10 CFR 50.54(a)

October 1, 2014 ZS-2014-0325

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
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: Proposed Revision to Quality Assurance Project Plan

References:

1) Gerard van Noordennen (Zion*Solutions*, LLC) Letter to U. S. NRC Document Control Desk, "License Amendment Change Request Related to the Unloaded Spent Fuel Pool, Zion Nuclear Power Station, Units 1 and 2", dated March 17, 2014
2) John Sauger (Zion*Solutions*, LLC) Letter to U. S. NRC Document Control Desk, "Supplement 1 to License Amendment Request Related to the Unloaded Spent Fuel Pool, Zion Nuclear Power Station, Units 1 and 2", dated September 10, 2014
3) John Hickman (NRC) email to Gerard van Noordennen, "Comment on the License Amendment Request Related to Unloaded SFP," dated July 30, 2014
4) NRC Administrative Letter 95-06, "Relocation of Technical Specification Administrative Controls Related To Quality Assurance," dated December 12, 1995

The purpose of this letter is to request a change, in accordance with 10 CFR 50.54(a), to Revision 6 of the Zion Nuclear Power Station (ZNPS) Quality Assurance Project Plan (QAPP). The proposed change involves elimination of commitments to ANSI Standards and Regulatory Guides in various sections. By January 31, 2015, all spent fuel and GTCC Waste is planned to be removed from the Spent Fuel Pool and transferred to the Independent Spent Fuel Storage Installation (ISFSI) at the ZNPS site. All safety-related Structures, Systems, and Components (SSCs) have been removed from service and have undergone or are undergoing demolition. Therefore, the current commitments to various ANSI standards and Regulatory Guides will no longer be necessary. The only SSCs that remain subject to the QAPP are ISFSI related and the Type B radioactive waste packages shipped to an offsite disposal facility. The SSCs related to the ISFSI are categorized as Important To Safety and are subject to the guidance of Regulatory Guide 7.10, Revision 2, "Establishing Quality Assurance Program for Packaging Used in the Transportation of Radioactive Material". This guidance will be utilized to satisfy the criteria of Appendix B to 10 CFR 50 and the Quality Assurance requirements of 10 CFR 71 and 10 CFR 72.

Since the proposed change involves a reduction in commitment to the current QAPP, Zion*Solutions*, LLC (Zion*Solutions*) hereby requests NRC review and approval of the proposed change to the QAPP. Enclosure 1 provides a detailed description and justification of the

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proposed change including a comparison matrix of Regulatory Guide 7.10. The comparison matrix demonstrates that the provisions included in Regulatory Guide 7.10 have been adequately addressed in the QAPP and implementing procedures. Enclosure 1 also includes a comparison of the 10 CFR 71, Subpart H requirements to the QAPP to demonstrate that these criteria are adequately addressed. Proposed Revision 7 will also continue to meet the 10 CFR 50, Appendix B and 10 CFR 72, Subpart G requirements. Enclosure 2 includes a summary of changes. Enclosure 3 includes the proposed Revision 7 to the QAPP.

Proposed Revisions 5 and 6 were included with a license amendment request, as modified, (References 1, 2 and 3) to transfer the remaining administrative Technical Specifications to the QAPP (Reference 4). Revision 7 will be available for implementation once the license amendment is issued and after fuel transfer to the ISFSI is scheduled to be completed in January 2015. Revision 7 includes the proposed changes from Revisions 5 and 6. In accordance with 10 CFR 50.54(a), Zion*Solutions* will implement proposed Revision 7 to the QAPP upon approval by the NRC or after 60 days from the date of this letter and after all spent fuel has been transferred to the ISFSI. Similar changes have been proposed and approved at the Yankee Nuclear Power Station, Haddam Neck Plant, and Humboldt Bay Plant.

There are no regulatory commitments contained within this letter.

If you should have any questions regarding this submittal, please contact me at (224) 789-4025.

Respectfully,

Gerard van Noordennen

Gerard van Noordennen
Vice President of Regulatory Affairs
Zion*Solutions,* LLC

Enclosures:

1) Description and Justification of the Proposed Change to the QAPP Including a Comparison Matrix of Regulatory Guide 7.10
2) Summary of Changes
3) Quality Assurance Project Plan, ZS-QA-10, Proposed Revision 7

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Zion Nuclear Power Station (ZNPS)

Description and Justification of the Proposed Change to the QAPP Including a Comparison Matrix of Regulatory Guide 7.10

ZionSolutions ZS-QA-10 rev. 7 QAPP "RG 7.10 (Rev. 2) Compliance Matrix"

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
1. GUIDANCE ON § 71.103, QUALITY ASSURANCE ORGANIZATION	
1.1 Structure and Authority For each function, the structure of the organization and the assignment of responsibility should ensure that: -The formal organization structure is documented on organization charts that identify each organizational element that functions under the QA program,	An organizational chart is provided in the QAPP, Figure 1.
-The required authority and organizational freedom, including sufficient independence from influences of cost and schedule, are provided,	Section 3.1 states, "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."
-The specified quality requirements are achieved and maintained by those who have been assigned the responsibility for performing the work,	The Zion Restoration 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. Section 3.2.2 states, "The achievement of quality is the responsibility of all employees and is led by management. The QAPP provides for a

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
	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."
-Measures are established to provide adequate control over activities important to safety (e.g. inspecting, cleaning, purchasing, preparing the packaging for extent of quality assurance controls are to be applied to delivery), and	Section 3.2.1 states, "Procedures describe how Zion*Solutions* implements the requirements of the QAPP. These procedures document methods for planning, reviewing, implementing, controlling, and verifying that activities subject to this QAPP are performed in accordance with the applicable requirements from these documents: 10CFR50, Appendix B, 10CFR71 (Subpart H), 10CFR72 (Subpart G), NRC Regulatory Guide 7.10."
-Conformance to established requirements is verified by individuals and groups not directly responsible for performing the work. Note: If, because of limited personnel, multiple functions including QA are performed by the same individuals, measures should be established to ensure that the designated individuals when performing QA and QC functions have the responsibility and authority to stop unsatisfactory work, stop delivery or installation of nonconforming material, and have direct access to management levels that can ensure that QA procedures important to safety have been accomplished.	Section 3.10.1 states, "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."
The duties and qualifications required for (1) the individual who has overall authority and responsibility for the QA program as well as (2) other personnel performing QA and QC functions, and those individuals should have the written endorsement of top management.	The "Statement of Quality Assurance Policy " signed by the President and Chief Executive Officer states, "The QA Manager has been delegated the authority to implement and revise the provisions of this QAPP, and to regularly assess the scope, status, implementation and effectiveness of this QAPP. The GM reports to the President, and Section 2.4 states, "The GM has

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
	overall authority and responsibility for the establishment and effective implementation of the QAPP." Section 2.6 states, "The QAM reports to the GM, and has access to the EnergySolutions Corporate QA Director for quality matters. The QAM is responsible for establishing and maintaining the QAPP, monitoring the project's quality objectives through overview and inspection 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." For both parts (1) & (2), Appendix B contains the qualification requirements applicable to the Quality Assurance Manager and other plant personnel performing quality activities, as follows: "Each member of the facility staff (including audit/survey, surveillance and inspection personnel) shall have sufficient qualifications to perform their assigned duties. Implementing procedures provide the guidance used for determining and assessing appropriate staff qualifications." Section 3.2.3.2, Inspection and Test Personnel, states, "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."

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
	Section 3.2.3.3, Lead Auditors and Inspectors, states, "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. 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. Auditor and Inspector certification documentation shall be maintained in accordance with approved procedures."
1.2 Top Management Endorsement of a QA Program Top management should maintain a continuing involvement in QA matters in order to ensure that the QA program is effective. To ensure the commitment of top management, the company/corporate president or chief executive officer should establish a written policy stating that it is company/corporate policy to perform work on items important to safety in accordance with the requirements of Subpart H, as described in Policy Statement the QA program plan and implemented in the QA program implementing documents. The policy statement should also identify the functions and positions who have delegated authority for the following tasks: • Implement and revise the provisions of the described QA program. • Regularly assess the scope, status, implementation, and effectiveness of the QA program.	The "Statement of Quality Assurance Policy" signed by the President and Chief Executive Officer states, "The QA Manager has been delegated the authority to implement and revise the provisions of this QAPP, and to regularly assess the scope, status, implementation and effectiveness of this QAPP." The "Statement of Quality Assurance Policy" also includes the following: "This Quality Assurance Project Plan (QAPP) defines the Zion*Solutions* LLC Quality Assurance Program to be implemented during the Zion Station Restoration 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," Part 71, Subpart H, "Quality Assurance Requirements for Packaging and Transportation of Radioactive Waste…" and "The QAPP applies to all activities associated with structures, systems, and components (SSCs) which are important to safety (10 CFR 72). The QAPP also applies to transportation packages licensed by the NRC under 10 CFR 71."
2. GUIDANCE ON §71.105, "QUALITY ASSURANCE PROGRAM"	
2.1 General Guidance on QA Programs	The QAPP has been previously approved by the NRC under Appendix

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
In its program description submittal, the OA program user should identify to the NRC how each of the regulations in Subpart H of 10 CFR Part 71 applies to its particular situation and how it will be satisfied. The information supplied for NRC review will vary as a function of the nature of activities in which the OA program user is involved. For example, an individual or organization using a general license solely for transportation of radioactive material in packages purchased or leased for that purpose would be expected to address regulations governing activities such as procurement, shipment, and handling. By contrast, someone who designs and fabricates packaging would be expected to address criteria for design and testing, as well as material procurement activities. Elements common to all QA program descriptions include the quality organization and program, corrective action, QA records, and audits. In developing its programs, prospective QA program users can refer to the NRC's guidance in this regulatory guide, as well as the additional guidance on graded QA in NUREG/CR-6407. In developing its program, QA program users should apply each of the applicable Subpart H regulations in a graded approach (i.e., to an extent that is consistent with its importance to safety). Following the NRC staffs technical review and determination that the QA program submittal meets regulatory requirements, the Commission issues a QA Program Approval. The approval expires on the last day of the month stated on the approval form and may be renewed (at the request of the QA program user and in accordance with 10 CFR 71.38) not less than 30 days prior to expiration. All changes to the approved QA program description require NRC approval. Therefore, before implementing any change in the QA program description that was used as the basis for NRC approval, the QA program user should submit the proposed change for NRC review	B to 10 CFR Part 50, and was also subsequently accepted under 10 CFR 71.101(f). This compliance matrix is intended to identify to the NRC how each of the regulations in Subpart H of 10 CFR Part 71 applies to the Zion situation and how it will be satisfied. As stated in Section 1.0, "The QAPP is implemented through the use of approved procedures (i.e., policies, directives, procedures, manuals, instructions, or other documents) which provide written guidance for the control of important to safety items and activities and provides for the development of documentation to demonstrate objective evidence of compliance with stated requirements."

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
and approval. Requests for review and approval of such changes are handled through amendments to the QA Program Approvals and do not affect the renewal dates. The only exception to the requirement for NRC approval of any change relates to QA programs that the NRC staff approved under Appendix B to 10 CFR Part 50, which was subsequently accepted under 10 CFR 71.101(f). This exception allows a nuclear power plant licensee to change such a QA Program to the extent permitted under 10 CFR 50.54(a)(3). Based on NRC approval of its QA program description submittals, a QA program user will translate the regulations discussed in its submittals into lower-level (working-level) implementing procedures that govern the conduct of QA activities that are important to safety. If the NRC staff reviews a QA program submittal and finds that it inadequately describes how the requirements will be met or fails to specifically address some Subpart H regulation(s), the staff will ask the QA program user to submit additional information to correct the deficiencies.	
2.2 Scope of QA Program The QA program user should establish measures for identifying (1) the components, structures, and systems to be covered by the QA program, and (2) the approach for verifying that the applicable components, structures, and systems meet design objectives. Although 10 CFR Part 71 allows the development of a "graded" QA program, this does not preclude the alternative of defining a program based on maximum controls if such a program is deemed necessary to attain the confidence needed for meeting design objectives. In particular, the QA program user should establish measures to ensure that the following requirements are fulfilled: • Activities important to safety are performed using specified equipment and under suitable environmental conditions.	For item (1), Appendix A addresses all SSCs to which the QAPP is applicable. For item (2), various sections of the QAPP identify the approach for verifying that the applicable components, structures, and systems meet design objectives. For bullet 1, Sections 3.4, 3.5, 3.7, 3.8, 3.12, 3.13 & 3.14 identify the controls and practices necessary to ensure that activities important to safety are performed using specified equipment and under suitable environmental conditions . For bullet 2, all sections of the QAPP specify the QA and QC

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
• QA/QC manuals specify the designated QA and QC designated responsibilities for implementation of activities important to safety. • The QA program user has established indoctrination and training programs to ensure that personnel performing activities important to safety are trained and qualified to perform those activities.	responsibilities applicable to the implementation of activities important to safety. For bullet 3, Section 3.2 establishes the requirements for indoctrination and training programs to ensure that personnel performing activities important to safety are trained and qualified to perform those activities.
2.3 Applicability of QA Program Measures covered by the QA program should be compatible with and emphasize characteristics identified in the manufacturer's QA program. The QA program user should establish the rationale to Identify items that are classified as important to safety and subject to the user's QA program.	Appendix A of the QAPP address the applicability of the QAPP, including all SSCs, In Appendix A, the NAC MAGNASTOR Final Safety Analysis Report (FSAR), the NAC MAGNATRAN Safety Analysis Report (SAR), associated NAC specifications, and NUREG/CR-6407 are identified as input references for determining Important to Safety classifications.
2.4 Documentation The QA program user should ensure that (1) written procedures and instructions describe all activities that are important to safety and applicable to the design, procurement, fabrication, and testing of packaging, and (2) those procedures and instructions will be in place before the QA program user engages in those activities. With respect to anticipated activities important to safety that the QA program user has not yet initiated, the user should identify the implementing procedures by title and procedure number, and should provide a brief description of the content of those procedures with an estimated date for their completion. The following table shows a suitable format for listing procedures to demonstrate implementation of a documented QA program. (Table 1 omitted.)	Section 1.1 states, "The QAPP is implemented through the use of approved procedures (i.e., policies, directives, procedures, manuals, instructions, or other documents) which provide written guidance for the control of important to safety items and activities and provides for the development of documentation to demonstrate objective evidence of compliance with stated requirements." Section 3.2.1 states, "Procedures describe how ZionSolutions implements the requirements of the QAPP. These procedures document methods for planning, reviewing, implementing, controlling, and verifying that activities subject to this QAPP are performed in accordance with the applicable requirements from these documents: 10CFR50, Appendix B, 10CFR71 (Subpart H), 10CFR72 (Subpart G), NRC Regulatory Guide 7.10." (The Quality Assurance Criterion to Implementing Procedure Matrix is contained in Attachment 1)
2.5 Controlled Conditions The QA program user should establish measures to ensure that activities important to safety are accomplished using appropriate production and	Section 2.0 "Quality Responsibilities" provides general responsibilities by functional areas.

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
test equipment, suitable environmental conditions, applicable codes and standards, and proper work instructions. The QA program user should also document the assignment of responsibility for each task and method used to verify conformance to these quality requirements.	Section 1.1 states, "The QAPP is implemented through the use of approved procedures (i.e., policies, directives, procedures, manuals, instructions, or other documents) which provide written guidance for the control of important to safety items and activities and provides for the development of documentation to demonstrate objective evidence of compliance with stated requirements." Section 3.5 states, "Management is responsible for ensuring that ITS 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."
3. GUIDANCE ON §71.107, "PACKAGE DESIGN CONTROL" Essential elements of adequate design control are (1) good relationships among those responsible for preparing design disclosures, (2) conducting independent design analyses, (3) coordinating interfaces, and (4) maintaining lines of communication. To ensure an adequate commitment to control of design activities, applicants should consider the three principal areas of (1) control of the design process, (2) control of design input, and (3) control of design verification, as defined in regulatory positions 3.1 - 3.3. Since users of packaging do not normally perform design activities, this section of Subpart H should not be applicable to users of packaging. However, users should establish and verify that the packaging was designed under the control of an NRC- approved QA program. Computer-aided design (CAD) is extensively used in current design applications. Designs developed using CAD methods are prepared and stored electronically. Thus, applicable QA procedures that address	ZionSolutions does not design packages to be licensed under 10 CFR 71 or 10 CFR 72. Per the RG 7.10 guidance on 10 CFR 71.07 (see left column), "Since users of packaging do not normally perform design activities, this section of Subpart H should not be applicable to users of packaging. However, users should establish and verify that the packaging was designed under the control of an NRC-approved QA program." Zion has verified that the NAC MAGNASTOR System was designed under the control of an NRC-approved QA Program (the NAC QA Program). Zion has also verified that 10 CFR 71 licensed shipments of B and C waste from the Zion site contracted to EnergySolutions were designed under the control of an NRC-approved QA Program (the EnergySolutions QA Program). Therefore, this section of Subpart H is not applicable to ZionSolutions, as we are users of the packaging was designed under the control of an NRC- approved QA program. However, guidance is provided in this

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
software verification/validation, management of electronic records, and quality control of electronic data should address the control of electronic data in design applications to ensure authenticity and technical accuracy. The Nuclear Information and Records Management Association (NIRMA), American National Standards Institute (ANSI), and the Electric Power Research Institute (EPRI) provide guidance for use in developing QA programs for managing electronic data. In addition, NRC Generic Letter 88-18, "Plant Record Storage on Optical Disks" (Ref. 5), and Regulatory Information Summary 00-18, "Guidance on Managing Quality Assurance Records in Electronic Media" provides guidance on the use of optical disc document imaging systems for retrieving record copies of QA records. 3.1 Control of Design Process Measures such as "classification of characteristics" should be established to ensure that packaging designs are reviewed to emphasize critical parameters that can be controlled by inspections or tests and to identify test and inspection criteria and quality standards. Recognized engineering practices such as prescribing drafting room standards, checking methods, review and approval requirements, issuance and distribution requirements (including revisions to them), maintaining current "as-built" configurations, and storage and control of original and master copies should be established to control the preparation of drawings and specifications. 3.2 Control of Design Input Measures should be established to ensure that appropriate codes and standards are used in the design of the packaging. In the absence of such codes and standards for formulation of the design activities, alternative approaches should be identified. Measures should be established to ensure (1) that all design parameters,	section primarily for two purposes: 1) To provide for an appropriate interface with the NRC packaging Certificate Holder to ensure ISFSI or site SSCs do not adversely affect the important-to safety SSCs at the ISFSI, and 2) To provide guidance for the engineering of ISFSI and decommissioning activities, and ensuring adequate technical review is applied to changes, tests and experiments. Appendix A to the QAPP explains the interface between Zion engineering and design and the design authority for the packaging design (the Certificate Holder, NAC) as follows: "The safety classification of NRC Licensed ISFSI Dry Fuel Storage Components and Transportation Packages may not be revised using the Zion Design Control process. These modifications must be made by the NRC Certificate Holder. The Certificate Holder is responsible for design and licensing controls for these components under their NRC approved Quality Assurance Program. Zion utilizes these types of components and packages under the provisions of NRC General License for Radioactive Material Transportation Packages (10 CFR 71) and Spent Fuel Storage (10 CFR 72)." Section 2.8 states that the Engineering Manager (EM) is "...responsible for the engineering of ISFSI and decommissioning activities, and ensuring adequate technical review is applied to changes, tests and experiments." Section 3.3 states, "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

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
e.g., criticality physics, cooling, and decontamination of an item, have been properly considered, reviewed, and approved by the responsible design organization and that the parameters are in accordance with the applicable performance codes, standards, and regulatory requirements and (2) that maintenance, repair, in-service inspection, handling, storage, and cleaning requirements are specified in design documents. 3.3 Control of Design Verification Methods to be used In verifying the adequacy of the design (e.g., qualification testing, design review, or alternative calculations, including use of computer programs) should be established. Technically qualified individuals or groups responsible for design verification should not be in the administrative line of authority of the original designer. The designer's immediate supervisor may perform the verification provided: _ The supervisor is the only technically qualified individual, _ The need is documented and approved in advance by the supervisor's management, and _ The QA audits cover the effectiveness of the use of supervisors as design verifiers to guard against abuse of this practice. During the sequence of design verification, changes to the final design may result; consequently, measures should be established for ensuring that drawing and specification changes are reviewed and approved by the same individuals or organizations that reviewed and approved the original documents. Changes in design that could result in conditions different from those prescribed on the CoC should be approved by NRC prior to implementation. Design verification, if other than by qualification testing of a prototype or lead production unit, should be satisfactorily completed prior to (1) release for procurement or fabrication and (2) release to other	design document distribution. These design controls are intended to apply to those ISFSI or site SSCs that may impact the important-to safety SSCs at the ISFSI." ZionSolutions does not utilize computer codes and calculations in the design process. Specific measures applicable for control of RECORDS are addressed in subsequent sections of this matrix.

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
organizations for use in other design activities except when this timing cannot be met. In these cases, design verification may be deferred provided the justification for this action is documented and the unverified portion of the design output documents are appropriately identified and controlled. When a test program is used to verify the adequacy of a design, the prototype should be subjected to the most adverse design conditions.	
4. GUIDANCE ON §71.109, "PROCUREMENT DOCUMENT CONTROL" The QA program user should establish measures to control the preparation, review, concurrence, and approval of all procurement documents. 4.1 Content of Procurement Documents The QA program user should establish measures to ensure that procurement documents include the following information (as applicable): • the scope of work to be performed by the prospective supplier • the design-basis technical requirements (or references thereto), including applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and standards, special process instructions, and test and inspection requirements • applicable Subpart H requirements that should be complied with and described in the supplier's QA program (Qualified QA personnel from the purchaser's organization should review and concur in the supplier's QA program or portions thereof before the purchaser initiates activities affected by the program. Also, if sub-tier suppliers are involved, the QA program user should specify the QA provisions appropriate to Procedure those procurements. The extent of the supplier's and sub-tier supplier's QA programs will depend on the particular item or service being	Section 3.4 states, "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. Management is responsible for supplying personnel to perform the procurement process and ensuring that project-specific requirements for procurement documents are documented. 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. 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.

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
procured.) • permission to gain access to the supplier's and sub-tier supplier's plant facilities and records for inspection and audit purposes (Procurement documents should identify the type of verification activities required of any sub-tier suppliers for supplied materials, as well for any design, fabrication, assembly, testing, maintenance, and repair services or activities supplied.) • identification of the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, results of chemical and physical tests on material) that the supplier(s) must prepare, maintain, and submit to the purchaser for approval • requirements for reporting and approving disposition of nonconformances • identification of records that the supplier must retain, control, and maintain, as well as those records that the supplier must deliver to the purchaser prior to installation of hardware [These records should include the pertinent documentation to be furnished with the procured materials or services (e.g., CoC, as-built drawings, photographs, sketches, use and maintenance manuals). If the pertinent documentation is in an electronic format, the QA program user should specify the software system that must be used to prepare and deliver the documentation.] 4.2 Replacement Part Procurement Measures should be established to require that procurement of replacement parts important to safety be reviewed by QA personnel to ensure that appropriate technical and QA requirements are included in purchase orders and that the purchase orders are placed with suppliers previously qualified during fabrication of the packaging. If replacement parts are purchased from suppliers not previously identified as qualified sources, the QA program user must assure himself or herself that the	QA shall review all Important to Safety (ITS) procurements for the appropriate Quality Assurance requirements prior to issuance. Changes to procurement documents receive the same level of review and approval as the original." In addition, Procedure AD-16, "Requisitioning Material, Equipment & Services", includes guidance to ensure the following specific points are adequately addressed in procurement documents for important-to-safety scope: • material and component identification requirements, • drawings, specifications, codes and standards, • special process instructions, • test and inspection requirements, • replacement parts must meet or exceed original criteria,

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
replacement parts meet requirements at least as stringent as the original criteria. 4.3 Review and Changes to Procurement Documents The QA program user should establish measures to ensure that review and approval of procurement documents are recorded prior to release, and that changes and revisions to those documents are subject to at least the same review and approval as the original documents.	
5. GUIDANCE ON §71.111, "INSTRUCTIONS, PROCEDURES, AND DRAWINGS" 5.1 Quality Assurance Program Procedures The QA program user should establish measures to ensure that the following requirements are fulfilled: • Activities important to safety are prescribed and accomplished in accordance with current documented instructions, procedures, or drawings that have been approved by appropriate levels of management. • Instructions, procedures, and drawings specify the methods for complying with each of the applicable sections of Subpart H of 10 CFR Part 71. • All work activities are coordinated with QA personnel to ensure that the work controlling documents incorporate appropriate inspection and hold points to verify that initial work, planned work, effective repairs, or rework have been performed satisfactorily. • Instructions, procedures, and drawings include quantitative acceptance criteria (e.g., dimensions, tolerances, and operating limits) and qualitative acceptance criteria (e.g. workmanship samples) to verify that activities important to safety have been satisfactorily accomplished. • Written procedures address the use, management, storage, and protection of electronic records and data. The QA program user should also maintain information on the specific software applications and	Section 1.0 states, "The QAPP is implemented through the use of approved procedures (i.e., policies, directives, procedures, manuals, instructions, or other documents) which provide written guidance for the control of important to safety items and activities and provides for the development of documentation to demonstrate objective evidence of compliance with stated requirements." Section 3.2..1 states, Procedures describe how ZionSolutions implements the requirements of the QAPP. These procedures document methods for planning, reviewing, implementing, controlling, and verifying that activities subject to this QAPP are performed in accordance with the applicable requirements from...10CFR71, Subpart H..." (see Attachment 1). Section 3.5 states, "Management is responsible for ensuring that ITS 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." "Management is responsible for maintaining these documents current to reflect actual work practice. Instructions, procedures, work instructions and drawings

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
storage or computing hardware. 5.2 QA Review and Concurrence The QA program user should establish measures to ensure that the QA organization reviews and concurs in inspection plans; test, calibration, and special process procedures; and specifications as well as any changes thereto. Prior to fabrication of an item, the QA organization should review and concur in the related manufacturing plans, as they relate to scheduled witness and hold points during fabrication.	are prepared, reviewed, issued, and controlled in accordance with approved procedures." Section 3.10.2 states, "Responsibilities for identifying and specifying hold points are established in approved procedures. Quality Assurance, Engineering / 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." Procedure AD-6, "Procedure Control Program," describes the process for development, review approval and revision of procedures, including the review and approval by appropriate levels of management. This includes the interaction with quality assurance personnel for verification activities, including establishing the appropriate qualitative and quantitative acceptance criteria. Procedure AD-20, "Records Management Program," identifies the types of acceptable storage media and associated acceptance and maintenance criteria for each. Records are processed from the Zion site into the Exelon electronic records system in accordance with approved procedures.
6. GUIDANCE ON §71.113. "DOCUMENT CONTROL" 6.1 Controlled Documents The QA program user should maintain each of the documents under the control of the QA program to reflect the current status. As a minimum, the QA program user should exercise control over the following: • design documents (e.g., drawings, specifications, and computer codes) • procurement documents • QA and QC manuals	Section 3.6 states, "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." In nearly each section of the QAPP where the various types of

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
• operating, maintenance, and modification procedures • inspection and test procedures • nonconformance reports • design change requests • corrective action reports 6.2 Control of Document Generation and Issuance The QA program user should establish controls to ensure that all documents and changes thereto are adequately reviewed and approved prior to their issuance. These controls should include measures (e.g., the use of a master document list) to ensure that current issues of applicable documents are available at the location where the activity is being performed to preclude use of *obsolete* or superseded documents. The QA program user should *also* check all packaging affected by design changes to verify that it is in accordance with the appropriate revision. In addition, the QA program user should identify (by function or position) the individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto. 6.3 Control of Document Changes The QA program user should establish measures to ensure that changes to documents are reviewed by the same organization that performed the original review and approval and the changes are in accordance with established configuration control procedures. 6.4 Control of Electronic Documents If the documents are stored electronically, the QA program user should establish controls over access to the documents to ensure that the latest versions of the documents are available and changes to the documents are properly authorized and implemented. The software and hardware systems used to store electronic information should be reliable to avoid alteration or corruption of the information.	documents are described, the QAPP specifies appropriate controls for quality documents, regardless of the media and calls for specific controls to be contained in implementing procedures. Procedure AD-6, "Procedure Control Program," describes the process for development, review approval and revision of procedures. Procurement documents, nonconformance reports and corrective action reports are not controlled documents at ZionSolutions. They function as QA records rather than controlled documents. Section 3.6 states, "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." "In addition, the QA program user should identify (by function or position) the individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto." The numerous implementing procedures that describe the creation and control of the various types of documents generated identify (by function or position) the individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto. Implementing Procedure AD-5 "Document Control" provides requirements for control of documents of all types of media. Procedure AD-20, "Records Management Program," identifies the types of acceptable storage media and associated acceptance and maintenance criteria for each. Records are processed from the Zion site into the Exelon electronic records system in accordance with approved procedures.

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
7. GUIDANCE ON §71.115, "CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES" The QA program user should establish measures in the areas identified below to ensure that materials, equipment, and services conform to procurement documents. 7.1 Procurement Document Planning The OA program user should establish procurement planning procedures that describe each procurement step leading to contract award for items and services. These procedures should identify the organizations responsible for each procurement step. 7.2 Selection of Procurement Sources The OA program user should establish measures for evaluating and selecting procurement sources, including the extent of QA and engineering involvement. Specifically, the OA program user should consider establishing the following provisions (if applicable): • the supplier's capability to comply with applicable sections of Subpart H • results of the survey of the supplier's facility and QA program • review of the supplier's previous records and performance. 7.3 Bid Evaluation and Award The OA program user should establish measures to ensure that designated individuals or organizations evaluate proposed suppliers, as applicable to the type of procurement, based on technical considerations, conformance to OA requirements, production capability, and past performance. Prior to contract award, the OA program user should resolve (if possible) all unacceptable conditions identified during the bid evaluation. If any unacceptable conditions cannot be resolved prior to	The QAPP (as delineated below) establishes the measures necessary to assure that purchased material, equipment, and services, whether purchased directly or through contractors or subcontractors, conform to the requirements of the procurement documents. These measures shall be specified in implementing procedures. For Important to Safety procurements, Procedure AD-16, "Requisitioning Material, Equipment & Services", assigns responsibility for implementation to the ISFSI Manager. Section 3.7 states, "Zion*Solutions* procurement controls establish measures to ensure those procured items and services for ITS 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." Section 3.7.1 states, "Project technical, procurement, and QA personnel participate, as appropriate, in evaluation of potential procurement sources for ITS-A / ITS-B. Supplier evaluations include elements of the QA Program applicable to the purchased item or services." "Once selected, QA shall evaluate the supplier and if acceptable, add the supplier to the Zion*Solutions* approved supplier list. In addition, 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."

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
contract award, the QA program user should obtain the supplier's commitment that the conditions will be resolved at a mutually agreeable date during the contract period. 7.4 Supplier Performance Control The QA program user should establish measures for pre- and post-award activities, such as meetings and other communications, to ensure that the supplier understands procurement requirements, including, if applicable, "hold points" (i.e., pre-established Inspection points in the manufacturing process that require Inspection approval and release by the QA organization prior to further processing) during manufacturing and testing and before shipment. 7.5 Verification Activities The QA program user should establish the extent to which source surveillance will be performed during fabrication, assembly, maintenance, modification, repair, inspection, testing, and shipment to ensure conformance with the purchase order requirements. The source surveillance should cover the following aspects: • instructions specifying characteristics or processes to be witnessed, inspected, or verified • the documentation required • identification of those responsible for implementing source surveillance The QA program user should also establish the extent to which inspection will be performed upon receipt of supplier-furnished hardware to ensure that items are properly identified and correspond with procurement documentation. When acceptance of an item is contingent on tests after installation in the package, the QA program user and item supplier should mutually establish the relevant acceptance documentation prior to its use.	Section 3.7.3 states, "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. • Verifying material identification and traceability control. • Verifying 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." Section 3.7.4 states, "Receiving inspection shall be performed for purchased items that are ITS (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 ITS SSC as applicable. Nonconforming conditions or

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
In addition, the QA program user should take appropriate measures (such as source surveillance and audits of records) to ensure that the supplier performed the design and fabrication of packaging under the control of an NRC-approved QA program. 7.6 Controlling Nonconformances The QA program user should establish measures to ensure the proper disposition of items or services that do not meet procurement requirements. These measures should include evaluation of nonconforming items categorized by the supplier, along with technical justification and recommended disposition (e.g., "use as is" or "repair"). 7.7 Records The QA program user should establish measures to ensure that the supplier furnishes to the purchaser the following records (as a minimum): • documentation that identifies material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications met by the items) • documentation that identifies any procurement requirements that have not been met, along with a description of those nonconformances designated "use as is" or "repair" • documentation that the supplied material and equipment meets the applicable procurement requirements prior to installation or use • appropriate documentation, as identified in the purchase order, that will accompany the NRC-approved packaging during transport and be 'received at the destination by the user. Such documents should (1) be referenced in the CoC, (2) relate to the use and maintenance of the packaging, and (3) identify necessary	discrepancies identified during a receipt inspection shall be documented on Condition Report (CR). The controls used for procuring items or services include the requirement that the suppliers/subcontractors are required to implement their QA Program that meets the applicable requirements of this QAPP for the requested item or service for important-to-safety category A and B. These supplier/subcontractor QA programs must be reviewed and accepted by ZionSolutions 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." Procedure AD-16, "Requisitioning Material, Equipment & Services", includes guidance to ensure the following specific points are adequately addressed in procurement documents for important-to-safety scope: • ensure that the supplier understands procurement requirements, • establishing, if applicable, "hold points" • provide for the evaluation of nonconforming items categorized by the supplier, along with technical justification and recommended disposition (e.g., "use as is" or "repair") • establish requirements for supplier CofC • establish documentation and records requirements, including requirements for electronic media, if applicable, and retention requirements.

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
actions to be taken prior to delivery of the licensed material to a carrier for transport. If the pertinent documentation is in an electronic format, the QA program user should specify the software system that must be used to prepare and deliver the documentation. The QA program user should retain the documentation at the facility or site of material or equipment use.	
8. GUIDANCE ON §71.117, "IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS" The QA program user should establish measures to ensure that materials, parts, and components, including partially fabricated assemblies, are adequately identified to preclude the use of incorrect or defective items. These measures should provide the means for physical identification (e.g., stamping, tags, labels, or lot-follower cards) and traceability to appropriate documentation (e.g., mill reports, drawings, or specifications) throughout fabrication, installation, and use. Also, when replacement of limited-life items is specified, the OA program user should establish measures to preclude use of items for which the shelf life or prescribed operation time has expired. In addition, the OA program user should establish measures to facilitate continued processing when required inspections or tests have not been completed in order to maintain physical identity and control over affected materials.	Section 3.8 states, "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. Identification of each item is maintained throughout fabrication, shipping and handling, erection, installation, and use so that the item can be traced to its documentation. Traceability is maintained to an extent consistent with the item's importance to safety." Procedure AD-16, "Requisitioning Material, Equipment & Services", and Procedure AD-17, "Receipt Inspection Storage and Control of Purchased Equipment, Material and Services" includes guidance to ensure the identification and control are adequately addressed for important-to-safety scope in the procurement stages. The implementation of any Important to Safety work at the ISFSI would invoke the use of Procedure AD-3, "ISFSI Work Control", and the generation of a Work Order subject to QA review. Any appropriate in-process inspections / Hold Points would be included in the Work Order to verify adequate identification and control of Important to Safety items.
9. GUIDANCE ON §71.119, "CONTROL OF SPECIAL PROCESSES" Special processes are not normally performed by the user of packaging. However, if packaging maintenance requires the use of special processes (e.g., welding or heat treating) or nondestructive testing, or if special processes are required to meet CoC requirements, the QA	Section 3.9 states: "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.

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
program user should establish measures to ensure that the special processes are controlled in accordance with the following requirements: • Procedures, equipment, and personnel are qualified in accordance with applicable codes, standards, and specifications. • The operations are performed by qualified personnel and accomplished in accordance with written process or procedure sheets that direct the recording of evidence of verification. • Qualification records of procedures, equipment, and personnel are established, filed, and kept current.	Documentation of personnel, equipment, and process qualifications is maintained in accordance with procedures." Procedure AD-16, "Requisitioning Material, Equipment & Services", includes guidance to ensure the requirements for special processes are adequately addressed for important-to-safety scope in the procurement stages. The implementation of any Important to Safety work at the ISFSI would invoke the use of Procedure AD-3, "ISFSI Work Control", and the generation of a Work Order subject to QA review. Any appropriate in-process inspections / Hold Points would be included in the Work Order to verify special process procedures, equipment, and personnel are currently qualified in accordance with applicable codes, standards, and specifications.
10. GUIDANCE ON §71.121, "INTERNAL INSPECTION" 10.1 The QA program user should establish measures to ensure that the following requirements are fulfilled: • Inspection procedures, instructions, or checklists are available for each work operation, where necessary to ensure quality. • Documents developed include methods for identifying characteristics and activities to be inspected, acceptance and rejection criteria, and the individuals or groups responsible for performing the inspection. • Objective evidence of inspection results is recorded. • Hold or witness points are identified. • The appropriate personnel approve data to ensure that all inspection requirements have been satisfied.	Section 3.10.2 states, "Responsibilities for identifying and specifying hold points are established in approved procedures. Quality Assurance, Engineering / 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." Section 3.10.3 states, "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;

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
• The prerequisites to be satisfied prior to inspection are identified, including operator qualification and equipment calibration. Where sampling is used to verify acceptability of a group of items, the standard used as the basis for acceptance should be identified. 10.2.1 Receiving Inspections The QA program user should establish measures to ensure that items that are important to safety (i.e., the features of a structure, component, or system under control of the QA program and necessary to ensure the integrity of the packaging and its capability to prevent or mitigate the consequences that could result from release of radioactive material) meet the requirements specified on the purchase order when the items are received at the plant. The QA program user should establish the criteria for acceptance of each of these inspections, as well as the action to be taken if noncompliance is encountered. These visual inspections should Include the following aspects: • surface conditions • weld and structural Integrity • the condition of flange faces or sealing areas, gaskets, seals, gauges, rupture disks, valves, and pressure relief devices • the condition of tie-down members (if applicable) • labeling and marking • leak-tightness of the packaging In addition, the QA program user should establish provisions to control accepted items until they are placed in stock or released for use, as well as provisions for the proper disposition of rejected items. 10.2.2 In-Process Inspections The QA program user should establish measures to ensure that process specifications and their supporting	• 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." Section 3.7.4 states, "Receiving inspection shall be performed for purchased items that are ITS (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. NOTE: all Important to Safety packaging has been previously received at the ZionSolutions ISFSI. The implementation of any Important to Safety work at the ISFSI would invoke the use of Procedure AD-3, "ISFSI Work Control", and the generation of a Work Order subject to QA review. Any appropriate in-process inspections / Hold Points would be included in the Work Order. Procedures OP-2, "ISFSI Surveillance and Inspections Program", OP-3, "VCC Screen Inspection at the ISFSI", and OP-4, "VCC and ISFSI Pad Inspection Program", provide the measures for the maintenance inspection to ensure adequate maintenance of the Important to Safety packaging. These measures include identification of the items to be

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
documentation provide for indirect control by monitoring processing methods equipment, and personnel if direct inspection is impractical. 10.2.3 Final Inspections The QA program user should establish measures to ensure that (1) final inspections provide for resolution of nonconformances identified in earlier inspections, (2) the inspected item is identifiable and traceable to specific records and is adequately protected from physical or environmental damage, and (3) supervisors review inspection records to verify that all inspection requirements have been satisfied. For packaging use, the QA program user should establish checklists to ensure that inspections are performed to verify the following: • Packages are properly assembled. • Moderators and neutron absorbers are present, if applicable. • Valves through which primary coolant flows are protected against tampering. • Valves are set to specifications. • All shipping papers are properly completed. • Packages are conspicuously and durably marked as required by the regulations set forth by the U.S. Department of Transportation (DOT). • Measures are established to ensure that appropriate personnel designated by the package user sign the shipping tags or indicators prior to authorization for shipping. 10.2.4 Maintenance Inspections The QA program user should establish measures for an inspection program to ensure adequate maintenance of packaging. This inspection program should identify the items to be maintained, criteria for acceptability or replacement, and the frequencies of inspection assigned to each item.	maintained, criteria for acceptability or replacement, and frequencies of inspection assigned to each item. Section 3.2.3.2 states. "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." Section 3.10.1 states, "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." Section 3.10.4 states, "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 nonconformances." Procedure AD-20, "Records Management Program," identifies the types of records considered QA records, and establishes the retention periods for each.

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
10.2.5 Inspectors The QA program user should establish measures to ensure that (1) inspectors are qualified in accordance with applicable codes, standards, and company training programs; (2) such qualifications and certifications are kept current; and (3) inspection personnel are independent from all individuals performing the activity being inspected. 10.2.6 Inspection Documentation The QA program user should maintain inspection records as QA records to document performance of inspection activities.	
11. GUIDANCE ON §71.123, " TEST CONTROL" 11.1 Requirements The QA program user should establish measures to ensure that applicable test programs, including prototype qualification tests, production tests, proof tests, and operational tests, are accomplished in accordance with written procedures. The QA program user should also establish measures to ensure that modifications, repairs, and replacements are tested in accordance with the original design and testing requirements. 11.2 Procedures The QA program user should establish measures to ensure that test prerequisites identified in the appropriate design disclosures (e.g., instrument calibrations, monitoring to be performed, mandatory hold points, suitable environmental conditions to be maintained, condition of the test equipment, methods for physical identification of test specimen, methods for documenting or recording test data, and criteria for acceptance) are properly translated into test procedures.	Section 3.11 states, 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. Section 3.11.1 states, Engineering / 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. 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. Section 3.11.2 states, Test results are documented and evaluated by a

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
11.3 Acceptance Tests The QA program user should establish measures, as appropriate, to ensure that acceptance tests are conducted prior to delivering packages for transport to a carrier. These measures should identify the basis for acceptance criteria (e.g., CoC, maintenance and operational manuals furnished by the packaging manufacturers). Tests should typically include the following considerations: • structural integrity • leak-tightness (on containment vessel as well as auxiliary equipment and shield tanks) • component performance for valves, gaskets, and fluid transport devices • shielding integrity • thermal integrity 11.4 Maintenance Tests The QA program user should establish maintenance test programs to ensure that packages remain usable and free of excessive radiation and contamination. These test programs should include measures to ensure that qualified and responsible individuals document, evaluate, and assess the acceptability of all test results. 11.5 Results The OA program user should establish measures to ensure that test results are documented, evaluated, and maintained as QA records. These records should be readily available if questions arise concerning operational aspects of the packages. In addition, a qualified individual or group should determine the acceptability of the records.	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. For 10 CFR 71 licensed Type B and C waste shipment offsite, tests are conducted in accordance with the NRC packaging Certificate Holder procedures and processes. In the case of the 10 CFR 72 licensed storage packages at the ISFSI, the testing required for acceptance has already been completed during the fuel transfer project. The implementation of any Important to Safety work at the ISFSI in the future would invoke the use of Procedure AD-3, "ISFSI Work Control", and the generation of a Work Order subject to QA review. Any appropriate test guidance would be included in the Work Order to verify acceptability of Important to Safety items.
12. GUIDANCE ON §71.125, "CONTROL OF MEASURING AND TEST EQUIPMENT" 12.1 Calibration Control	Section 3.12 states, Measuring and Test Equipment (M&TE) used for important-to-safety activities is controlled to ensure accuracy. The calibration process assures that all measuring instruments used in the acceptance of material, equipment, and assemblies are calibrated and

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
The QA program user should establish measures to ensure that measurement and test equipment (e.g., gauges, fixtures, reference standards, and devices used to measure product characteristics) is calibrated, adjusted, and maintained at prescribed intervals or prior to use. Such equipment should be labeled or tagged to indicate the planned date of its next calibration, and the calibration records should be identified, traceable, and maintained as QA records. The QA program user should also establish measures to ensure that in-house reference or transfer standards used in calibrating measuring and test equipment are traceable to nationally recognized standards. Calibrating standards should have known valid relationships to nationally recognized standards. If no known recognized standard exists, the QA program user should document the basis for calibration. 12.2 Out-Of-Calibration Equipment When test and measuring equipment is found to be out of calibration, the QA program user should take measures to validate previous inspection and test results up to the time previous calibration. In addition, the QA program user should repair or replace any measuring equipment that is consistently out of calibration.	properly adjusted at specified intervals to maintain accuracy within pre-determined limits. Engineering / technical support representatives specify the devices to be controlled, the controlling and calibration methods, and calibration intervals to maintain accuracy within the necessary limits. 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 M&TE 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

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
	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. The implementation of any Important to Safety work at the ISFSI in the future would invoke the use of Procedure AD-3, "ISFSI Work Control", and the generation of a Work Order subject to QA review. Provisions for use of any M&TE in accordance with all requirements would be included in the Work Order for any M&TE used to verify acceptability of Important to Safety items.
13. GUIDANCE ON §71.127, "HANDLING, STORAGE, AND SHIPPING CONTROL" 13.1 Preservation The QA program user should establish measures to ensure that cleaning, handling, storage, and shipping are accomplished in accordance with design requirements to preclude damage or deterioration by environmental conditions such as temperature and humidity. When necessary, the QA program user should also establish provisions for the use of special handling, lifting, or storage devices (e.g. cranes, shock absorbers, or special markings) to adequately identify and preserve packaging components or assemblies. In addition, the QA program user should ensure that conditions identified in the CoC are adhered to when unloading packaging. 13.2 Preparation, Release, and Delivery to Purchaser The QA program user should establish measures to ensure that a final pre-release review has been completed. This review should ensure that packaging (1) is prepared for delivery to the purchaser in accordance with approved drawings, specifications, and government regulations; (2)	Section 3.13 states, 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. Section 3.13.1 states, 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. 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

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
has passed all applicable inspections and tests; (3) is properly identified by physical markings or tags; and (4) contains operating manuals, maintenance manuals, and generic procedures relating to its use. Program In addition, the QA program user should establish measures to ensure that the following requirements are fulfilled: • Cavities within gas-cooled package containments have been adequately dried, and cavities within liquid-cooled packages have been drained to allow adequate void space. • All conditions (including specified operations, inspections, and tests) have been completed prior to delivery to a carrier. • All NRC and DOT requirements have been satisfied prior to delivery to a carrier. • All necessary shipping papers have been prepared as required and reviewed by qualified personnel to verify completeness and accuracy.	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. Section 3.13.2 states, ZionSolutions shall meet the requirements of 10CFR71 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. For 10 CFR 71 licensed Type B and C waste shipment offsite, handling, storage and shipping are conducted in accordance with the NRC packaging Certificate Holder procedures and processes. In the case of the 10 CFR 72 licensed storage packages at the ISFSI, the ultimate shipment of these will be a very significant effort. The implementation of any Important to Safety work such as this would invoke the use of Procedure AD-3, "ISFSI Work Control", and the generation of a Work Order subject to QA review. Any appropriate handling, storage and shipping control measures would be included in the Work Order. Procedure AD-17, "Receipt Inspection Storage and Control of Purchased Equipment, Material and Services" includes guidance to ensure handling, storage and shipping are adequately addressed for any

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
	important-to-safety items during the conduct of any necessary maintenance or repair activities.
14. GUIDANCE ON §71.129,"INSPECTION, TEST, AND OPERATING STATUS" The QA program user should establish measures to ensure that the status of inspections, tests, and operating conditions (including maintenance of items) is known by organizations responsible for ensuring quality. The QA program user should also establish measures to control the application and removal of status indicators (e.g., tags, markings, stamps) and to ensure that bypassing a required inspection or test or any other required operation is procedurally controlled under the cognizance of the QA organization.	Section 3.14 states, Methods to indicate the status of inspections, tests, and operating status of systems for important-to-safety items and other selected tasks shall be utilized. 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.
15. GUIDANCE ON §71.131,"NONCONFORMING MATERIALS, PARTS, OR COMPONENTS" An acceptable program for controlling nonconforming items should include the following principal elements: • proper identification • segregation of discrepant or nonconforming items • disposition of the nonconforming items • evaluation of the nonconforming items	Section 3.15 states, "ITS 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.
16. GUIDANCE ON §71.133,"CORRECTIVE ACTION" 16.1 Reporting	"Section 3.16 states, "Conditions adverse to quality (e.g., nonconformances, failures, malfunctions, deficiencies, defective material, etc.) are promptly identified and evaluated to determine

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
The QA Program user should establish measures to ensure that the causes of conditions detrimental to quality (e.g., those resulting from failures, malfunctions, deficiencies, deviations, or defective material and equipment) are promptly identified and reported to appropriate levels of management. In addition, the QA program user should establish measures to obtain corrective actions from suppliers and ensure that follow-up actions are documented to verify that the corrective actions were implemented and effective. 16.2 Closeout, Retrieval, and Disposition of Records The QA program user should establish measures to ensure that corrective actions designated by cognizant individuals have been implemented to preclude recurrence. In addition, the QA program user should identify (by function or position) the individuals or organizations responsible for closing out corrective actions and documenting their resolution.	corrective action in accordance with established procedures. 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." Procedure AD-16, "Requisitioning Material, Equipment & Services", includes guidance to ensure the requirements for corrective actions are applied to suppliers for important-to-safety scope.
17. GUIDANCE ON §71.135, "QUALITY ASSURANCE RECORDS" 17.1 General QA records should furnish documentary evidence of the activities that *affect* quality and should provide sufficient information to allow each record to be identified with the items or activities to which it applies. As a minimum, QA records should include the following information: • design, procurement, manufacturing, and installation records • supplier evaluations • nonconformance reports • results of inspections and tests • failure analyses • as-built drawings and specifications • qualification of personnel, procedures, and equipment • calibration procedures • training and retraining records	Procedure AD-20, "Records Management Program," by use of the Site Records Retention Schedule (SRRS) identifies the full range of records required to be retained, and the retention periods, including those required by 10 CFR 71.135. The procedure establishes the various types of acceptable storage media. Records are processed from the Zion site into the Exelon electronic records system for indexing, storage and retrieval in accordance with approved procedures. The Exelon records system is administered in accordance with the NRC-approved Exelon licensee QA Program. Section 3.17.1 states, "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

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
• corrective action reports • records demonstrating evidence of operational capability • records verifying repair, rework, and replacement • audit plans, audit reports, and corrective actions • records that are used as a baseline for maintenance In addition, the QA program user should retain records that show evidence of package delivery to a carrier and proof that all NRC and DOT requirements have been satisfied (with their retention times identified). Where applicable, inspection and test records should contain the following information: • a description of the observation • evidence of completion of the inspection or test operation • results of inspections or tests with appropriate data • conditions that are detrimental to quality • names of inspectors, testers, or data recorders • evidence of acceptability 17.2 Generating Records The QA program user should establish measures to ensure that methods employed to generate and manage documents that are designated as QA records result in information that is retrievable, intelligible, and reliable. Such records should reflect the work accomplished and should be stored in a manner that avoids unnecessary delay when the record is needed. In addition, procedures for generating QA records should address both hard copy records and electronic information. 17.3 Indexing and Classification Records The QA program user should classify QA records as either "lifetime" or "nonpermanent": • Lifetime records include those pertaining to package fabrication and those associated with a particular item while it is installed in the	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." Section 3.17.2 states, "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." Section 3.17.3 states, "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." Section 3.17.4 states, "The records shall be distributed, handled, and controlled in accordance with written procedures. Measures shall be established to preclude the entry of unauthorized personnel into the storage area, or the distribution of records to unauthorized personnel. Records maintained by the supplier at their facility or other location shall be accessible to the purchaser or their designated alternate." Section 3.17.5 states, "Records shall be classified for retention and storage requirements as either lifetime or nonpermanent. In addition, retention periods specified in various governing codes and standards (e.g. 10CFR71, 10 CFR 72) will be included in the retention

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
packaging or stored for future use. These records demonstrate the capability for safe operation; provide evidence of repair, rework, replacement, or modification; aid in determining the cause of an accident or malfunction of an item; and provide a baseline for in-service inspection. • Nonpermanent records are those that show evidence that an activity has been performed but do not meet the criteria for lifetime records. Records pertaining to use of a package should be retained for a period of 3 years after the shipment. 17.4 Receipt, Retrieval, and Disposition of Records The QA program user should establish measures to provide a receipt control system, including identification of functions or positions in each organization responsible for receiving records and assessing the current status of records in their possession. The QA program user should also establish measures to ensure that records that are maintained in-house or at other locations are identifiable and retrievable, and are not disposed of until prescribed conditions are satisfied. For electronic records the software systems employed to image and store information should be compatible with new hardware as current technologies are implemented. In addition, before installing any new hardware systems, the QA program user should have a procedure in place to ensure that the new systems can reliably store and retrieve information from existing software systems. 17.5 Storage, Preservation, and Safekeeping The QA program user should establish measures to ensure that the following requirements are fulfilled: • Facilities used to store records should be constructed to minimize the risk from damage or destruction by severe natural conditions, such as wind, flood, fire, temperature, humidity, mold, or infestation by insects or rodents. • Records should be firmly attached in binders or placed in	requirements established in approved procedures for QA records." Section 3.17.6 states, "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. 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 or servers. 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." Procedure AD-20, "Records Management Program," provides for the prompt replacement of records that are damaged or lost.

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
folders or envelopes for storage in steel file cabinets. • Electronic records should be maintained in facilities that minimize or eliminate the potential for destruction of information as a result of demagnetization. • Electronic records should be backed up daily to eliminate the potential for loss of information as a result of equipment failure or human error. • If dual storage facilities are used to ensure the record integrity, the storage facilities should be sufficiently remote from each other to preclude a single event (such as a fire or flood) from damaging both facilities. • The QA program user should take measures to protect special records (e.g., radiographs and microfilm) from excessive light, electromagnetic fields, and temperature. • The QA program user should take measures to prevent unauthorized personnel from entering record storage areas. • Electronic Information storage systems should be accessible only through security measures such as passwords, and the number of personnel who have authorized access should be limited. In addition, personnel who have authorized access should have identified privileges, such as "read only" or "read and add only." • The QA program user should establish measures to ensure prompt replacement of a record that is lost or damaged.	
18. GUIDANCE ON §71.137, "AUDITS" 18.1 Elements of an Audit Program A comprehensive audit program should include the following elements: • assurance of the authority and organizational independence of the auditors • a commitment to adequate manpower, funding, and facilities to implement the audit • identification of audit personnel and their qualifications	Section 3.18 states, "Planned internal audits are scheduled and performed per approved procedures or checklists. Elements of the QAPP will be audited at least every 24 months to provide comprehensive, independent verification and evaluation of all aspects of the quality assurance program and to determine its effectiveness. Scheduling, preparation, personnel selection, performance, reporting, response, follow-up action, and records management will be performed in accordance with approved procedures. Audits of ITS-A / B suppliers and subcontractors will be conducted as

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
• provisions for reasonable and timely access of audit personnel to facilities, documents, and qualified personnel necessary for performing audits • use of established procedures and checklists • methods for reporting audit findings to responsible management of both audited and auditing organizations • provisions for the audit team to gain access to levels of management that have responsibility and authority for corrective action • methods for verifying that effective corrective action has been accomplished on a timely basis The QA program user should also establish and maintain a list to reflect the current status of the activities important to safety that are to be audited and the frequency at which each quality criterion is to be audited. The frequency of audits should be based on each activity's importance to safety; however, each quality criterion should be audited at least once each year. The QA program user should also establish measures to ensure that packaging manufacturers are audited to assess the extent of their compliance with purchase orders and to verify that their work is controlled under an NRC-approved QA program. In addition, the QA program user should also identify (by function or position) the individuals or groups that have the responsibility and authority to ensure that corrective actions resulting from audit findings are accomplished on a timely basis. The QA program user should re-audit deficient areas on a timely basis to verify implementation of corrective actions. 18.2 Scheduling of Audits The QA program user should establish schedules for internal audits,	necessary, but not less than once every three years, to assess compliance with applicable requirements of this QAPP." Section 3.18.1 states, "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" Section 3.18.2 states, "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

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
external audits, and audits performed by management. These schedules should ensure that key activities of the QA program (e.g., design, fabrication) receive priority consideration. For audits performed by management, the schedules should identify the level of management (usually from the corporate office or another division) designated to assess the overall effectiveness of the implementation of the described in-house QA program. The QA program user should also identify the activities important to safety (e.g., procurement, training of personnel) that should be included in the audit program. Management audits should be conducted at least once every 12 months. For internal audits, the schedules should ensure that applicable elements of the QA program are audited annually or at least once within the life of the activity, whichever is shorter. For external audits, the schedules should ensure that all elements of a major supplier's (or major contractor's) QA programs are audited on a triennial basis. The 3-year period should begin with performance of an audit when sufficient work is in progress to demonstrate implementation of a QA program that has the required scope for purchases placed during the 3-year period. 18.3 Team Selection The QA program user should establish the qualifications of the lead auditor and audit team members and specify their respective responsibilities with respect to evaluating and issuing audit reports. The auditing organizations should have the responsibility to establish qualifications for prospective audit personnel and the requirements for use of technical specialists to accomplish auditing activities that are important to safety. The QA program user should select the lead auditor	applicable. Audit files are retained as quality records in accordance with approved procedures." The results of internal audits, surveillances and independent assessments and audits of Subcontractors will be utilized as input into the continuous improvement effort through identification in the CR system. Re-audit of deficient areas will be performed when required." Section 3.2.4 requires a biennial independent management assessment of the Quality Assurance Program. Other internal audits are addressed in Section 3.18. Additional requirements for External audits, including re-audit schedules not to exceed three (3) years is contained in Implementing Procedure QA-2. Section 3.2.3.3 states, "Quality Assurance (QA) Lead Auditors are qualified and certified by ZionSolutions or by approved suppliers. Lead Auditors are qualified in accordance with established procedures, and records are maintained. Proficiency evaluations are performed annually and documented for individuals performing audit activities and appropriate certification renewal or re-qualification actions are taken." Additional guidance and requirements for audit team selection, including the use of technical specialists is contained in Implementing Procedure QA-2. Implementing Procedure QA-2 provides guidance on the conduct of audits, including development of audit plans, the conduct of audits, the conduct and purpose of audit exit meetings, the generation and transmittal or reports, the interface with corrective actions processes, and the required follow-up actions.

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
and audit team members from personnel who do not have direct responsibility in the areas being audited. Specific guidance for determining qualifications for the lead auditor and individual audit team members may be obtained from ANSIIASME NQA-1. 18.4 Pre·Audit Conference Prior to an audit, the QA program user should specify the nature and scope of the pre-audit conference between management of the organizations being audited and the team conducting the audit. The purpose of the pre-audit conference should be to meet counterparts, confirm the audit scope and dates, establish channels of communication, discuss the sequence and duration of the audit, prepare an agreed-upon agenda for the audit, and set the time for the post-audit conference. 18.5 Post·Audit Conference The QA program user should establish measures to conduct a post-audit conference between management of the organizations being audited and the team conducting the audit to present the results and clarify any misunderstandings that may arise. 18.6 Reporting and Response The QA program user should establish measures to Identify time constraints imposed for issuing audit reports and the requested date for a corrective action response by the audited organization. The response should clearly state the corrective action taken to prevent recurrence of nonconformances. If corrective action cannot be taken immediately, the response of the audited organization should include scheduled dates for initiation and completion of the corrective action.	

Regulatory Guide 7.10 Revision 2	ZS-QA-10 Rev. 7 References
18.7 Follow-up Action The audit team leader should verify that (1) the audited organization provides a timely response to the audit report, (2) the response is adequate, and (3) the corrective action has been accomplished within the prescribed schedule.	

Attachment 1

10 CFR 71 Criterion	Implementing Procedure No. and Title
71.103 - Quality Assurance Organization	AD-1, ISFSI Organization and Responsibilities QA-1, Quality Program Administration
71.105 - Quality Assurance Program	QA-1, Quality Program Administration
71.107 - Design Control	EF-1, ISFSI Engineering Evaluations and Design Control Program
71.109 - Procurement Document Control	AD-16, Requisitioning Material, Equipment & Services
71.111 - Instructions, Procedures, And Drawings	AD-6, Procedure Control Program EF-2, ISFSI Drawing Control
71.113 - Document Control	AD-5, Document Control EF-2, ISFSI Drawing Control
71.115 - Control Of Purchased Material, Equipment, And Services	AD-16, Requisitioning Material, Equipment & Services AD-17, Receipt Inspection, Storage and Control of Purchased Equipment, Material & Services QA-2, Quality Assessments QA-3, Quality Inspection Program
71.117 - Identification And Control Of Materials, Parts, and Components	AD-16, Requisitioning Material, Equipment & Services AD-17, Receipt Inspection, Storage and Control of Purchased Equipment, Material & Services
71.119 - Control Of Special Processes	AD-3, ISFSI Work Control OP-5, VCC Repair
71.121 - Internal Inspection	QA-3, Quality Inspection Program
71.123 - Test Control	AD-3, ISFSI Work Control EF-1, ISFSI Engineering Evaluations and Design Control Program OP-2, ISFSI Surveillance and Inspections Program OP-4, VCC and ISFSI Pad Inspection Program
71.125 - Control Of Measuring And Test Equipment	AD-3, ISFSI Work Control AD-16, Requisitioning Material, Equipment & Services
71.127 - Handling, Storage, And Shipping Control	AD-16, Requisitioning Material, Equipment & Services AD-17, Receipt Inspection, Storage and Control of Purchased Equipment, Material & Services
71.129 - Inspection, Test, And Operating Status	AD-3, ISFSI Work Control AD-17, Receipt Inspection, Storage and Control of Purchased Equipment, Material & Services
71.131 – Nonconforming Materials, Parts, Or Components	AD-21, Nonconformance Reporting AD-15, Evaluation of Component or Equipment Failure or Deviation for 10CFR21 Reportability

10 CFR 71 Criterion	Implementing Procedure No. and Title
71.133 - Corrective Action	AD-8, Corrective Action Program
71.135 - Quality Assurance Records	AD-20, Records Management Program
71.137 - Audits	QA-1, Quality Program Administration QA-2, Quality Assessments

Zion Nuclear Power Station (ZNPS)

Summary of Changes

SUMMARY OF CHANGES (ZS-QA-10, Rev. 7)

Purpose

The purpose of this summary is to characterize the proposed changes to be included in the Zion*Solutions* (ZS) Quality Assurance Project Plan (QAPP) Revision 7. The proposed revision is a substantial revision to the QAPP and will replace the current QAPP Revision 6 in its entirety. Major or substantial changes are described along with the justifications for those changes. In addition, the various minor changes are discussed in summary form.

Background

The revision reflects a simplification of the QAPP for the ZS Independent Spent Fuel Storage Installation (ISFSI) and the ZS Unit 1 and Unit 2 decommissioning and demolition (D&D) that is based on the current decommissioning status of ZS Unit 1 and Unit 2, the remaining decommissioning activities, and the long-term passive operational status of the ZS ISFSI.

Radiological risk factors associated with D&D activities have been significantly reduced. All spent fuel and Greater Than Class C (GTCC) waste have been transferred to the ISFSI. The ISFSI has transitioned to long-term passive operations. Additionally, although there remains Class B and Class C radioactive waste to be shipped offsite for disposal, the QAPP still applies to those activities.

The QAPP Revision 7 applies to all activities associated with structures, systems, and components (SSCs) which are important to safety (10 CFR 72). The QAPP also applies to transportation packages licensed by the NRC under 10 CFR 71. For other ISFSI and D&D activities, administrative programs and procedures ensure compliance with governing regulations and include appropriate controls for activities under the radiological control programs previously contained in the Technical Specifications.

The proposed revision to the QAPP is appropriate for the remaining D&D activities and ISFSI operations. All safety related systems have been removed from service and have undergone partial or complete demolition. The ISFSI has transitioned to long-term passive operations. The system is inherently safe by design. The main function of the ISFSI organization is to monitor the environment in a way that demonstrates the integrity of the system. While it continues to be important to maintain an appropriate quality standard that preserves the passive functionality of the system, it can be accomplished satisfactorily through conformance to RG 7.10.

The proposed revision will continue to satisfy the criteria of 10 CFR 50, Appendix B and the QA requirements of 10 CFR 71, Subpart H, and 10 CFR 72, Subpart G.

Change 1 – Substantive Changes:

Substantive Change 1A: In the QAPP revision 7, the program basis was changed from NQA-1 (1994) to Regulatory Guide 7.10 "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material", revision 2 (RG 7.10). The highest level of safety significance remaining on the ZS project are Important-to Safety (ITS) activities under 10 CFR 71 and 10 CFR 72. There are no SSCs or activities remaining at the Zion site that is Safety-Related as defined in 10 CFR 50 Appendix B. The NRC Quality Assurance program guidance for ITS activities under 10 CFR 71 and 10 CFR 72 is in RG 7.10. This is a reduction in commitment, but it is acceptable due to the current state of decommissioning at the Zion site and the passive operational status of the ZS ISFSI.

Substantive Change 1B: Throughout the QAPP revision 7 the phrase "ITDC (various criterion) requirements are addressed via a graded approach." The ITDC classification has been eliminated from the DSAR, so reference to ITDC and QA Requirements for ITDC has been eliminated. The ITDC definition has been removed from the DSAR based on the administrative controls that are now in the QAPP in Appendix B. These controls are implemented by procedures and programs and changes are controlled by the 10 CFR 50.59 review process.

Substantive Change 1C: The Station Review Committee (SRC), Project Review Advisory Board (PRAB) and Quality Council have been removed from QAPP revision 7. In the place of these, Section 3.2.4 identifies an Independent Management Assessment (IMA) function. In anticipation of the remaining number of ITS and/or radiological items that will require regulatory reviews at the ISFSI and remaining D&D activities, this revision incorporates significant changes to the quality review functions described in the QA program. Individual(s) that perform IMAs are assigned by the General Manager (GM).

An IMA is performed to monitor overall performance and confirm that activities affecting quality comply with the QAPP and that the QAPP is effectively implemented.

Specific changes are summarized as follows:

- Currently, the SRC is required to be composed of at least four members plus a Chairman. The IMA will not be required to be performed by a committee.
- An IMA may be conducted by as few as one person appointed by the GM.
- The SRC is required, collectively, to have experience and competence in a number of technical areas. This revision does not specify qualification, experience, or competency requirements for personnel performing IMAs.
- There would be no requirement for quarterly meetings as there is no committee to meet. IMAs will be performed periodically as directed by the GM.
- The IMAs will be governed by implementing procedure and will include implementation of the QAPP, decommissioning activities, the safe storage of spent nuclear fuel, and other activities as directed by the GM.
- The PRAB and Quality Council were not regulatory based independent review organizations as the SRC was, and were essentially managerial tools or enhancements.

The requirements for an independent review function was based on ANSI N18.7-1976 as endorsed by Regulatory Guide 1.33, Revision 2, and were satisfied by the SRC. The composition and function of the SRC as described in the QAPP Revision 6 follows the guidance provided in ANSI N18.7-1976, Section 4.3.1. The program described therein was intended for operating nuclear power plants. 10 CFR 50, Appendix B, does not specifically require an independent review function (as described in ANSI N18.7) as part of its quality assurance program requirements. Appendix B, 10 CFR 50, Criterion II states in part: "The applicant shall regularly review the status and adequacy of the quality assurance program."

The Qualified Technical Review Program will continue to be implemented as described in Appendix B, Section 5.9.1. Qualified Technical Reviewers are knowledgeable in the subject area being reviewed, meet the experience and education requirements, are trained in performing 10 CFR 50.59 and 10 CFR 72.48 reviews and do not have direct responsibility for the document under review.

Substantive Change 1D: In Appendix B, section 5.3.1, the guidance for determination of the appropriate ANSI N18.1 qualifications for staff qualifications other than Health Physics was stated to be contained in implementing procedures. Previously the guidance in the QAPP was as follows: "Each member of the facility staff shall meet or exceed the minimum qualifications of ANSI N18.1, "Selection and Training of Nuclear Power Plant Personnel," dated March 8, 1971..." Although at face value this appears to be a reduction in commitment, in fact, the interpretation and application of "each member..." had been by implementing procedure. In any case, this change is deemed acceptable due to the current state of decommissioning at the Zion site and the passive operational status of the ZS ISFSI.

Change 2 - Editorial / Administrative Improvements and Clarifications:

Extensive editorial changes to eliminate redundancy, provide clarity, and improve readability were made. The types of changes of this nature are as follows:

Editorial Changes Type 1: In numerous instances, historical details that were not necessary were eliminated. In addition, references to the ISFSI construction of Dry Cask Storage phases that have been already completed were eliminated. This includes the removal of the section on "Classification of Project Tasks" that previously served as guidance for the design of DCS SSCs, which are all completed at this time. Incorrect or mixed tenses were corrected.

Editorial Changes Type 2: Given the change of program basis from NQA-1 to RG 7.10 discussed above, simplification of the program guidance was made in several areas, especially in these areas:

- Design Control
- Identification and Control of Materials, Parts and Components
- Test Control

Although at face value these represent reductions in commitment, this is acceptable due to the current state of decommissioning at ZS and the passive operational status of the ISFSI. Moreover, in many cases the guidance has been moved from the QAPP to implementing procedures. The proposed revision continues to satisfy the criteria of 10 CFR 50, Appendix B and the Quality Assurance requirements of 10 CFR 71 and 10 CFR 72.

Editorial Changes Type 3: In numerous instances unnecessary duplication / repetition was eliminated from the QAPP rev. 7, especially in these areas:

- QA Program
- Control of Purchased Materials, Equipment and Services
- Inspection
- Quality Assurance Records

Editorial Changes Type 4: In the QAPP revision 7, the applicability of the QAPP is concisely stated in the "Statement of Quality Assurance Policy" and in Appendix A. Therefore, in numerous instances throughout the QAPP statements regarding the applicability of the QAPP were eliminated.

Editorial Changes Type 5: In the QAPP revision 7, section 4.0, several references applicable to the design and execution of the DCS aspects of the project, as well as a few unnecessary historical references were removed. Also, the previous "Appendix A, List of Acronyms" was removed as it is unnecessary. Throughout the QAPP revision 7, acronyms are defined at first use.

In summary, these types of changes are considered editorial and do not alter the intent or purpose of the QAPP and continue to satisfy the criteria of Appendix B to 10CFR 50 and the Quality Assurance requirements of 10 CFR 71 and 10 CFR 72.

Change 3 – Use of Generic Organization Titles:

Section 2.0 of the QAPP revision 7 is prefaced by the following note: "This QAPP uses Generic Titles. Alignment between these Generic Titles and actual titles are maintained current in approved company documents." The entire section 2.0 was rewritten using these Generic Titles, and these are depicted in Figure 1 of the QAPP. Implementing procedures contain the guidance on how alignment is maintained from the actual site organization back to the QAPP.

These types of changes are specifically identified under 10 CFR 50.54(a)(3)(iii) as not representing a reduction in commitment, and therefore continue to satisfy the criteria of Appendix B to 10CFR 50 and the Quality Assurance requirements of 10 CFR 71 and 10 CFR 72.

OVERALL EVALUATION:

This revision is a major rewrite of the QAPP. It includes extensive editing to eliminate redundancy, provide clarity, and improve readability. Detailed implementation methodology found in the QAPP Revision 7 is contained in administrative procedures. This editing, however, did not alter the effectiveness of the QAPP.

Where content in sections of the revised QAPP differs in any substantial way from the content in Revision 6, the differences were evaluated and determined to be acceptable due to the current state of decommissioning at the Zion site and the passive operational status of the ZS ISFSI. The proposed revision continues to satisfy the criteria of Appendix B to 10 CFR 50 and the Quality Assurance requirements of 10 CFR 71 and 10 CFR 72.

Zion*Solutions*, LLC
ZS-2014-0325: Enclosure 3

Zion Nuclear Power Station (ZNPS)

Quality Assurance Project Plan
ZS-QA-10
Proposed Revision 7

ZIONSOLUTIONS LLC

Quality Assurance Project Plan

ZS-QA-10

Zion*Solutions* LLC

Zion Station Restoration Project

Revision 7

September 24, 2014

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ZION*SOLUTIONS* LLC
ZION STATION RESTORATION PROJECT

STATEMENT OF ASSURANCE POLICY

This Quality Assurance Project Plan (QAPP) defines the Zion*Solutions* LLC Quality Assurance Program to be implemented during the Zion Station Restoration 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," 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."

Implementation of the requirements of the QAPP are done in a graded approach commensurate with an item or activities importance to safety. This graded approach is responsive to NRC Regulatory Guide 7.10.

The QA Manager has been delegated the authority to implement and revise the provisions of this QAPP, and to regularly assess the scope, status, implementation and effectiveness of this QAPP.

The QAPP applies to all activities associated with structures, systems, and components (SSCs) which are important to safety (10 CFR 72). The QAPP also applies to transportation packages licensed by the NRC under 10 CFR 71. The applicability of the requirements of the QAPP to other items and activities is determined on a case-by-case basis.

9-18-2014

President, Zion*Solutions* LLC

DAVID LOCKWOOD VIA EMAIL 9/18/14.

Chief Executive Officer, Zion*Solutions* LLC

9/18/14

TABLE OF CONTENTS

TABLE OF CONTENTS

1.0 Introduction

The Zion Nuclear Power Station (ZNPS) located in Zion, Illinois, prior to September 1, 2010, was being maintained in a SAFSTOR condition by Exelon Corporation.

Effective September 1, 2010, Energy*Solutions* entered into an agreement with Exelon under which Zion*Solutions,* a wholly-owned subsidiary of Energy*Solutions*, assumed ownership of the facility, took possession of the licenses, and has undertaken decommissioning activities, conducted by Energy*Solutions* and affiliated companies.

The nuclear fuel stored in the Spent Fuel Pool (SFP) was placed in Dry Cask Storage (DCS) casks and stored in an Independent Spent Fuel Storage Installation (ISFSI), a secured storage pad on the ZNPS site. The ISFSI is also being used to store Greater than Class C (GTCC) waste.

1.1 Project Quality Assurance Program

The Quality Assurance Project Plan (QAPP) provides a consolidated overview of the quality program controls which govern the decommissioning of the Zion Nuclear Plant and operation and maintenance of the Independent Spent Fuel Storage Installation (ISFSI). The QAPP describes the quality assurance organizational structure, functional responsibilities, levels of authority and interfaces. 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 guidance in NRC Regulatory Guide 7.10 has been incorporated.

The Zion*Solutions* QAPP is considered a QA Project Plan under the EnergySolutions QA Program (QAP). 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 QAPP is implemented through the use of approved procedures (i.e., policies, directives, procedures, manuals, instructions, or other documents) which provide written guidance for the control of important to safety items and activities and provides for the development of documentation to demonstrate objective evidence of compliance with stated requirements.

1.2 Scope

The QAPP applies to all activities associated with structures, systems, and components (SSCs) which are important to safety (10 CFR 72) as listed in Appendix A of this QAPP. The QAPP also applies to transportation packages licensed by the NRC under 10 CFR 71. The QAPP applies to decommissioning activities (10 CFR 50, Appendix B) in a graded approach commensurate with an item or activities importance to safety, as stipulated below:

- Applicable portions of Sections 3.1, 3.2, 3.16, 3.17 and 3.18 of this QAPP apply to decommissioning activities.

- Appendix B of this QAPP applies to decommissioning activities.

The applicability of the requirements of the QAPP may be extended to other activities as designated by the General Manager. Decommissioning activities are otherwise controlled by procedures, processes and policies deemed adequate by the management responsible for the successful completion of those activities.

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.

Note: This QAPP uses Generic Titles. Alignment between these Generic Titles and actual titles are maintained current in approved company documents.

2.1 Responsibility

2.1.1 The Decommissioning Plant Manager shall be responsible for overall plant operations and shall delegate in writing the succession to this responsibility during his absence. The Decommissioning Plant Manager or his designee shall approve, prior to implementation, each proposed test, experiment, or modification to systems or equipment that affect the safe storage of nuclear fuel.

2.2 Organization

2.2.1 General Organizational Requirements - Onsite and offsite organizations shall be established for station and corporate management, respectively. The onsite and offsite organizations shall include the positions for activities affecting the safe storage of nuclear fuel.

a. Lines of authority, responsibility, and communication shall be established and defined for the highest management levels through intermediate levels to and including all operating organization positions. These relationships shall be documented and updated, as appropriate, in the form of organization charts, functional descriptions of departmental responsibilities and relationships, and job descriptions for key personnel positions, or in equivalent forms of documentation.

b. The Decommissioning Plant Manager shall be responsible for overall plant safety and shall have control over those on site activities necessary for safe storage of nuclear fuel.

c. The President, Zion *Solutions,* shall have corporate responsibility for the safe storage of nuclear fuel and shall take any measures needed to ensure acceptable performance of the staff in operating, maintaining, and providing technical support to the plant to ensure the safe storage of nuclear fuel.

d. The individuals who carry out health physics and quality assurance functions may report to an appropriate onsite manager; however, they shall have sufficient organizational freedom to ensure their ability to perform their assigned functions.

2.3 President, Zion*Solutions*

The President manages the operation of Energy*Solutions* stewardship projects at U.S. Reactor sites, and assures that the Zion*Solutions* project receives timely and effective support from Energy*Solutions* corporate groups. The President meets periodically with the GM and other key managers to review the operation of the Zion ISFSI and of decommissioning and to address project management, quality, and related issues.

2.4 General Manager (GM) Zion*Solutions*

This project executive provides direct oversight of the project, and other selected tasks, to ensure the project is properly planned, staffed and executed. The GM has overall authority and responsibility for the establishment and effective implementation of the QAPP. The GM 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 ISFSI and decommissioning.

2.5 Licensing Manager (LM)

The LM is responsible for the day-to-day licensing activities, interfaces with the Nuclear Regulatory Commission (NRC) and Exelon, and is the Single Point of Contact for licensing and regulatory matters and concerns. The LM is responsible for assessing QAPP changes for determining compliance with licensing basis requirements, and for managing submittals to the NRC.

2.6 Quality Assurance Manager (QAM)

The QAM reports to the GM, and has access to the Energy*Solutions* Corporate QA Director for quality matters. The QAM is responsible for establishing and maintaining the QAPP, monitoring the project's quality objectives through overview and inspection 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 provides orientation and training on applicable quality requirements to the Zion*Solutions* organization. The QAM periodically provides reports on project quality activities to the GM, and the management team.

2.7 Training Manager (TM)

The TM is responsible for overview and management of the project training program. The TM shall periodically evaluate and report the status of the training program and effectiveness of the training process to the GM.

2.8 Engineering Manager (EM)

The EM is responsible for the engineering of ISFSI and decommissioning activities, and ensuring adequate technical review is applied to changes, tests and experiments.

2.9 ISFSI Manager (IM)

The IM is responsible for overseeing all ISFSI activities, including Security Plan and Emergency Plan activities for the ISFSI.

2.10 Decommissioning Plant Manager (DPM)

The DPM is responsible for all decommissioning activities, including fire protection activities at the decommissioning site, and for all industrial safety activities for the entire site. The DPM is also responsible for the functions described in Appendix B of this QAPP.

2.11 Radiation Protection Manager (RPM)

The RPM is responsible for all radiation protection, environmental protection, site closure, and waste shipping activities at the entire site.

3.0 QUALITY ASSURANCE REQUIREMENTS

3.1 Organization

The Zion Restoration 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 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 QA Director 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.

3.2 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.

3.2.1 QAPP Application

Procedures describe how Zion*Solutions* implements the requirements of the QAPP. These procedures document methods for planning, reviewing, implementing, controlling, and verifying that activities subject to this QAPP are performed in accordance with the applicable requirements from these documents:

- 10CFR50, Appendix B
- 10CFR71, Subpart H
- 10CFR72, Subpart G
- NRC Regulatory Guide 7.10

3.2.2 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 as necessary to verify the effectiveness of the QAPP.

3.2.3 Personnel Qualification and Certification

3.2.3.1 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.

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.

3.2.3.2 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.

3.2.3.3 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. 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.

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

3.2.4 Independent Management Assessment

Independent Management Assessments are periodically performed to monitor overall performance and confirm that activities affecting quality comply with the QAPP and that the QAPP is effectively implemented. Independent Management Assessment is performed by individual(s) designated by the President, independent of activities assessed and who provide the appropriate level of expertise in the activities assessed. The Independent Management Assessment results are communicated in an understandable form and in a timely fashion to a level of management having the authority to effect corrective action. In addition, these results are reported in a timely fashion to the GM.

3.3 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.

These design controls are intended to apply to those ISFSI or site SSCs that may impact the important-to safety SSCs at the ISFSI.

3.3.1 Design Control Program

The program will ensure that the activities associated with the design of structures, systems and components and modifications thereto, are executed in a planned, controlled, and orderly manner.

The program utilizes the guidance of NUREG/CR-6407 to classify structures, systems and components such that appropriate quality requirements are identified and documented on drawings, component lists, or procurement documents, as applicable.

The program includes provisions to control design inputs, processes, outputs, changes, interfaces, records, and organizational interfaces.

Design inputs (e.g., performance, conditions of the facility license, quality, and quality verification requirements) shall be correctly translated into design outputs (e.g., specifications, drawings, procedures, and instructions).

The final design output shall relate to the design input in sufficient detail to permit verification.

The design process shall ensure that materials, parts, equipment and processes are selected and independently verified consistent with their importance to safety to ensure they are suitable for their intended application.

Changes to final designs (including field changes and modifications) and dispositions of non-conforming items to either use-as-is or repair shall be subjected to design control measures commensurate with those applied to the original design and approved by the organization that performed the original design or a qualified designee.

Interface controls (internal and external between participating design organizations and across technical disciplines) for the purpose of developing, reviewing, approving, releasing, distributing, and revising design inputs and outputs shall be defined in procedures.

Design documentation and records, which provide evidence that the design and design verification process was performed in accordance with the QAPP, shall be collected, stored, and maintained in accordance with documented procedures. This documentation includes final design documents, such as drawings, and specifications, and revisions thereto and documentation which identifies the important steps, including sources of design inputs that support the final design.

3.3.2 Design Verification

The program will verify the acceptability of design activities and documents for the design of items. The selection and incorporation of design inputs and processes, outputs and changes are verified.

Verification methods include, but are not limited to, design reviews, alternative calculations, and qualification testing. The extent of this verification will be a function of the importance to safety of the item, the complexity of the design, the degree of standardization, the state of the art, and the similarity with previously proven designs. Standardized or previously proven designs will be reviewed for applicability prior to use.

When a test program is used to verify the acceptability of a specific design feature, the test program will demonstrate acceptable performance under conditions that simulate the most adverse design conditions that are expected to be encountered.

Independent design verification is to be completed before design outputs are used by other organizations for design work and before they are used to support other activities such as procurement, manufacture, or construction. When this timing cannot be achieved, the unverified portion of the design is to be identified

and controlled. In all cases, the design verification is to be completed before relying on the item to perform its Important to safety function.

Individuals or groups responsible for design reviews or other verification activities shall be identified in procedures and their authority and responsibility shall be defined and controlled. Design verification shall be performed by any competent individuals or groups other than those who performed the original design but who may be from the same organization. The designer's immediate supervisor or manager may perform the design verification provided:

1. The supervisor or manager is the only technically qualified individual capable of performing the verification.

2. The need is individually documented and approved in advance by the supervisor's or managers management, and

3. The frequency and effectiveness of the supervisors or managers use as a design verifier is independently verified to guard against abuse.

Design verification procedures are to be established and implemented to ensure that an appropriate verification method is used, the appropriate design parameters to be verified are chosen, the acceptance criteria is identified, the verification is satisfactorily accomplished and the results are properly recorded.

3.4 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.

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

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.

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.

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

3.5 Instructions, Procedures and Drawings

Management is responsible for ensuring that ITS 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.

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.

3.6 Document Control

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.

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.

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.

3.7 Control of Purchased Materials, Equipment and Services

Zion*Solutions* procurement controls establish measures to ensure those procured items and services for ITS 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.

Commercial grade items may be procured and dedicated for ITS 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.

3.7.1 Supplier Evaluation

Project technical, procurement, and QA personnel participate, as appropriate, in evaluation of potential procurement sources for ITS-A / ITS-B. Supplier evaluations include elements of the QA Program applicable to the purchased item or services.

Once selected, QA shall evaluate the supplier and if acceptable, add the supplier to the Zion*Solutions* approved supplier list. In addition, 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.

3.7.2 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.

3.7.3 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.
- Verifying material identification and traceability control.
- Verifying 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.

3.7.4 Receiving Inspection

Receiving inspection shall be performed for purchased items that are ITS (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 ITS SSC as applicable. Nonconforming conditions or discrepancies identified during a receipt inspection shall be documented on Condition Report (CR).

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

The controls used for procuring items or services include the requirement that the suppliers/subcontractors are required to implement their QA Program that meets the applicable requirements of this QAPP for the requested item or service for important-to-safety category A and B. These 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.

In the case of the qualification of M&TE calibration suppliers, the qualification of a supplier to perform ITS Category A and B calibrations may be based on the supplier possessing a current NVLAP / A2LA certification. This is consistent with the NRC regulatory position in the letter from NRC to Arizona Public Service Company titled "Palo Verde Nuclear Generating Station, Units 1, 2 and 3 – Approval of Change to Quality Assurance Program (Commercial-Grade Calibration Services) TAC Nos. MC4402, MC4403, and MC4404)" and associated NRC Safety Evaluation dated September 28, 2005.

3.8 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. Identification of each item is maintained throughout fabrication, shipping and handling, erection, installation, and use so that the item can be traced to its documentation. Traceability is maintained to an extent consistent with the item's importance to safety.

3.9 Control of 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.

3.10 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.

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

3.10.1 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.

3.10.2 Inspection Hold Points

Responsibilities for identifying and specifying hold points are established in approved procedures. Quality Assurance, Engineering / 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.

3.10.3 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.

3.10.4 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 nonconformances.

3.11 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.

3.11.1 Test Requirements

Engineering / 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.

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.

3.11.2 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.

3.12 Control of Measuring and Test Equipment

Measuring and Test Equipment (M&TE) used for important-to-safety activities is controlled 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. Engineering / technical support representatives specify the devices to be controlled, the controlling and calibration methods, and calibration intervals to maintain accuracy within the necessary limits.

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 M&TE 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.

3.13 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.

3.13.1 Requirements

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.

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.

3.13.2 USNRC-Licensed Packages

Zion*Solutions* shall meet the requirements of 10CFR71 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.

3.14 Inspection, Test, and Operating Status

Methods to indicate the status of inspections, tests, and operating status of systems for important-to-safety items and other selected tasks shall be utilized. 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.

3.15 Nonconforming Materials, Parts or Components

ITS 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.

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 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.

3.16 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.

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.

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

3.17 Quality Assurance Records

The requirements below do not apply to records that are determined to be exempt from records keeping requirements in accordance with the terms of any NRC-approved records exemption that may be granted to Zion*Solutions* for records related to the Zion station.

3.17.1 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.

3.17.2 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.

3.17.3 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.

3.17.4 Distribution and Control

The records shall be distributed, handled, and controlled in accordance with written procedures. Measures shall be established to preclude the entry of unauthorized personnel into the storage area, or the distribution of records to unauthorized personnel. Records maintained by the supplier at their facility or other location shall be accessible to the purchaser or their designated alternate.

3.17.5 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.

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.

In addition, retention periods specified in various governing codes and standards (e.g. 10CFR71, 10 CFR 72) will be included in the retention requirements established in approved procedures for QA records.

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

3.17.6 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.

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 or servers. 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 in accordance with approved procedures.

3.17.7 Disposition

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.

3.18 Audits

Planned internal audits are scheduled and performed per approved procedures or checklists. Elements of the QAPP will be audited at least every 24 months to provide

comprehensive, independent verification and evaluation of all aspects of the quality assurance program and to determine its effectiveness. Scheduling, preparation, personnel selection, performance, reporting, response, follow-up action, and records management will be performed in accordance with approved procedures.

Audits of ITS-A / B 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.

3.18.1 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

3.18.2 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 independent assessments and audits of Subcontractors will be utilized as input into the continuous improvement effort through identification in the CR system. Re-audit of deficient areas will be performed when required.

3.18.3 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.

4.0 REFERENCES

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."

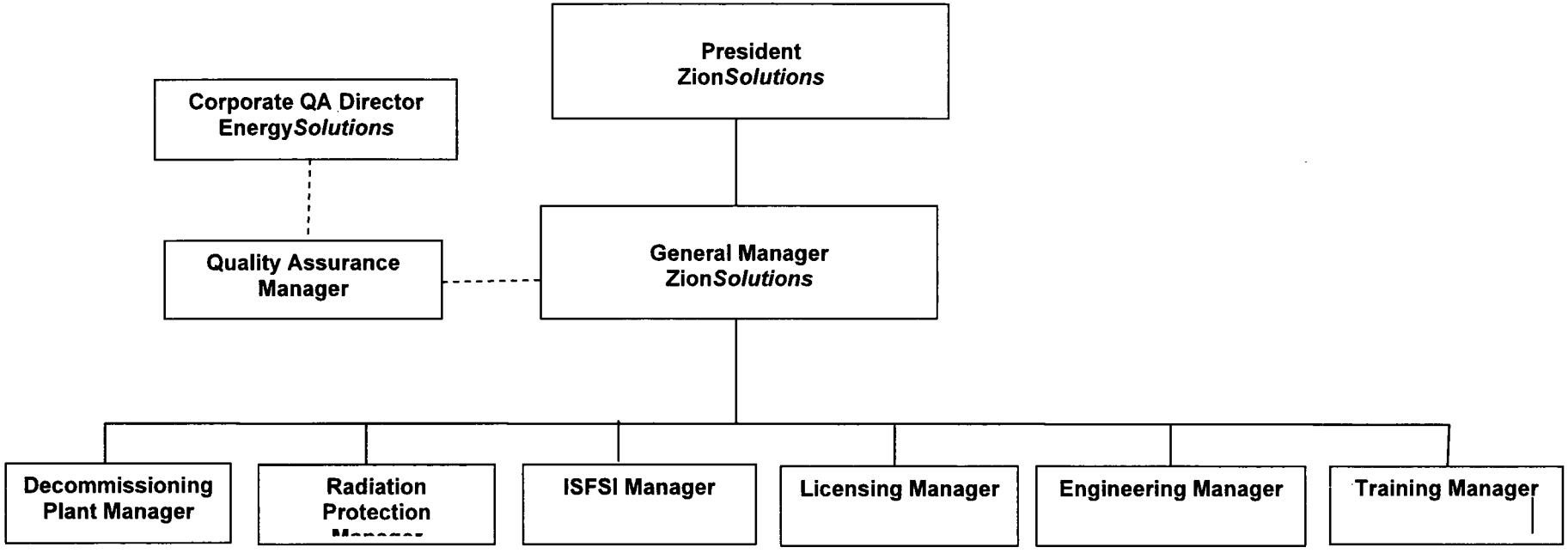
Title 10 of the Code of Federal Regulations, Part 71, Subpart H, "Quality Assurance Requirements for Packaging and Transportation of Radioactive Waste."

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.

Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material," Revision 2, March, 2005.

Figure 1
Zion*Solutions* Restoration Project Organization Chart (Generic Titles)



APPENDIX A

IMPORTANT-TO-SAFETY STRUCTURES, SYSTEMS AND COMPONENTS

The pertinent quality assurance requirements of 10CFR50, Appendix B, 10CFR 71 Subpart H and 10 CFR 72 Subpart G will be applied, as a minimum, to all quality activities affecting the Important-to-Safety Structures, Systems and Components (SSCs) associated with spent fuel storage and transportation packages.

NOTE

The safety classification of SSCs of the Plant and ISFSI Facility may be revised based on engineering evaluations and a revision to the Zion DSAR during the decommissioning process. These modifications are controlled in accordance with the Design Control process and are not considered a reduction in the commitments to the QAPP.

The safety classification of NRC Licensed ISFSI Dry Fuel Storage Components and Transportation Packages may not be revised using the Zion Design Control process. These modifications must be made by the NRC Certificate Holder. The Certificate Holder is responsible for design and licensing controls for these components under their NRC approved Quality Assurance Program. Zion utilizes these types of components and packages under the provisions of NRC General License for Radioactive Material Transportation Packages (10 CFR 71) and Spent Fuel Storage (10 CFR 72).

Important-to-Safety SSCs associated with spent fuel storage and radioactive material transportation packages are defined below:

IMPORTANT-TO-SAFTY AS DEFINED BY 10 CFR 71 AND 10 CFR 72

A. Dry Spent Fuel Storage (10 CFR 72)

SSC	Quality Category	Design/License Responsible
Transportable Storage Canister and Fuel Basket Assembly, Internals	ITS-A	NAC Intl.
Vertical Concrete Cask	ITS-B	NAC Intl.
ISFSI Pad	ITS-C	Zion

IMPORTANT-TO-SAFETY, STRUCTURES, SYSTEMS AND COMPONENTS

B. Transport of Spent Fuel and GTCC Waste (10 CFR 71)

SSC	Quality Category	Design/License Responsible
Transportable Storage Canisters and Fuel Basket Assembly	ITS-A	NAC Intl.
Transportable Storage Canister and Basket Assembly For GTCC Waste Containers	ITS-B	NAC Intl.
MAGNATRAN Transport Cask	ITS-A	NAC Intl.

C. Radioactive Material Transport Packages (10 CFR 71)

Radioactive Material Transport Packages subject to the provisions of 10 CFR 71, Subpart C, "General Licenses" are "Important-to-Safety" and subject to the applicable requirements of the QAPP.

NOTES:

1. See NAC MAGNASTOR Systems Final Safety Analysis Report (FSAR) and associated NAC specifications for additional classification information.

2. See NAC MAGNATRAN Transport Cask Safety Analysis Report and associated NAC specifications for additional classification information.

3. For the definition of Quality Categories Important-To-Safety (ITS) A, B, and C, refer to NUREG/CR-6407.

Appendix B

5.0 ADMINISTRATIVE CONTROLS (moved from Technical Specifications – Technical Specification numbering preserved to facilitate comparison)

5.1 Responsibilities – Incorporated into QAPP Section 2.1.

5.2 Organization – Incorporated into QAPP Section 2.2.

5.3 Facility Staff Qualifications

5.3.1 Staff Qualifications - Each member of the facility staff (including audit/survey, surveillance and inspection personnel) shall have sufficient qualifications to perform their assigned duties. Implementing procedures provide the guidance used for determining and assessing appropriate staff qualifications, including any qualifications required to meet ANSI N18.1. "Selection and Training of Nuclear Power Plant Personnel", dated March 8, 1971.

In addition, either the Manager of the Health Physics Department or the Lead Health Physicist shall meet or exceed the qualifications of "Radiation Protection Manager" of Regulatory Guide 1.8, September 1975.

5.5 Procedures

5.5.1 Procedures - Written procedures shall be established, implemented, and maintained covering the following activities:

b. Fire Protection Program implementation; and

c. All programs specified in 5.6 (below).

5.6 Programs and Manuals

The following programs shall be established, implemented and maintained.

5.6.1 Offsite Dose Calculation Manual (ODCM)

a. The ODCM shall contain the methodology and parameters used in the calculation of offsite doses resulting from radioactive gaseous and liquid effluents, in the calculation of gaseous and liquid effluent monitoring alarm and trip setpoints, and in the conduct of the radiological environmental monitoring program;

b. The ODCM shall also contain the radioactive effluent controls and radiological environmental monitoring activities, and descriptions of the information that should be included in the Annual Radiological Environmental Operating and Radioactive Effluent Release Reports required by 5.7.2 and 5.7.3 of this Appendix;

c. Licensee initiated changes to the ODCM:

1. Shall be documented and records of reviews performed shall be retained. This documentation shall contain:

I. Sufficient information to support the change(s) together with the appropriate analyses or evaluations justifying the change(s), and

II . A determination that the change(s) will maintain the levels of radioactive effluent control required by 10 CFR 20.1302, 40 CFR 190, 10 CFR 50.36a, and 10 CFR 50. Appendix I, and do not adversely impact the accuracy or reliability of effluent, dose or setpoint calculations:

2. Shall become effective after the approval of the Decommissioning Plant Manager or designee; and

3. Shall be submitted to the NRC in the form of a complete, legible copy of the entire ODCM as a part of or concurrent with the Radioactive Effluent Release Report for the period of the report in which any change in the ODCM was made effective. Each change shall be identified by markings in the margin of the affected pages, clearly indicating the area of the page that was changed, and shall indicate the date (i.e., month and year) the change was implemented.

5.6.2 Radioactive Effluent Controls Program - This program conforms to 10 CFR 50.36a for the control of radioactive effluents and for maintaining the doses to members of the public from radioactive effluents as low as reasonably achievable. The program shall be contained in the ODCM, shall be implemented by procedures, and shall include remedial actions to be taken whenever the program limits are exceeded. The program shall include the following elements, as applicable:

a. Limitations on the functional capability of radioactive liquid and gaseous monitoring instrumentation including surveillance tests and setpoint determination in accordance with the methodology in the ODCM;

b. Limitations on the concentrations of radioactive material released in liquid effluents to unrestricted areas, conforming to ten times the concentration values in 10 CFR 20, Appendix B, Table 2, Column 2;

c. Monitoring, sampling, and analysis of radioactive liquid and gaseous effluents in accordance with 10 CFR 20.1302 and with the methodology and parameters in the ODCM;

d. Limitations on the annual and quarterly doses or dose commitment to a member of the public from radioactive materials in liquid effluents released for each unit to unrestricted areas, conforming to 10 CFR 50, Appendix I;

e. Determination of cumulative and projected dose contributions from radioactive effluents for the current calendar quarter and current

calendar year in accordance with the methodology and parameters in the ODCM at least every 31 days;

f. Limitations on the functional capability and use of the liquid and gaseous effluent treatment systems to ensure that appropriate portions of these systems are used to reduce releases of radioactivity when the projected doses in a 31 day period would exceed 2 percent of the guidelines for the annual dose or dose commitment, conforming to Appendix I to 10 CFR 50;

g. Limitations on the dose rate resulting from radioactive material released in gaseous effluents to areas beyond the site boundary conforming to the following:

   1. For tritium and for all radionuclides in particulate form with half-lives greater than 8 days: less than or equal to a dose rate of 1500 mrem/yr to any organ;

h. Limitations on the annual and quarterly doses to a member of the public from tritium and all radionuclides in particulate form with half-lives greater than 8 days in gaseous effluents released from each unit to areas beyond the site boundary, conforming to Appendix I to 10 CFR 50; and

i. Limitations on the annual dose or dose commitment to any member of the public due to releases of radioactivity and to radiation from uranium fuel cycle sources, conforming to 40 CFR 190.

5.6 Programs and Manuals

5.6.3 Outdoor Storage Tank Radioactivity Monitoring Program - This program provides controls for the quantity of radioactivity contained in unprotected outdoor liquid storage tanks. This program is required if radioactive liquid is contained in unprotected (as defined below) outdoor storage tanks. The liquid radwaste quantities shall be determined in accordance with the ODCM.

The program shall include a surveillance program to ensure that the quantity of radioactivity contained in all outdoor liquid radwaste tanks that are not surrounded by liners, dikes, or walls, capable of holding the tank contents and that do not have tank overflows and surrounding area drains connected to the liquid radwaste treatment system is less than the amount that would result in concentrations less than the limits of 10 CFR 20, Appendix B, Table 2, Column 2, at the nearest potable water supply and the nearest surface water supply in an unrestricted area, in the event of an uncontrolled release of the tank contents.

5.7 Reporting Requirements

The following reports shall be submitted in accordance with 10 CFR 50.4 (note that a single submittal may be made for a multiple unit station):

5.7.1 (deleted)

5.7.2 Annual Radiological Environmental Operating Report - The Annual Radiological Environmental Operating Report covering unit activities during the previous calendar year shall be submitted before May 15 of each year. The report shall include summaries, interpretations, and analysis of trends of the results of the Radiological Environmental Monitoring Program for the reporting period. The material provided shall be consistent with the objectives outlined in (1) the ODCM and (2) Sections IV.B.2, IV.B.3, and IV.C of Appendix I of 10 CFR Part 50. In the event that some individual results are not available for inclusion with the report, the report shall be submitted noting and explaining the reasons for the missing results. The missing data shall be submitted in a supplementary report as soon as possible. A single submittal may be made for a multiple unit station.

5.7.3 Radioactive Effluent Release Report - The submittal should combine sections common to all units at the station. The Radioactive Effluent Release Report covering unit activities shall be submitted prior to May 1 of each year in accordance with 10 CFR 50.36a. The report shall include a summary of the quantities of radioactive liquid and gaseous effluents and solid waste released from the unit. The material provided shall be (1) consistent with the objectives outlined in the ODCM and Process Control Program and (2) in conformance with 10 CFR 50.36a and Section IV.B.1 of Appendix I t to 10 CFR Part 50. A single submittal may be made for a multiple unit station.

5.9 Reviews

5.9.1 Qualified Technical Review - Thorough reviews of the documents specified below shall be conducted by a Qualified Technical Reviewer. Persons performing these reviews shall be knowledgeable in the subject area being reviewed. Qualified Technical Reviews must be completed prior to implementation of proposed activities.

a. Qualified Technical Reviewers shall be individuals without direct responsibility for the document under review; these reviewers may be from the same functionally cognizant organization as the individual or group performing the original work.

b. Qualified Technical Reviewers shall have at least 5 years of professional experience and either a Bachelor's degree in Engineering or the Physical Sciences or shall have equivalent qualifications evaluated on a case by case basis and approved by the Decommissioning Plant Manager. The Decommissioning Plant Manager shall document the appointment of Qualified Technical Reviewers.

c. The following subjects shall be independently reviewed by a Qualified Technical Reviewer:

1. 10 CFR 50.59 and 10 CFR 72.48 evaluations for changes in the facility as described in the DSAR, changes in procedures as described in the DSAR, and tests or experiments not described in the DSAR to verify that such actions do not involve a change to the Technical Specifications or will not require NRC approval pursuant to 10 CFR 50.59 and 10 CFR 72.48;
2. Proposed changes to the programs required by section 5.6 above, and to verify that such changes do not involve a change to the Technical Specifications and will not require NRC approval pursuant to 10 CFR 50.59 and 10 CFR 72.48; and
3. Proposed changes to the license or Technical Specifications.