

To avoid inadvertent use, nonconforming items are segregated in holding areas when feasible, or in the case of large items, marking, or roping designates special storage areas.

Conditions that may be reportable per 10CFR72.242, 10CFR71.95, or 10CFR21, shall be reported in accordance with approved Quality Assurance procedures.

Management shall establish and implement a process for identifying, controlling, evaluating, and dispositioning nonconforming conditions. Such items, services or activities shall be documented and controlled to prevent inadvertent installation or use. Disposition of nonconformances shall be addressed in a timely manner by management. Personnel performing evaluations to determine a disposition 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 disposition of nonconformances is evaluated and approved by QA. Disposition of a nonconformance, involving repair or use-as-is, is based on documented technical justification to assure continued compliance with design, regulatory, and contractual requirements, and may include provisions for retest or re-inspection to the original acceptance criteria. Any changes to design require the same design controls as those applied to the original design. Accept-as-is dispositions of materials and items

require engineering approval. Accepted deviations are reflected in as-built records.

Reports of nonconforming conditions are closed and documented by QA personnel and records are maintained in accordance with approved procedures. Reports of conditions that are adverse to quality are analyzed to identify trends in quality performance.

4.16 Corrective Action

Conditions adverse to quality (e.g., nonconformances, failures, malfunctions, deficiencies, defective material, etc.) are promptly identified and evaluated to determine corrective action in accordance with established procedures. The identification, cause, and corrective action for significant conditions adverse to quality shall be documented and reported to appropriate levels of management.

ITDC Corrective Action requirements are addressed via a graded approach.

Corrective action shall be promptly initiated when it is determined that a condition adverse to quality exists. In cases where it is not possible to accomplish a corrective action immediately, the appropriate management provides a written response describing the cause of the deficiency and the proposed corrective action to be completed within a specified time.

Management shall exercise controls to ensure that conditions adverse to quality are promptly detected and corrected or prevented, and ensure continuous quality improvement in project activities and products. The management control systems established includes problem investigation, evaluation, reporting, and follow-up action taken to verify that corrective action has been thoroughly implemented and such conditions are effectively resolved.

For significant conditions adverse to quality, the condition, the cause of the condition and the corrective action taken is documented and reported to appropriate levels of management. Follow-up action shall be taken to verify effective implementation of the required corrective actions to prevent recurrence and to verify that they are effectively implemented. The GM, or designee, is responsible for reviewing the condition and determining validity. The GM will assure that validated conditions are processed in accordance with the project's corrective action program.

The QAM has the authority to stop work or ensure adequate controls are in place until effective corrective action has been taken and any applicable changes have been incorporated in procedures and communicated to appropriate personnel.

The QAM will periodically analyze and assess CRs for apparent trends and conformance to performance indicators. The GM, or designee, will evaluate recommendations for consideration to improve or enhance procedures, systems or processes.

4.17 Quality Assurance Records

ITDC Quality Assurance Records requirements are addressed via a graded approach.

4.17.1 Record Management System

Quality Records shall be identified, controlled and stored in accordance with written procedures.

The record system includes the retention of those design, fabrication, inspection, operation, and surveillance records essential to demonstrate product quality. It provides for the identification of materials and their corresponding manufacturing, installation, inspection, test, and audit results. Requirements and responsibilities for the transmittal, distribution, retention, maintenance, and disposition of records are specified in approved procedures. QA records shall be protected against damage, deterioration, unauthorized change, or loss. For any work performed, the records to be generated must be identified, along with a means of matching the record to the item or activity to which it applies. Records must be legible, reproducible, and accurate.

4.17.2 Authentication

Documents shall be considered valid records only if stamped, initialed, or signed and dated by authorized personnel or otherwise authenticated, including the use of electronic approval and authorization. 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.

4.17.3 Index

The records indexing system must include records identification, location of the record within the system, and minimum retention time. The records and/or indexing system(s) shall provide sufficient information to permit identification between the record and the items or activities to which it applies.

4.17.4 Distribution

The records shall be distributed, handled, and controlled in accordance with written procedures.

4.17.5 Classification of Records

Records shall be classified for retention and storage requirements as either lifetime or nonpermanent. Records that meet any of the following criteria are designated Lifetime records and must be maintained until completion of the project and turned over to Exelon if they will be of significant value in the following:

- Demonstrating the capability for safe operation.
- Determining the cause of an accident or the malfunction or failure of an item.
- Maintaining, reworking, repairing, replacing, or modifying an item.
- Providing required baseline data for in-service inspections.
- Used nuclear fuel records, including original fabrication, repair, and inspection
- ISFISI design and construction records
- DCS system design and fabrication records
- Fuel loading records

Project lifetime records shall include, as a minimum, design specifications, stress reports or stress calculations, "as-built" and interface control drawings, copies of material test reports, tabulation of materials for "as-built" configuration, NDE reports including examination reports, and nonconformance reports. Lifetime record retention is based on the life of the program, life of the item, life of the facility, or life of the license, as applicable.

Nonpermanent records are required to show evidence that an activity was performed in accordance with applicable requirements. Retention times must be established in writing.

QA records for packaging and transportation of radioactive materials include instructions, procedures, drawings, and closely related specifications such as required qualifications, procedures, and equipment. These records will be maintained for three years beyond the date Energy*Solutions* last engages in the packaging and transportation of

radioactive materials related to the Zion site under the rules of 10CFR71. Superseded procedures or instructions are retained for a minimum of three years after the procedure or instruction is superseded.

For subcontractors/sub-suppliers, the original QA record of the deliverables will be transmitted to Zion*Solutions* when applicable.

4.17.6 Correction

Methods of correcting errors shall be identified along with a means of documenting the authorized individual who made the corrections and the date.

4.17.7 Receipt Control

Each organization responsible for the receipt of records must designate an individual or organization responsible for receiving the records. Receipt control of records for permanent or temporary storage must include instructions for designating the required records to be controlled, identifying the records received, receiving and inspecting incoming records, determining the status, and forwarding to records storage facilities. Each receipt control system shall be structured to permit a current and accurate assessment of the status of records during the receiving process.

4.17.8 Storage Requirements

The records shall be stored in predetermined location(s) that meet the requirements of applicable standards, codes, and regulatory agencies. Prior to storage of records, a written storage procedure shall be prepared and responsibility assigned for enforcing the requirements of that procedure. This procedure shall include, as a minimum:

- A description of the storage facility;
- The filing system to be used;
- A method for verifying that the records received agree with the transmittal document and that the records are legible;
- A method of verifying that the records are those designated;
- The rules governing access to and control of the files;
- A method for controlling and accounting for records removed from the storage facility; and

- A method for filing supplemental information and disposing of superseded records.

Records shall be stored to prevent damage from moisture or temperature. All records maintained in hard copy form shall be firmly attached to binders or placed in folders, envelopes, or boxes for storage in file cabinets or within containers on shelving. Records may be stored in electronic media provided that the process for managing and storing the records are documented in approved procedures. Media used for the retention of records include, but are not limited to, microfilm, compact disks, magnetic media, optical disks, and hard disks. The format used must be capable of producing legible and complete documents during the entire retention period.

Records shall be stored in facilities that minimize the risk of damage or destruction from the following:

- Natural disasters such as wind, flood, or fires;
- Environmental conditions such as high and low temperatures and humidity; and
- Infestation by insects, mold, or rodents.

Records are maintained at an approved records storage facility or by storage of duplicate copies at separate geographical locations.

4.17.9 Authorized Personnel

Measures shall be established to preclude the entry of unauthorized personnel into the storage area. These measures shall guard against larceny and vandalism. Measures shall be taken to provide for replacement, restoration, or substitution of lost or damaged records.

4.17.10 Retrieval

Storage systems shall provide for retrieval of information in accordance with planned retrieval times based upon the record type. A list shall be maintained designating those personnel who shall have access to the files. Records maintained by the supplier at their facility or other location shall be accessible to the purchaser or their designated alternate.

4.17.11 Disposition

Records accumulated at Zion site shall be made accessible to Energy*Solutions* directly or through the procuring organization. These records shall be processed in accordance with this QAPP.

Various regulatory agencies have requirements concerning records that are within the scope of the QAPP. The most stringent requirements shall be used in determining the final disposition.

4.18 Audits

Planned internal audits are scheduled annually and performed per approved procedures or checklists. Elements of the QAPP will be audited at least annually to provide comprehensive, independent verification and evaluation of all aspects of the quality assurance program and to determine its effectiveness. Independent oversight of project activities will be accomplished by performing audits, surveillances, management assessments and/or independent assessments during the course of the Project. Scheduling, preparation, personnel selection, performance, reporting, response, follow-up action, and records management will be performed in accordance with Quality Procedures identified in the QA Program Implementation Matrix.

ITDC Audit requirements are addressed via a graded approach.

QA staff will perform project surveillances and overviews of deliverables to ensure compliance with the applicable QA requirements defined in this QAPP and as requested by the project team.

Audits of suppliers and subcontractors will be conducted as necessary but not less than once every three years to assess compliance with applicable requirements of this QAPP.

4.18.1 Scheduling, Preparation, and Performance

Internal and external audits are scheduled based on the status and importance of an activity. Schedules are updated as necessary to ensure that adequate coverage is maintained.

The audit scope shall encompass evaluation of quality system practices and/or procedures and the effectiveness of their implementation, monitoring of operations and activities, and a review of pertinent documents and their control and maintenance.

An audit team, composed of one or more qualified auditors is identified for each audit using personnel who have no direct responsibility for the activity being covered. A lead auditor, as a member of the team, is designated as a team leader.

The key elements of the audit program are:

- Scheduling and notifying management of scope and nature of audit
- Team selection, orientation, and planning
- Entrance conference
- Exit conference
- Reporting and response
- Follow-up action

4.18.2 Reporting, Response, Follow-up-Action, and Records

Audit reports are prepared upon completion of the audit and distributed to appropriate management for review and response. Management of the audited organizations provide a response to all identified conditions adverse to quality that includes corrective actions, including cause and action to prevent recurrence, and a schedule for completion, when applicable. Audit files are retained as quality records in accordance with approved procedures.

The results of internal audits, surveillances and assessments and independent assessments and audits of Subcontractors will be utilized as input into the continuous improvement program through identification in the CR system. Re-audit of deficient areas will be performed when required.

4.18.3 Surveillance

Surveillances are performed and documented when it is determined that it is necessary to monitor or observe an item or activity to verify conformance. Adequate demonstration of the areas covered by surveillance is a requirement to be considered as part of an effective audit program. Surveillance must be documented in sufficient detail to identify the activity covered, identify individuals doing surveillance, and to document results and any corrective measures necessary.

5.0 QUALITY MONITORING

Quality Assurance will utilize performance data from the project's CR system, Subcontractor corrective action systems, QA audit, surveillance, and assessment results to monitor the quality of project tasks and deliverables. This data will be used in determining areas requiring increased or decreased review by the established overview mechanisms. Data reviews will be performed on a periodic basis, but may be generated more frequently as necessary.

The QAM, using data from the project's CR system, also will perform trending of Zion*Solutions* quality activities. Trends identified will be reviewed by the QAM and appropriate actions will be developed to improve work activities and/or processes. Trending may result in Apparent Cause Evaluation (ACE) and/or Root Cause Analyses (RCA) as necessary.

6.0 ZION*SOLUTIONS* QUALITY COUNCIL

Zion*Solutions* will collaborate with its subcontractors and establish a committee to coordinate the quality overview of design, engineering, fabrication, installation and operation activities of the project including the implementation of the QAPP. The Zion*Solutions* Quality Council consists of key QA members of Zion*Solutions*, Energy*Solutions*, DFSS Designer, Design Authorities, and other supplier/subcontractor organizations. The Quality Council provides a united effort to coordinate, monitor, and effectively implement the project's oversight activities.

The Council will establish, review and evaluate quality performance indicators, discuss quality issues/concerns and assure effective corrective actions are implemented in a timely fashion. The Council will assure that design, fabrication, installation and operations activities are thoroughly and effectively overviewed and minimize duplication of oversight efforts.

It should be noted that the QAM has the primary responsibility for implementing this QAPP, and, in part, based upon supplier/subcontractor inputs will introduce and discuss Zion*Solutions* quality issues and topics to the committee.

7.0 REFERENCES

ANSI/ASME NQA-1-1994 Edition, "Quality Assurance Requirements for Nuclear Facility Applications."

Title 10 of the Code of Federal Regulations, Part 21, "Reporting of Defects and Noncompliance."

Title 10 of the Code of Federal Regulations, Part 50 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants."

Title 10 of the Code of Federal Regulations, Part 71, Subpart H, "Quality Assurance Requirements for Packaging and Transportation of Radioactive Waste."

Title 10 of the Code of Federal Regulations, Part 72, Subpart G, "Quality Assurance Requirements for the Independent Storage of Spent Nuclear Fuel, High Level Radioactive Waste, and Reactor-Related Greater Than Class C Waste."

NUREG/CR-6407 [INEL-95/0551], Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety, February 1996.

NUREG-1536, "Standard Review Plan for Dry Cask Storage Systems," January 1997.

NUREG-1567, "Standard Review Plan for Spent Fuel Storage Facilities," Draft Report, October 1996.

NUREG-1617, "Standard Review Plan for Transportation Packages for Spent Nuclear Fuel," Draft Report, March 1998.

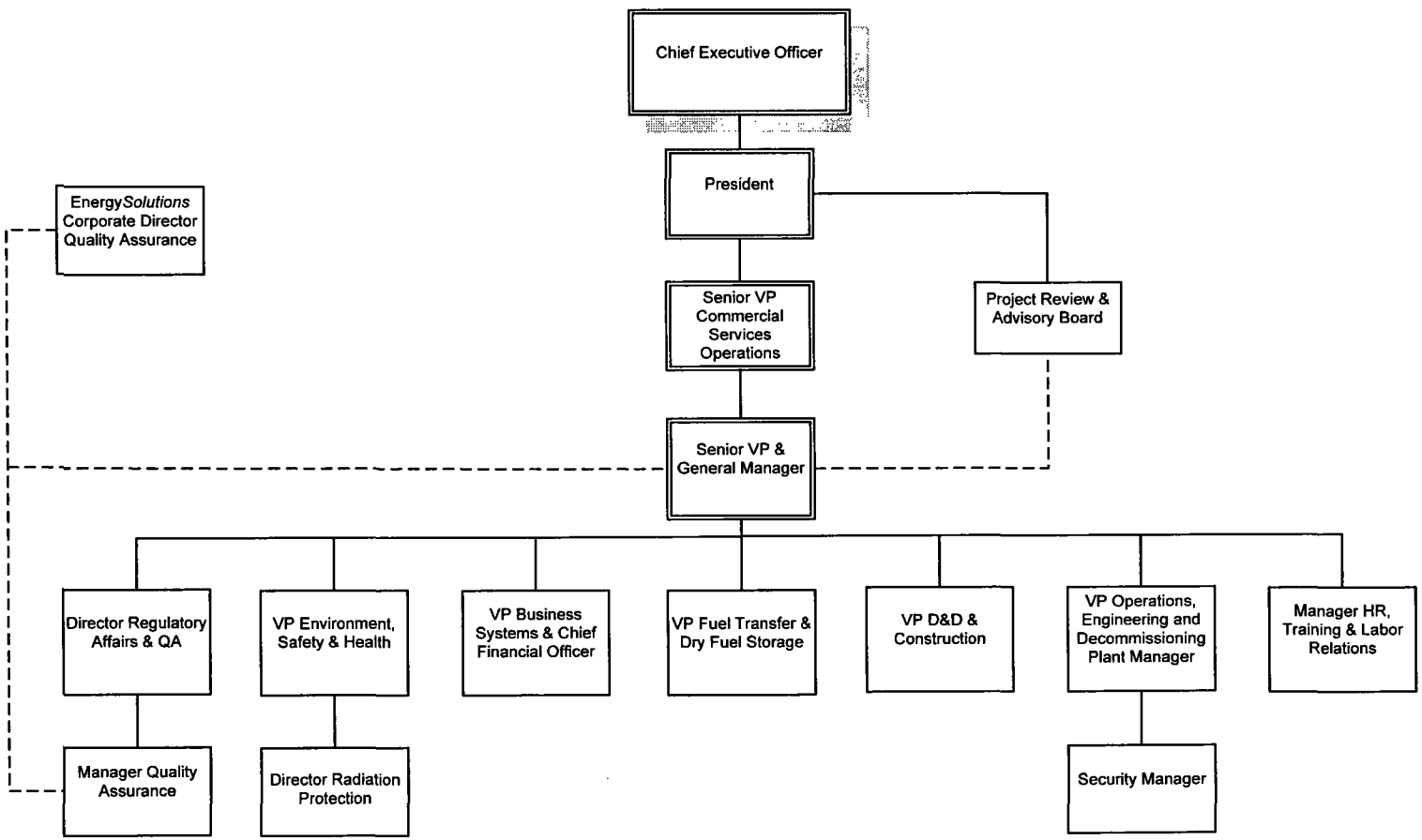
Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," Revision 1, June 1986.

Energy*Solutions* Quality Assurance Program, Rev. 0, effective May 31, 2007.

Exelon Quality Assurance Topical Report, Rev 84, implemented September 9, 2009.

Figure 1

Zion*Solutions* LLC
Restoration and Dry Cask Storage Project Organization Chart



Appendix A

List of Acronyms

ACE	Apparent Cause Evaluation
ASME	American Society of Mechanical Engineers
ANSI	American National Standards Institute
DCS	Dry Cask Storage
DFSS	Dry Fuel Storage System
ISFSI	Independent Spent Fuel Storage Installation
ITDC	Important to the Defueled Condition
ITS	Important To Safety
NUREG	Nuclear Regulatory Guide
PTSP	Project Technical Support Personnel
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
RCA	Root Cause Analysis
SAFSTOR	Safe Storage
SSC	Structures, Systems, and Components
USNRC	United States Nuclear Regulatory Commission